

Indiana Department of Homeland Security Radioactive Materials Control Program Draft Request for US Nuclear Regulatory Commission Agreement State Status Date Submitted: XX/XX/XXXX

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1.0 Preface

Formal Request for an Agreement State of Indiana

This document is prepared as the submittal for the State of Indiana's request to become an Agreement State as authorized by the Atomic Energy Act (AEA) of 1954, as amended. This Agreement will provide for the State of Indiana's assumption of regulatory authority over radioactive materials not involved in energy production used in the State of Indiana from the United States Nuclear Regulatory Commission (NRC).

2.0 Introduction

On June 11, 2021, Governor Eric J. Holcomb sent NRC Chairman Honorable Christopher T. Hanson a letter of intent for Indiana to enter into an Agreement with the NRC. Since that time, the Indiana Department of Homeland Security Radioactive Materials Control Program has been granted authority by the Indiana General Assembly for entering into an Agreement and establishing a regulatory program for Radioactive Materials, promulgated regulations for purposes of entering into an Agreement, trained and qualified staff for licensing and inspection responsibilities to be assumed under the Agreement, and developed this Request with the procedures, forms, and other content to meet the criteria and information needs in the NRC's Handbook for Processing an Agreement. References to the content are provided throughout this request. Key documents are available here in their entirety:

- Indiana Code Title 10, Article 19, Chapter 12 (2022), the enabling legislation found in Appendix 4.1-1
- The Radioactive Materials Rule (regulations) found in Appendix 4.1-2

3.0 Overview

This document is prepared using the guidance in the NRC Office of Nuclear Material Safety and Safeguards *Handbook for Processing an Agreement* dated April 1, 2021. The Information Needed and Evaluation Criteria specified in Section 4.0 of the Handbook are addressed herein to ensure that the State of Indiana has a compliant and compatible program for the control of licensees who possess, use, store, transfer, and dispose of radioactive materials in the State of Indiana.

The State of Indiana seeks to enter into an Agreement with the NRC assuming regulatory authority over byproduct materials, source materials, special nuclear materials in quantities not sufficient to form a critical mass, in addition, the State seeks to regain regulator authority over those materials transferred to the NRC by the Energy Policy Act of 2005. The following information is provided in support of this application to become an Agreement State.

4.0 Information Needed and Evaluation Criteria

This section addresses the information that the NRC requires, to review and Agreement request and the evaluation criteria that the NRC staff will use as a baseline. This is based on *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*, known as the Criteria Policy Statement, and described in Section 4.0 of the *Handbook for Processing an Agreement*. The Handbook criteria are in bold, and the content to meet the criteria follows.

4.1 Legal Elements

In this section is found the information needed to meet the evaluation criteria in the *Handbook for Processing an Agreement* Subsections:

4.1.1 Authority to Establish a Program and Enter into an Agreement

4.1.2 Organization of the Proposed Program; and

4.1.3 Content of the Proposed Agreement

The handbook criteria are in bold, and the content to meet the criteria follows.

4.1.1 Authority to Establish a Program and Enter into an Agreement.

4.1.1.1 Information Needed

For all categories of materials for which the state is requesting authority, the State should submit State law that:

4.1.1.1.a Establishes the Agreement materials program, defines its structure, and authorizes the Governor to enter into an Agreement with the Commission.

The Indiana Department of Homeland Security Radioactive Materials Control Program (hereinafter "the Department") statutory authority to establish the Agreement State program and define its structure is provided in IC 10-19-12-11

The governor, on behalf of the state, is authorized to enter into agreements with the U.S. Nuclear Regulatory Commission under Section 274b of the Atomic Energy Act of 1954, as amended, providing for discontinuance of certain of commission's licensing and related regulatory authority with respect to byproduct, source, and special nuclear materials and the assumption of regulatory authority therefore by this state.

The structure of the Agreement Materials Program is provided below in Section 4.1.2.

4.1.1.1.b Authorizes the program to issue licenses, including the following:

4.1.1.1.b.1 Authorizes the program to impose additional license requirements;

IC 10-19-12-6(a)(1) provides such authority by specifically stating the department shall have the authority to "...at any time after the filing of the application, and before the expiration of the license, require further written statements and may make such inspections as the department may deem necessary in order to determine whether the license should be modified, suspended, or revoked."

4.1.1.1.b.2 Authorizes the program to give exemptions from licensing requirements;

10-19-12-6(c) authorized the program to "...exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when the department makes a finding that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public."

4.1.1.1.b.3 Authorizes the program to recognize the licenses of other jurisdictions (that is reciprocity);

10-19-12-6(d) states "Rules and regulations promulgated under this chapter may provide for recognition of other state or federal licenses as the department shall deem desirable, subject to such registration requirements as the department may prescribe."

4.1.1.1.b.4 Makes it unlawful to acquire, possess, store, use, transfer or dispose of materials without a valid license, or to violate the conditions of a license;

IC 10-19-12-16 states "It shall be unlawful for any person to use, manufacture, produce, distribute, sell, transport, transfer, install, repair, receive, acquire, own, or possess any source of radiation unless licensed by or registered with the department in conformance with rules and regulations, if any, promulgated in accordance with the provisions of this chapter."

4.1.1.1.b.5 Authorizes the program to recognize licenses transferred from the NRC under the Agreement as State licenses.

10-19-12-6(d) states "Rules and regulations promulgated under this chapter may provide for recognition of other state or federal licenses as the department shall deem desirable, subject to such registration requirements as the department may prescribe."

4.1.1.1.c Authorizes the program to adopt regulation.

4.1.1.1.c.1 Specifies the procedures and requirements for adoption of regulations, including public participation.

IC 10-19-12-6 states "The department shall adopt rules under IC 4-22-2 for general and specific licensing of radioactive material, or devices or equipment utilizing such material. The rules must provide for the amendment, suspension, or revocation of licenses."

4.1.1.1.c.2 Allows the program to impose requirements in the form of other generic legally binding requirements, such as license conditions or orders.

IC 10-19-12-6(a)(4) states "The terms and conditions of all licenses shall be subject to amendment, revision, or modification by rules, regulations, or orders issued in accordance with the provisions of this chapter."

4.1.1.1.d Authorizes representatives of the program to enter premises and conduct inspections.

IC 10-19-12-9 states "The department or its duly authorized representatives shall have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this chapter and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative."

4.1.1.1.e Authorizes the program to require compliance with regulatory requirements by both licensees and unlicensed individuals.

IC 10-19-12-9 states "The department or its duly authorized representatives shall have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this chapter and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative."

4.1.1.1.f Authorizes the program to impose sanctions for violations of the regulations, orders, or license conditions.

IC 10-19-12-18(a) states: "Any person who violates any licensing or registration provision of this chapter or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license or registration certificate issued thereunder, or commits any violation for which a license or registration certificate may be revoked under rules or regulations issued under this chapter may be subject to a civil penalty, to be imposed by the department, not to exceed then thousand dollars (\$10,000)."

4.1.1.1.g Establishes conflict of interest and ethics regulations or procedures applicable to those portions of the State Radioactive Materials Control Program covered by the Agreement.

IC 10-19-12-13 states "Ordinances, resolutions, or regulations, now or hereafter in effect, of the governing body of a municipality or county or of state agencies, other than the department under section 5 of this chapter, relating to

byproduct, source, and special nuclear materials shall be superseded by this chapter."

4.1.1.2 Evaluation Criteria

4.1.1.2.a State law must authorize the Governor to enter into an Agreement. It must also designate a radiation control agency and provide it the necessary legal authority to be effective.

IC 10-19-12-11(a) states "The governor, on behalf of the state, is authorized to enter into agreements with the U.S. Nuclear Regulatory Commission under Section 274b of the Atomic Energy Act of 1954, as amended, providing for discontinuance of certain of the commission's licensing and related regulatory authority therefore by this state."

IC 10-19-12-5(a) states: "The Indiana Department of Homeland Security is designated as the state agency responsible for carrying out the duties of this chapter."

4.1.1.2.b State law must not create duplications, gaps, or conflicts in regulation. This includes duplications, gaps, or conflicts between the State and the NRC, State agencies, or State and local agencies. The law must not seek to regulate materials or activities reserved to the NRC.

The State of Indiana is incorporating the required parts of 10 CFR by reference to eliminate the possibility of duplications, gaps, or other conflicts in regulation, including duplications, gaps, or conflicts between the State and the NRC, State agencies, or State and local agencies.

Preventing duplications, gaps, and conflicts between State agencies is addressed at IC 10-19-12-13 which states that "Ordinances, resolutions, or regulations, now or hereafter in effect, of the governing body of a municipality or country or of state agencies, other than the department under section 5 of this chapter, relating to byproduct, source, and special nuclear materials shall be superseded by this chapter." 4.1.1.2.c State law must authorize issuing licenses as the means of giving the authority to possess and use Agreement materials. It should also authorize the reciprocal recognition of specific licenses issued by the NRC or other Agreement States.

> IC 10-19-12-6(a) states "The department shall adopt rules under IC 4-22-2 for general and specific licensing of radioactive material, or devices or equipment utilizing such material. The rules must provide for the amendment, suspension, or revocation of licenses."

IC 10-19-12-6(d) allows for "Rules and regulations promulgated under this chapter may provide for recognition of other state or federal licenses as the department shall deem desirable, subject to such registration requirements as the department may prescribe."

4.1.1.2.d State law should authorize the use of license conditions to address matters unique to the licensee. The law should allow license conditions to impose additional requirements when required to protect public health and safety. If the law restricts the use of license conditions, the State should show that they can provide adequate protection under the restrictions. The protection should be at least equivalent to using license conditions and orders.

> IC 10-19-12-6(a) states "The department shall adopt rules under IC 4-22-2 for general and specific licensing of radioactive material, or devices or equipment utilizing such material. The rules must provide for the amendment, suspension, or revocation of licenses."

4.1.1.2.e The law should permit exemptions from licensing requirements if the exemptions do not adversely affect public health and safety. This should include exemption(s) from licensing substantially equivalent to the following (or such exemptions must be included in the State's regulations). 10-19-12-6(c) states "The department is authorized to exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when the department makes a finding that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public."

Because Indiana is incorporating relevant parts of 10 CFR by reference, as is the case for the NRC, Indiana will authorize exemptions from licensing substantially equivalent to the requirement of *Handbook for Processing an Agreement* Section 4.1.1.2(e)1. through 4., below:

1. Prime contractors working for the U.S. Department of Energy (DOE) at U.S. Government-owned or controlled sites.

- Prime contractors researching, developing, manufacturing, storing, testing, or transporting atomic weapons or components.
- Prime contractors using or operating nuclear reactor or other nuclear devices in a U.S. Government-owned vehicle or vessel; and
- 4. Any other prime contractor (or subcontractors) of DOE or NRC when the State and NRC jointly determine (i) that the terms of the contract provide adequate assurance that the contractor can accomplish the work without undue risk to public health and safety and (ii) that the law authorizes exemptions.

The particular sections of 10 CFR the State of Indiana are incorporating by reference relevant to exempting the above contractors among other are 10 CFR 30.12

4.1.1.2.f The law must authorize the Agreement materials program to enforce regulations or generic legally binding requirements other than regulations. The law may authorize another agency (such as a board of health) to adopt the regulations. When appropriate, the law should provide for public participation.

IC 10-19-12-9 states "The department of its duly authorized representatives shall have the power to enter at all

reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this chapter and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative."

4.1.1.2.g The law must authorize inspections of licensee operations to ensure compliance with regulatory requirements. It should authorize inspections of unlicensed facilities to assess the risk resulting from accidents or environmental releases of materials. The law should permit access at all reasonable times.

§10-19-12-9 provides for inspection and entry upon any private or public property at all reasonable times:

"The department or its duly authorized representatives shall have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this chapter and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.

4.1.1.2.h The law must provide authority to take prompt enforcement action and should provide a variety of legal sanctions. The law should provide authority to suspend licenses and to impound materials. In cases of an imminent threat to public health and safety, the law should authorize immediate suspension without prior hearing.

§10-19-12-14(f) states "Whenever the department finds that an emergency exists requiring immediate action to protect the public health and safety, the department may adopt emergency rules under IC 4-22-2-37.1 or issue emergency orders under IC 4-21.5-4 to address the emergency."

§10-19-12-15 states "Whenever, in the judgment of the department, any person has engaged in or is about to engage in any acts or practices that constitutes or will constitute a violation of any provision of this chapter, or any rule, regulation, or order issued thereunder, the department may, in lieu of issuing an administrative order, apply for an order from a circuit or superior court in the county in which the person takes a substantial step toward violating a law, or a violation occurs. Upon a showing by the department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, a restraining order, or other order may be granted."

§10-19-12-17 states "The department shall have the authority in the event of an emergency to impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of this chapter, or any rules or regulations issued thereunder."

4.1.1.2.i The law should authorize suspension or revocation of a license for repeated or continued noncompliance. The authority to suspend or revoke a license may be conditioned on a prior administrative or judicial hearing. The program should also have authority to seek injunctive relief and refer licensees for criminal prosecution. The program should also consider authority to impose civil or administrative monetary penalties.

§10-19-12-15 states "Whenever, in the judgment of the department, any person has engaged in or is about to engage in any acts or practices that constitutes or will constitute a violation of any provision of this chapter, or any rule, regulation, or order issued thereunder, the department may, in lieu of issuing an administrative order, apply for an order from a circuit or superior court in the county in which the person takes a substantial step toward violating a law, or

a violation occurs. Upon a showing by the department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, a restraining order, or other order may be granted."

§10-19-12-17 states "The department shall have the authority in the event of an emergency to impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of this chapter, or any rules or regulations issued thereunder."

§10-19-12-18(a) states in part "Any person who violates any licensing or registration provision of this chapter or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license or registration certificate issued there under, or commits any violation for which a license or registration certificate may be revoked under rules or regulations issued under this chapter may be subject to a civil penalty, to be imposed by the department, ..."

4.1.1.3 Additional Criteria for Low Level Waste Agreements

The law must authorize appropriate restrictions on land ownership and use of sites used for disposal of LLRW for an indefinite period after closure.

The State of Indiana is not requesting regulatory authority on land ownership and the use of sites used for the disposal of low-level radioactive waste depositories in the state of Indiana for an indefinite period after the closure of the site.

4.1.1.4 Additional Evaluation Criteria for 11e.(2) Byproduct Material Agreements

The law should clearly authorize the Agreement Materials program to carry out the requirements of the Uranium Mill Tailings Radiation Control Act of 1978, as amended (UMTRCA). The State of Indiana is not requesting regulatory authority for the requirements of the Uranium Mill Tailings Radiation Control Act of 1968, as amended (UMTRCA)

Attachment 4.1-1 – Indiana Code, Title 10, Article 19, Chapter 12

IC 10-19-12-1 Nuclear regulatory agreement

Sec. 1. This agreement shall be effective immediately upon:

(1) approval by the U.S. Nuclear Regulatory Commission; and

(2) signing by the governor and the chairman of the U.S. Nuclear Regulatory Commission.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-2 Public policy

Sec. 2. It is the policy of the state in furtherance of its responsibility to protect the occupational health and safety, public health and safety, and environment to:

(1) institute and maintain a regulatory program for sources of ionizing radiation and nonionizing radiation so as to provide for compatibility and equivalency with the standards and regulatory programs of the federal government, an integrated effective system of regulation within the state, and a system consonant insofar as possible with those of other states;

(2) institute and maintain a program to permit development and use of sources of radiation for peaceful purposes consistent with the health and safety of the public; and

(3) provide for the availability of capacity either within or outside Indiana for the disposal of low-level radioactive waste generated within Indiana except for waste generated as a result of defense or federal research and development activities and to recognize that such radioactive waste can be most safely and efficiently managed on a regional basis.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-3 Purpose

Sec. 3. It is the purpose of this chapter to provide:

(1) a program of effective regulation of sources of radiation for the protection of the occupational health and safety and public health and safety;

(2) a program to promote an orderly regulatory pattern within Indiana, among the states, and between the federal government and Indiana, and facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized; (3) a program to establish procedures for assumption and performance of certain regulatory responsibilities with respect to byproduct, source, and special nuclear materials; and

(4) a program to permit use of sources of radiation consistent with the health and safety of the public.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-4 Definitions

Sec. 4. As used in this chapter:

(1) "Byproduct material" means:

(A) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(B) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content;

(C) any discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(D) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; and

(E) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial, medical, or research activity, if the governor, after determination by the NRC, declares by order that the source would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety.

(2) "Civil penalty" means any monetary penalty levied on a licensee or registrant because of violations of statutes, regulations, licenses, or registration certificates, but does not include criminal penalties.

(3) "Closure" or "site closure" means all activities performed at a waste disposal site, such as stabilization and contouring, to assure that the site is in a stable condition so that only minor custodial care, surveillance, and monitoring are necessary at the site following termination of a licensed operation.

(4) "Decommissioning" means final operational activities at a facility to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material, and to carry out any other activities to prepare the site for post operational care.
(5) "Department" means the Indiana department of homeland security

established by IC 10-19-2-1.

(6) "Disposal of low-level radioactive waste" means the isolation of such waste from the biosphere by emplacement in a land burial facility.

(7) "General license" means a license effective under regulations promulgated by the department without the filing of an application with the department or the issuance of licensing documents to particular persons to transfer, acquire, own, possess, or use quantities of, or devices or equipment utilizing, radioactive material.

(8) "High-level radioactive waste" means:

(A) irradiated reactor fuel;

(B) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and

(C) solids into which such liquid wastes have been converted.

(9) "Ionizing radiation" means gamma rays and x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.
(10) "Low-level radioactive waste" means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material.

(11) "Nonionizing radiation" means the following:

(A) Any electromagnetic radiation, other than ionizing electromagnetic radiation.

(B) Any sonic, ultrasonic, or infrasonic wave.

(12) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, state agency other than the department, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but not including federal government agencies.

(13) "Radiation" means ionizing radiation and nonionizing radiation.

(14) "Radiation generating equipment" means any manufactured product or device, or component part of such a product or device, or any machine or system that during operation can generate or emit radiation except those that emit radiation only from radioactive material.

(15) "Radioactive material" means material (solid, liquid, or gas) that emits ionizing radiation spontaneously. It includes accelerator produced, byproduct, naturally occurring, source, and special nuclear materials.

(16) "Registration" means registration with the department in accordance with rules and regulations adopted pursuant to this chapter.

(17) "Source material" means uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain by weight one-twentieth of one percent (0.05%) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

(18) "Source material mill tailings" means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from underground solution extraction processes, but not including underground ore bodies depleted by such solution extraction processes. (19) "Source material milling" means any processing of ore, including

underground solution extraction of unmined ore, primarily for the purpose of extracting or concentrating uranium or thorium that results in the production of source material mill tailings.

(20) "Sources of radiation" means collectively, radioactive material and radiation generating equipment.

(21) "Special nuclear material" means plutonium, uranium 233, and uranium enriched in the isotope 233 or in the isotope 235, but does not include source material; or any material artificially enriched by any of the foregoing, but does not include source material.

(22) "Specific license" means a license, issued to a named person upon application filed under the regulations promulgated under this chapter, to use, manufacture, produce, transfer, receive, acquire, or possess quantities of, or devices or equipment utilizing, radioactive material.

(23) "Spent nuclear fuel" means irradiated nuclear fuel that has undergone at least one (1) year's decay since being used as a source of energy in a power reactor. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive material associated with fuel assemblies. (24) "Transuranic waste" means radioactive waste containing alpha emitting transuranic elements, with radioactive half-lives greater than five (5) years, in excess of ten (10) nanocuries per gram.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-5 Duties; registration, regulation, and use of radiation generating equipment

Sec. 5. (a) The Indiana department of homeland security is designated as the state agency responsible for carrying out the duties of this chapter.

(b) The executive director of the department may use the authority granted under $\underline{IC \ 10-19-3-4}$ and $\underline{IC \ 10-19-3-5}$ to carry out the duties of this chapter.

(c) The department shall, for the protection of the occupational health and safety, public health and safety, and environment, do the following:

(1) Develop programs for evaluation and control of hazards associated with use of sources of radiation.

(2) Develop programs with due regard for compatibility with federal programs for regulation of byproduct, source, and special nuclear materials.

(3) Adopt rules and regulations, which may provide for licensing and registration, relating to control of sources of radiation with due regard for compatibility with the regulatory programs of the federal government.

(4) Issue such orders or modifications thereof as may be necessary in connection with proceedings under this chapter.

(5) Advise, consult, and cooperate with other state agencies, the federal government, other states and interstate agencies, political subdivisions, and other organizations concerned with control of sources of radiation.

(6) Have the authority to accept and administer grants, or other funds or gifts, conditional or otherwise, in furtherance of its functions, from the federal government and from other sources, public or private.

(7) Encourage, participate in, or conduct studies, investigations, training, research, and demonstrations relating to control of sources of radiation.
 (2) Callest and disconsistent information relating to control of sources of radiation.

(8) Collect and disseminate information relating to control of sources of radiation, including maintenance of a file of:

(A) all license applications, issuances, denials, amendments, transfers, renewals, modifications, suspensions, and revocations;

(B) registrants possessing sources of radiation requiring registration under the provisions of this chapter and any administrative or judicial action pertaining thereto; and

(C) all of the department's rules and regulations relating to regulation of sources of radiation, pending or promulgated, and proceedings thereon.

(d) Registration of radiation generating equipment and regulations regarding the use of radiation generating equipment shall be in accordance with IC 16-41-35.

(e) The department shall coordinate the registration, regulation, and use of radiation generating equipment under subsection (d). The department shall do the following in carrying out the duties of this subsection:

(1) Consult with and review regulations and procedures of a state agency or department that regulates, in part, radiation or radiation generating equipment to prevent unnecessary duplication, inconsistencies, or gaps in regulatory requirements.

(2) Review, before and after, the holding of any public hearing required under the provisions of this chapter prior to promulgation, the proposed rules and regulations of any state agencies that relate to the use and control of radiation, to assure that the rules and regulations are consistent with other agencies. Proposed rules and regulations are not effective until thirty (30) days after submission to the department, unless either the governor or the department waives all or part of the thirty (30) day period. The waiting period runs concurrently with any other waiting period required by state law.

(3) Consult with state agencies in an effort to resolve inconsistencies if the department determines that a proposed rule or regulation is inconsistent with an existing rule or regulation.

(4) Notify the governor if an inconsistency under subdivision (3) has not been resolved. Upon notification, the governor may find that the proposed rules and regulations or parts thereof are inconsistent with the rules and regulations of other agencies of the state and may issue an order to that effect in which event the proposed rules or regulations or parts thereof shall not become effective. The governor may, in the alternative, upon a similar determination, direct the appropriate agency or agencies to amend or repeal existing rules or regulations to achieve consistency with the proposed rules or regulations.

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(f) The agencies of the state shall keep the department fully and currently informed as to their activities relating to development and regulation of sources of radiation.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-6 General and specific licensing

Sec. 6. (a) The department shall adopt rules under <u>IC 4-22-2</u> for general and specific licensing of radioactive material, or devices or equipment utilizing such material. The rules must provide for the amendment, suspension, or revocation of licenses. The rules must also provide the following:

(1) Each application for a specific license shall be in writing and shall state such information as the department, by rule or regulation, may determine to be necessary to decide the technical and financial qualifications or any other qualifications of the applicant as the department may deem reasonable and necessary to protect the occupational health and safety and public health and safety. The department may at any time after the filing of the application, and before the expiration of the license, require further written statements and may make such inspections as the department may deem necessary in order to determine whether the license should be modified, suspended, or revoked. All applications and statements shall be signed by the applicant or licensee. The department may require any applications or statements to be made under oath or affirmation.

(2) Each license shall be in such form and contain such terms and conditions as the department may by rule or regulation prescribe.

(3) No license issued under the authority of this chapter and no right to possess or use sources of radiation granted by any license shall be assigned or in any manner disposed of unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of this chapter, and shall give its consent in writing.

(4) The terms and conditions of all licenses shall be subject to amendment, revision, or modification by rules, regulations, or orders issued in accordance with the provisions of this chapter.

(b) The department is authorized to require registration or licensing of other sources of radiation.

(c) The department is authorized to exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when the department makes a finding that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public.

(d) Rules and regulations promulgated under this chapter may provide for recognition of other state or federal licenses as the department shall deem desirable, subject to such registration requirements as the department may prescribe.

As added by P.L.28-2022, SEC.2.

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IC 10-19-12-7 Fees

Sec. 7. (a) The department shall prescribe and collect such fees as may be established by regulation for radiation protection services provided under this chapter. Fees collected under this section shall be deposited in the fire and building services fund established under IC 22-12-6-1. Services for which fees may be established include the following:

(1) Registration of sources of radiation.

(2) Issuance, amendment, and renewal of licenses for radioactive materials.

(3) Inspections of registrants or licensees.

(4) Environmental surveillance activities to assess the radiological impact of activities conducted by licensees.

(b) In determining rates of such fees, the department shall, as an objective, obtain sufficient funds therefrom to reimburse the state for all or a substantial portion of the direct and indirect costs of the radiation protection services specified in subsection (a). The department shall take into account any special arrangements between the state and a registrant, a licensee, another state, or a federal agency whereby the cost of the services is otherwise partially or fully recovered.

(c) The department may, upon application by an interested person, or on its own initiative, grant such exemptions from the requirements of this section as it determines are in the public interest. Applications for exemption under this subsection may include activities such as, but not limited to, the use of licensed materials for educational or noncommercial displays or scientific collections.

(d) When a registrant or licensee fails to pay the applicable fee, the department may suspend or revoke the registration or license or may issue an appropriate order.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-8 Surety requirements; radiation funds; site surveillance and care

Sec. 8. (a) For licensed activities involving disposal of low-level radioactive waste, the department shall, and for other classes of licensed activity the department may, establish by rule or regulation standards and procedures to ensure that the licensee will provide an adequate surety or other financial arrangement to permit the completion of all requirements established by the department for the decontamination, closure, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with such licensed activity, in case the licensee should default for any reason in performing such requirements.

(b) All sureties required under subsection (a) that are forfeited shall be paid to the department for deposit by the state treasurer in a special fund called the radiation site closure and disposal fund. All money in this fund is hereby appropriated and may be expended by the department as necessary to complete such requirements on which licensees have defaulted. Money in this fund shall not be used for normal operating expenses of the department. Money in the fund shall not revert back to the state general fund.

(c) For licensed activities involving the disposal of low-level radioactive waste the department shall, and for other classes of licensed activity when radioactive material that will require surveillance or care is likely to remain at the site after the licensed activities cease, the department may, establish by rule or regulation standards and procedures to ensure that the licensee, before termination of the license, will make available such funding arrangements as may be necessary to provide for long-term site surveillance and care.

(d) All funds collected from licensees under subsection (c) shall be paid to the department for deposit by the state treasurer in a special fund called the radiation long-term care fund. All funds accrued as interest on money deposited in this fund are hereby appropriated and may be expended by the department for the continuing long-term surveillance, maintenance, and other care of facilities from which such funds are collected as necessary for protection of the public health and safety and the environment. Money in the fund shall not revert back to the state general fund. Notwithstanding any other provisions of this subsection, if title to and custody of any radioactive material and its disposal site are transferred to the United States upon termination of any license for which funds have been collected for such long-term care, the collected funds and interest accrued thereon shall be transferred to the United States.

(e) The sureties or other financial arrangements and funds required by subsections (a) and (c) shall be established in amounts sufficient to ensure compliance with those standards, if any, established by the U.S. Nuclear Regulatory Commission pertaining to closure, decommissioning, reclamation, and long-term site surveillance and care of such facilities and sites.

(f) In order to provide for the proper care and surveillance of sites subject to subsection (c), the department, on behalf of the state, may acquire by gift or transfer from another government agency or private person any land and appurtenances necessary to fulfill the purposes of this section. Any such gift or transfer is subject to approval and acceptance by the department.

(g) The department may by contract, agreement, lease, or license with any person, including another state agency, provide for the decontamination, closure, decommissioning, reclamation, surveillance, or other care of a site subject to this section as needed to carry out the purposes of this section.

(h) In the event that a person licensed by any governmental agency other than the department desires to transfer a site to the state for the purpose of administering or providing long-term care, a lump sum deposit shall be made to the radiation long-term care fund. The amount of such deposit shall be determined by the department taking into account the factors in subsections (c) and (e).

(i) All state, local, or other governmental agencies, shall be exempt from the requirements of subsections (a) and (c). *As added by P.L.28-2022, SEC.2.*

IC 10-19-12-9 Inspection and compliance

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Sec. 9. The department or its duly authorized representatives shall have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this chapter and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-10 Record keeping

Sec. 10. The department is authorized to require by rule, regulation, or order the keeping of such records with respect to activities under licenses and registration certificates issued under this chapter as may be necessary to effectuate the purposes of this chapter. These records shall be made available for inspection by, or copies thereof shall be submitted to, the department on request. *As added by P.L.28-2022, SEC.2.*

IC 10-19-12-11 Federal-state agreements; assumption of regulatory authority

Sec. 11. (a) The governor, on behalf of the state, is authorized to enter into agreements with the U.S. Nuclear Regulatory Commission under Section 274b of the Atomic Energy Act of 1954, as amended, providing for discontinuance of certain of the commission's licensing and related regulatory authority with respect to byproduct, source, and special nuclear materials and the assumption of regulatory authority therefore by this state.

(b) Any person who, on the effective date of an agreement under subsection (a), possesses a license issued by the U.S. Nuclear Regulatory Commission for radioactive materials subject to the agreement shall be deemed to possess a like license issued under this chapter, which shall expire either ninety (90) days after receipt from the department of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-12 Federal-state agreements; inspection and training programs

Sec. 12. (a) The department is authorized to enter into an agreement or agreements with the U.S. Nuclear Regulatory Commission under Section 274i of the Atomic Energy Act of 1954, as amended, other federal government agencies as authorized by law, other states or interstate agencies, whereby this state will perform on a cooperative basis with the commission, other federal government agencies, other states, or interstate agencies, inspections or other functions relating to control of sources of radiation. Page|24 (b) The department may institute training programs for the purpose of qualifying personnel to carry out the provisions of this chapter, and may make said personnel available for participation in any program or programs of the federal government, other states, or interstate agencies in furtherance of the purposes of this chapter.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-13 Conflicting laws

Sec. 13. Ordinances, resolutions, or regulations, now or hereafter in effect, of the governing body of a municipality or county or of state agencies, other than the department under section 5 of this chapter, relating to byproduct, source, and special nuclear materials shall be superseded by this chapter. *As added by P.L.28-2022, SEC.2.*

IC 10-19-12-14 Administrative procedure; public notice and hearing

Sec. 14. (a) Rules shall be promulgated under this chapter in accordance with $\underline{IC 4-22-2}$.

(b) Orders shall be issued under this chapter in accordance with $\underline{IC 4-21.5}$.

(c) In any proceeding for licensing ores processed primarily for their source material content and disposal of byproduct material or for licensing disposal of low-level radioactive waste, the department shall provide:

(1) an opportunity, after public notice, for written comments and a public hearing, with a transcript;

(2) an opportunity for cross-examination; and

(3) a written determination of the action to be taken, which is based upon findings included in the determination and upon evidence presented during the public comment period.

(d) In any proceeding for licensing ores processed primarily for their source material content and disposal of byproduct material or for licensing disposal of low-level radioactive waste, the department shall prepare, for each licensed activity that has a significant impact on the human environment, a written analysis of the impact of such licensed activity on the environment. The analysis shall be available to the public before the commencement of hearings held pursuant to subsection (c) and shall include the following:

(1) An assessment of the radiological and nonradiological impacts to the public health.

(2) An assessment of any impact on any waterway and groundwater.

(3) Consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted.

(4) Consideration of the long-term impacts, including decommissioning, decontamination, and reclamation of facilities and sites associated with the licensed activities and management of any radioactive materials that will

remain on the site after such decommissioning, decontamination, and reclamation.

(e) The department shall prohibit any major construction with respect to any activity for which an environmental impact analysis is required by subsection (d) prior to completion of such analysis.

(f) Whenever the department finds that an emergency exists requiring immediate action to protect the public health and safety, the department may adopt emergency rules under IC 4-22-2-37.1 or issue emergency orders under IC 4-21.5-4 to address the emergency.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-15 Injunction proceedings

Sec. 15. Whenever, in the judgment of the department, any person has engaged in or is about to engage in any acts or practices that constitute or will constitute a violation of any provision of this chapter, or any rule, regulation, or order issued thereunder, the department may, in lieu of issuing an administrative order, apply for an order from a circuit or superior court in the county in which the person takes a substantial step toward violating a law, or a violation occurs. Upon a showing by the department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, a restraining order, or other order may be granted.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-16 Prohibited uses of sources of radiation

Sec. 16. It shall be unlawful for any person to use, manufacture, produce, distribute, sell, transport, transfer, install, repair, receive, acquire, own, or possess any source of radiation unless licensed by or registered with the department in conformance with rules and regulations, if any, promulgated in accordance with the provisions of this chapter.

As added by P.L.28-2022, SEC.2.

IC 10-19-12-17 Impounding sources of radiation

Sec. 17. The department shall have the authority in the event of an emergency to impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of this chapter or any rules or regulations issued thereunder. *As added by P.L.28-2022, SEC.2.*

IC 10-19-12-18 Civil penalties

Sec. 18. (a) Any person who violates any licensing or registration provision of this chapter or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license or registration certificate issued thereunder, Page|26

or commits any violation for which a license or registration certificate may be revoked under rules or regulations issued under this chapter may be subject to a civil penalty, to be imposed by the department, not to exceed ten thousand dollars (\$10,000). If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty. The department shall have the power to compromise, mitigate, or remit such penalties.

(b) Whenever the department proposes to subject a person to the imposition of a civil penalty under the provisions of this section, it shall issue an order in accordance with IC 4-21.5.

(c) The department is authorized to institute a civil action to collect a penalty imposed pursuant to this section. The department shall have the exclusive power to compromise, mitigate, or remit such civil penalties as are referred to the department for collection.

(d) All money collected from civil penalties under this section shall be deposited in the fire and building services fund established by <u>IC 22-12-6-1</u>. *As added by P.L.28-2022, SEC.2.*

Attachment 4.1-2 - Indiana Radioactive Materials Rules

Enter when received from NRC

4.1.2 Organization of the Proposed Program

The organization of an agreement materials program provides the basic organizational structure and resources to conduct the program activities. The Agreement materials program organization thus influences the ability of the program to protect public health and safety against radiation hazards.

4.1.2.1 Information Needed. The State should submit a concise narrative description of the materials program.

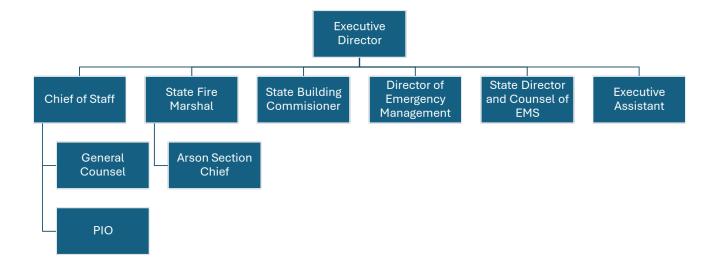
4.1.2.1.a A brief history of radiation control in the State

Radiation based control programs in the State of Indiana started in the late 1970s/early 1980s, with the Radiological Emergency Preparedness Program. At this time the authority for radiological issues was housed with the Indiana State Department of Health (ISDH). ISDH also performed

inspection when radioactive materials were found in the public sector, such as scrap yards and landfills. In 2014, the responsibility was split between ISDH and the Indiana Department of Homeland Security (IDHS). IDHS received the responsibility for issues related to radioactive materials and all response and preventative measures related to radiation, while ISDH retained responsibility for electronically produced radiation. IDHS's radiation control programs included the Radiological Emergency Preparedness Program, the Radiological Transportation Program, the Preventative Radiological/Nuclear Detection Program, and the orphan sources program for radioactive materials found in the public sector. In 2021, Governor Eric Holcomb signed legislation indicating the intention for the State of Indiana to develop a radioactive materials control program and subsequently acquire the responsibility for regulating the use of radioactive materials in the State of Indiana.

4.1.2.1.b A description of the current structure of the program, including regional offices.

The State of Indiana seeks to enter into an Agreement with the NRC for assuming regulatory authority over byproduct radioactive materials, source materials, special nuclear materials in quantities not sufficient to form a critical mass, and those materials transferred to the NRC by the Energy Policy Act of 2005. This authority will reside in the Indiana Department of Homeland Security for the State of Indiana. Staff administering the program are part of the Radioactive Materials Control Program (RMCP). Essentially all required regulatory elements of the RMCP are carried out by the staff within the Indiana Department of Homeland Security. The RMCP is within the Indiana Department of Homeland Security and falls under the Arson Section Chief as shown in Figure 1.



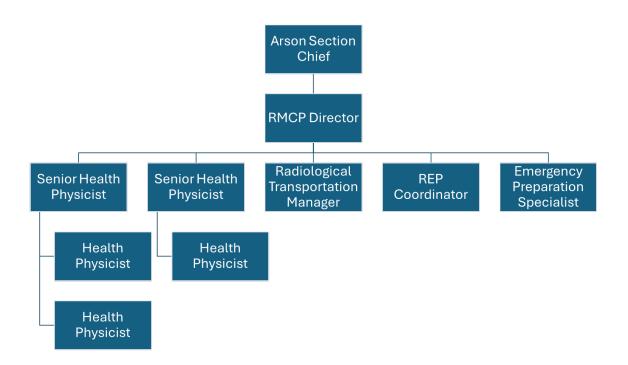


Figure 1: Indiana Department of Homeland Security Organization Chart

4.1.2.1.c Individual discussions of each of the program elements in Section 4.0 of the Handbook

Legal Elements of the Agreement State Radioactive Materials Control Program

The Radioactive Materials Control Program is founded in the statute described in the Indiana Code Chapter 10-19-12. The statute designates the Indiana Department of Homeland Security as the radiation control agency and, among other duties, provides radioactive materials licensing, inspection, and regulatory compliance enforcement authority to IDHS. In accordance with IC 4-22-2, IDHS makes rules to regulate radioactive materials licensees. All statutory information needed to address the evaluation criteria in the Handbook for

Processing and Agreement is provided in Section 4.1.1 of this application.

The Indiana Department of Homeland Security has chosen to incorporate parts of Title 10 Chapter I of the Code of Federal Regulations (10 CFR) by reference, rather that create separate compatible rules. The RMCP's rules are found in Indiana Code, Title 10 Public Safety, Article 19 Department of Homeland Security, Chapter 12 Nuclear Regulatory Commission. The current version of the Radioactive Materials Rule is attached as Appendix 4.1-2.

Legal elements of the RMCP are understood by the staff of the RMCP for administrative and operational purposes. When legal assistance is needed, for example with revising statues or regulations, or for routine or escalated enforcement actions, the Office of General Counsel may provide official policy and legal advice. The Office of General Counsel is shown in Figure 6.

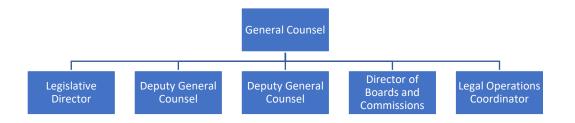


Figure 6: Office of General Counsel

The Office of General Counsel assists the RMCP with rulemaking, provides legal counsel to RMCP staff, and conducts legal review and interpretation for the RMCP staff. The General Counsel provides legal counsel for the RMCP. The Office of General Counsel can assist in the legal matters that arise between Department staff and programs, other state agencies, local agencies, federal agencies, business entities and the public.

For the Agreement State application process, the office of the Office of General Counsel have worked with RMCP staff in revising Indiana Statute to ensure there exists authority to enter into an Agreement, revising the Radioactive Materials Control Rules to ensure compatibility with NRC regulations and to meet the requirements of Indiana Code Chapter 10-19-12, and reviewed this Request for an Agreement for legal purposes. The Radiation Program Director has direct access to the Office of General Counsel and staff of attorneys and policy advisors.

4.1.2.1.d For each program element, cross references to the pertinent portions of the States Supporting documentation for the application.

Table 2 provides a cross-reference from each of the elements in the Handbook for Processing an Agreement to Indiana references.

Table 2

Cross Reference of Program Elements 4.1 Through 4.7 to Indiana and NRC References

<u>Section</u>	<u>Program</u> <u>Element</u>	<u>Information from</u> <u>Indiana</u>	<u>Criteria</u> <u>Numbe</u> <u>r</u>	<u>References</u>
4.1	Legal Elements			
4.1.1	Statutory Authority	Indiana Statutes Title 290. Department of Homeland Security Article 3. Standards for Protection Against Radiation	1, 2, 9b, 12, 13, 14, 17, 19, 21, 23, 24, 25, 27, 28, 29, 30, and 31	Criteria Policy Statement; Suggested State Legislation; Statement of Principles and Policy for the Agreement State Program
4.1.2	Program Organization	Application text in Section 4.1.2	1,24 and 33	Criteria Policy Statement; Program descriptions of existing Agreement States from IMPEP reports; MD 5.9; SA-200
4.1.3	Content of Agreement	Application text in Section 4.1.3, including Proposed Agreement.	27	Criteria Policy Statement MD 5.8
4.2	Regulatory Requiremen ts Program Elements			

4.2.1	Regulations or Legally Binding Requirements	Incorporation of 10 CFR 20 by reference with exceptions	1, 2, 3, 4, 5, 6, 7, 8, 9a, 10, 11, 22, 23, and 32	Criteria Policy Statement MD 5.9; SA-200; 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 38, 40, 61, 70, 71, and 150.
4.3	Licensing Program Elements			
4.3.1	Materials Licensing	RMCPP 1.1 Review of Initial Application for License or an Amendment Request RMCPP 1.2 Renewal of Licenses RMCPP 1.3 License Termination/Revocatio n RMCPP 1.4 NRC Licenses Affected by Agreement States RMCPP 4.1 Renewal Notices, Receipt, and Tracking of Licensing Actions. The Department is incorporating by reference specific licensing procedures and licensing guidance of the NRC including the NUREG 1556 Series.	1, 7, 8, 9a, 13, 14, 15, 20, and 23	Criteria Policy Statement; MD 5.6; SA-104; NUREG-1556 series; NUREG- 1757; NUREG- 1575 (MARSSIM).

4.3.2	Sealed Source & Device Safety Evaluations	N/A	13 and 23	Criteria Policy Statement; NUREG-1556, Volume 3; MD 5.6
4.3.3	Low-Level Waste Site Licensing	N/A	9b and 13	Criteria Policy Statement; NUREG-1199; NUREG 1200; NUREG-1300; NUREG-1274; MD 5.6; SA-109.
4.3.4	Uranium or Thorium Mill Licensing	N/A	29, 30, 31, 32, 33, 34, and 35	Criteria Policy Statement; Uranium Recovery Regulations, Guidance and Communications; MD 5.6; SA-110.
4.3.5	Licensing Quality Assurance	RMCPP 1.2 Renewal of Licenses RMCPP 1.3 License Termination/Revocatio n RMCPP 1.4 NRC Licenses Affected by Agreement States RMCPP 4.1 Renewal Notices, Receipt, and Tracking of Licensing Actions. The Department is incorporating by reference specific licensing procedures and licensing guidance	1 and 13	Criteria Policy Statement; MD 5.6; SA-104.

		of the NRC including the NUREG 1556 Series.		
4.3.6	Licensing Administrativ e Procedures	RMCPP 1.2 Renewal of Licenses RMCPP 1.3 License Termination/Revocatio n RMCPP 1.4 NRC Licenses Affected by Agreement States RMCPP 4.1 Renewal Notices, Receipt, and Tracking of Licensing Actions. The Department is incorporating by reference specific licensing procedures and licensing guidance of the NRC including the NUREG 1556 Series.	1, 13, and 25	Criteria Policy Statement.
4.4	Inspection Program Elements			
4.4.1	Procedures for Inspecting Facilities Where Radioactive Material Is Stored or Used	RMCPP 2.1 Scheduling of Inspections RMCPP 2.2 Inspection Preparations RMCPP 2.3 Performance-Based Inspections	1, 16, 18, and 36	Criteria Policy Statement; MD 5.6; SA-101; SA- 102; IMC 1220; IMC 2800; IMC 2801; NRC Inspection Procedures in the IP 8XXXX series.

		RMCPP 2.4 Documentation of Inspection Results		
		RMCPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions		
		RMCPP 2.6 <i>Materials</i> Inspection Checklist and Definitions		
		RMCPP 2.7 Assuring the Technical Quality of Inspections		
		RMCPP 4.2 Tracking Inspections		
		The Department is incorporating by reference specific inspection procedures and guidance of the NRC including NUREG- 1556.		
4.4.2	Procedures for Assuring the Technical	RMCPP 2.7 Assuring the Technical Quality of Inspections	1 and 16	Criteria Policy Statement; MD 5.6; SA-102; IMC
	Quality of Inspections and Inspection Reports	The Department is incorporating by reference specific inspection procedures and guidance of the NRC including NUREG- 1556.		2800; IMC 2801.

4.4.3	Administrativ e Procedures for Inspections	RMCPP 2.1 Scheduling of Inspections RMCPP 2.2 Inspection Preparations RMCPP 2.3 Performance-Based Inspections RMCPP 2.4 Documentation of Inspection Results RMCPP 4.2 Tracking Inspections The Department is incorporating by reference specific inspection procedures and guidance of the NRC including NUREG- 1556.	1	Criteria Policy Statement; IMC 2800; IMC 2801.
4.5	Enforcemen t Program Elements			
4.5.1	Routine Enforcement Procedures	RMCPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions It is attached in Section 4.5.2.	18, 19 and 23	Criteria Policy Statement; NRC Enforcement Policy; IMC 2800; IMC 2801.
4.5.2	Escalated Enforcement Procedures	RMCPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions	18, 19 and 23	Criteria Policy Statement; NRC Enforcement Policy; IMC 2800; IMC 2801.

4.6	Technical Staff and Training			
4.6.1	Organization	RMCPP 5.1 <i>Qualifications and</i> <i>Training</i> Attachment 5.1-1 <i>Health Physicist</i>	20 and 34	Criteria Policy Statement; MD 5.6; SA-103
		<i>Qualification Journal</i> It is attached in Section 4.6.2		
4.6.2	Qualification Program	RMCPP 5.1 <i>Qualifications and</i> <i>Training</i> Attachment 5.1-1 <i>Health Physicist</i> <i>Qualification Journal</i>	2, 20 and 34	Criteria Policy Statement; MD 5.6; IMC 1248; NRC/OAS Training Work Group "Recommendation s for Agreement State Training Programs".
4.6.3	Current Staff Qualification Program	Table 4.6-4 <i>Current</i> <i>Staff Training</i> <i>Completion</i> Appendix 4.6-1 <i>Letter</i> <i>of Current Staff</i> <i>Qualification</i>	20 and 34	Criteria Policy Statement; MD 5.6; IMC 1248.
		Appendix 4.6-2 <i>Current Staff</i> <i>Qualification Journals</i> Appendix 4.6-3 <i>Resumes of Current</i> <i>Staff</i>		

4.7	Event and Allegation Response Program Elements			
4.7.1	Procedures for Responding to Events and Allegations	RMCPP 3.1 <i>Management of</i> <i>Allegations</i> RMCPP 3.2 <i>Incident</i> <i>Response</i> RMCPP 3.3 <i>Scrap Yard</i> <i>Incident Response</i>	1 and 11	Criteria Policy Statement; MD 5.6; MD 8.8; IMC 1301; IMC 1302; IMC 1303; IMC 1330; SA-105; SA-300; SA-400.
4.7.2	Procedures for Identifying Significant Events and Submittals for Entry into the Nuclear Material Event Database	RMCPP 3.4 Nuclear Materials Event Database (NMED) Input	1 and 11	Criteria Policy Statement; SA- 300.

4.1.3 Content of the Proposed Agreement

Indiana is applying for a limited Agreement transferring to the State the authority to regulate byproduct materials as defined in 42 U.S.C. § 2014(e)(1), (3), and (4); source materials; and special nuclear materials, in quantities not sufficient to form a critical mass. The proposed Agreement follows below, and is formatted in accordance with, and with the content from, the Exhibit in NRC Management Directive 5.8. Indiana is not applying for an Agreement transferring to the State authority to regulate byproduct materials as defined in 42 U.S.C. § 2014(e)(2); for the regulation of the land disposal of byproduct, source, or special nuclear waste received from other persons; or for the evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided in the regulations or orders of the Commission.

The State of Indiana is requesting regulatory authority for 42 U.S.C. § 2014(e)(1)

42 U.S.C. § 2014(e)(1) defines byproduct material as "any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material".

The State of Indiana is requesting regulatory authority for 42 U.S.C. § 2014(e)(3).

Byproduct materials as defined in 42 U.S.C. § 2014(e)(3) is "any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity."

The State of Indiana is requesting regulatory authority for 42 U.S.C. § 2014(e)(4).

The definition in 42 U.S.C. § 2014(e)(4) is "any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency (EPA), the Secretary of the Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity."

The State of Indiana is requesting regulatory authority for source materials, and special nuclear materials, in quantities not sufficient to form critical mass.

AN AGREEMENT

BETWEEN

THE UNITED STATES NUCLEAR REGULATORY COMMISSION

<u>AND</u>

THE STATE OF INDIANA

FOR THE

DISCONTNUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY

<u>AND</u>

RESONSIBILITY WITHIN THE STATE OF INDIANA PURSUANT TO

SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMNDED

WHEREAS, The United Sates Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § et seq. (hereinafter referred to as the Act), to enter into an agreement with the Governor of the State of Indiana (hereinafter referred to as the State) providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in 42 U.S.C. § 2014(e)(1), (3) and (4); source material; and special nuclear material in quantities not sufficient to form a critical mass; and

WHEREAS, The Governor of the State is authorized under IC 10-19-12-11 to enter into this Agreement with the Commission; and

WHEREAS, The Governor of the State of Indiana certified on [DATE] that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

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WHEREAS, The Commission found on [DATE] that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and

WHEREAS, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuming that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, The Commission and the State recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions form licensing of those materials subject to this Agreement; and

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, it is hereby agreed between the Commission and the Governor of Indiana Acting on behalf of the State as Follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State of Indiana under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. <u>Byproduct material as defined in 42 U.S.C. § 2014(e)(1);</u>
- B. Byproduct material as defined in 42 U.S.C. § 2014(e)(3);
- C. <u>Byproduct material as defined in 42 U.S.C. § 2014(e)(4);</u>
- D. Special nuclear material, in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority, and the Commission shall retain authority and responsibility with respect to:

1. <u>The regulation of the construction, operation, and decommissioning of any</u> production or utilization facility or any uranium enrichment facility;

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- 2. <u>The regulation of the export from or import into the United States of byproduct,</u> <u>source, or special nuclear material, or any production or utilization facility.</u>
- 3. <u>The regulation of the disposal into the ocean or sea of byproduct, source, or</u> <u>special nuclear material waste as defined in the regulations or orders of the</u> <u>Commission.</u>
- 4. <u>The regulation of the disposal of such other byproduct material as the</u> <u>Commission from time to time determines by regulation or order should,</u> <u>because of the hazards thereof, not to be disposed without a license from the</u> <u>Commission.</u>
- 5. <u>The evaluation of radiation safety information on sealed sources or devices</u> <u>containing byproduct, source, or special nuclear material and the registration of</u> <u>the sealed sources or devices for distribution, as provided for in regulations or</u> <u>orders of the Commission.</u>
- 6. <u>The regulation of activities not exempt from Commission regulation as stated in</u> <u>10 CFR Part 150;</u>
- 7. <u>The extraction or concentration of source material from source material ore and</u> <u>the management and disposal of the resulting byproduct material;</u>
- 8. <u>The regulation of the land disposal of byproduct, source, or special nuclear</u> waste materials received from other persons.

ARTICLE III

With the exception of those activities identified in Article II, paragraphs one through four, this Agreement may be amended, upon application by the State and approval by the Commission, to include the additional areas specified in Article II, paragraphs five, seven and eight, whereby the State can exert regulatory authority and responsibility with respect to those activities and materials.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulations, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under Section 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and State programs for protection against hazards of radiation will be coordinated and compatible. The state agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and the licensee performance that may have generic implication or otherwise be or regulatory interest.

ARTICLE VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed on Article I licensed by the other party or by any other Agreement State.

Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which reciprocity will be accorded.

ARTICLE VIII

The commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of Indiana may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act, if the Commission finds that (1) such termination or suspension is required to protect health and safety, or (2) the State of Indiana has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274 j of the Act, temporarily suspend all or part of this agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on [DATE] and shall remain in effect unless and until such time as it is terminated pursuant to Article VII.

Done at Rockville, Maryland this [DATE] day of [MONTH], [YEAR]

FOR THE UNITED STATE NUCLEAR REGULATORY COMMISSION

<u>, Chairman</u>

Done at Indianapolis, Indiana this [DATE] day of [MONTH], [YEAR] FOR THE STATE OF INDIANA

, Governor

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4.2 **Regulatory Requirements Program Elements**

A State may adopt regulatory requirements in a State specific format or adopt the NRC regulations by reference. Alternatively, the State may use the Suggested State Regulations (SSR), published by the Conference of Radiation Control Program Directors, as a model for its regulations.

The State of Indiana is incorporating the required and relevant Parts of the Code of Federal Regulations (CFR) by reference to avoid incompatibility with US NRC regulations as much as possible. The Indiana Radioactive Material Rules refers to the Parts incorporated by Reference, and the exceptions to incorporation. A complete copy of the Indiana Radioactive Material Rules is attached as Appendix 4.2-1. Parts 19, 20,30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, 71, and 150 of the CFR are incorporated by reference with the exception of those sections reserved to the NRC or otherwise states in the rule.

By incorporating these Parts of the CFR by reference, the State of Indiana will remain compatible in Compatibility Categories A, B, and C, as well as all program elements identified as having a health and safety role.

Indiana Standards for Protection Against Radiation are based on those of 10 CFR 20, including the dose limits for occupationally exposed persons and members of the public; limits on the concentration and quantity of materials released to the environment; and technical definitions and terminology, units of radioactivity and radiation dose, radiation symbols, labels, and warning signs.

Indiana has adopted those regulatory requirements designated by the NRC with significant transboundary implications. These provide the requirements that affect the movement of materials across State borders, provide certain other regulations, such as the concentrations of materials where the end user is exempt from licensing, and other requirements where a consistent nationwide approach is necessary.

By incorporating Parts of the CFR by reference, Indiana's regulations will provide what is needed for an orderly pattern of regulation, avoiding conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulations of agreement material on a nationwide basis and will not result in undesirable consequences. Indiana's regulations cover all categories of material being requested under the Agreement, and do not claim any intent to regulate materials or activities over which the NRC retains jurisdiction.

4.2.1 Regulations or Legally Binding Requirements

Indiana has adopted those NRC requirements designated as Compatibility Category A as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by the State of Indiana are identical to those of the NRC and provide uniformity in the regulation of agreement material. This is because the State is incorporating by reference Parts 19, 20, 30, 31, 32, 33, 34, 35, 37, 39, 40, 70, and 71 of the Code of Federal Regulations (CFR), except for those sections exclusively reserved for the NRC.

Indiana has adopted those regulatory requirements that satisfy the criteria for Compatibility Category B as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category B are those that apply to activities that have direct and significant transboundary implications. The program elements adopted by the state of Indiana are identical to those of the NRC and provide uniformity in the regulation of agreement material.

Indiana has adopted those regulatory requirements that satisfy the criteria for Compatibility Category C as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category C are those that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. The program elements adopted by the State of Indiana are identical to those of the NRC and provide uniformity in the regulation of agreement material. This is because the State is incorporating by reference Parts 19, 20,30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, and 71, 150 of the Code of Federal Regulations (CFR), except for those sections exclusively reserved for the NRC.

Indiana has adopted those regulations that satisfy the criteria for the health and safety category as defined in the Handbook to Management Directive 5.9. These are NRC program elements that are not required for compatibility (i.e., Category D), but that have been identified as having a health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Failures could lead to an exposure to an individual in excess of the basic radiation protection standard in Category A if its essential objectives were not adopted.

Although not required for compatibility, the State adopts program elements in this category, based on those of NRC, because of particular health and safety considerations. The State of Indiana incorporates health and safety elements that are identical to those of the NRC because the State incorporating by reference Parts 19, 20,30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, and 71, 150 of the Code of Federal Regulations (CFR), except for those sections exclusively reserved for the NRC. Incorporation is found in the Indiana Radioactive Material Rules. The rule in its entirety is attached as Appendix 4.2-1.

The State of Indiana is incorporating the required parts of 10 CFR by reference to eliminate the possibility of duplications, gaps, or other conflicts in regulation, including duplications, gaps, or conflicts between the State and the NRC, State agencies, or State and local agencies.

The Rule in its entirety is attached as Appendix 4.2-1.

The State of Indiana, in requesting an Agreement to regulate byproduct and/or source material as provided in the Atomic Energy Act, as amended, shall not have jurisdiction over areas under NRC jurisdiction on the date that the Agreement becomes effective. An orderly pattern of regulation ensures a transfer of regulatory authority to the State of Indiana from the Nuclear Regulatory Commission, on the date the Agreement becomes effective.

4.3 Licensing Program Elements

The Indiana Department of Homeland Security Radioactive Materials Control Program will conduct its licensing program using the U.S. Nuclear Regulatory Commission (NRC) Licensing Guidance, NUREG-1556 Series, as the basis for reviewing new license applications, license renewals, and amendments. Additionally, the Radioactive Materials Control Program Procedures (RMCPP) will be used for administrative licensing functions.

The Radioactive Materials Control Program Procedures (RMCPP) are broad and relate to all licensing activities, while the NUREG-1556 Series focuses on specific licenses or licensing activities and provides guidance to staff and for applicants and licensees when submitting a new application, renewal, or an amendment to an existing license.

Most licensing administrative guidance is provided through RMCPP Section 1, along with an RMCPP from Section 4. The RMCPPs are listed here and are found in this Section 4.3.

RMCPP No.	Title
RMCPP 1.1	Review of Initial Application for License or an Amendment Request
RMCPP 1.2	Renewal of Licenses
RMCPP 1.3	License Termination/Revocation
RMCPP 1.4	NRC Licenses Affected by Agreement States
RMCPP 4.1	Renewal Notices, Receipt, and Tracking of Licensing Actions

In Section 4.3.1, the guidance for technical reviews (NUREG 1556 Series) and information for license applicants are addressed. The procedure for assuring the technical quality of licenses, RMCPP 1.1 *Review of Initial Application for License or an Amendment Request* is in Section 4.3.5.

RMCPP 1.2 Renewal of Licenses, RMCPP 1.3 License Termination/Revocation, RMCPP 1.4 NRC License Affected by Agreement States, and RMCPP 4.1 Renewal Notices, Receipt, and *Tracking of Licensing Actions* are included in Section 4.3.6 Administrative Licensing Procedures.

Since Indiana is not seeking an Agreement providing responsibility for evaluating radiation safety information on sealed sources or devices, registration for distribution, the technical evaluation of a proposed license for a low level radioactive waste land disposal site, or conducting the evaluation of a regulatory program for 11e.(2) byproduct material including uranium or thorium mining facilities, the content of Section 4.3.2, 4.3.3, and 4.3.4 is simply a statement about this lack of applicability.

List of Acronyms/Abbreviations

AAPM	American Association of Physicists in Medicine
ACMUI	American Committee on the Medical Use of Isotopes
ACR	American College of Radiology
AEA	Atomic Energy Act
ARDL	Academic Research and Development License
ALARA	As Low As Reasonably Achievable
ALI	Annual Limit on Intake
ANSI	American National Standards Institute
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
AU	Authorized User
Bg	Background
Bq	Becquerel
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
CFR	Code of Federal Regulations
Ci	Curie
Cm	centimeter
cm ²	square centimeter
Co-57	Cobalt-57
Co-60	Cobalt-60
COC	Certificate of Compliance
CPM	counts per minute
DFP	Decommissioning Funding Plan
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DIS	Decay-In-Storage
DOE	United State Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
DOJ	United States Department of Justice
DOT	United States Department of Transportation
DP	Decommissioning Plan
dpm	disintegration per minute
dpm/cm ²	disintegrations per minute per square centimeter
DU	Depleted Uranium
ECD	Electron Capture Device
EPA	United States Environmental Protection Agency
F-18	Fluorine-18
FA	Financial Assurance
FBI	United States Federal Bureau of Investigation
FDA	United States Food and Drug Administration
FE	Focus Element
FSME	Office of Federal and State Materials and Environmental Management Programs
ft	foot
GBq	Gigabecquerel
GC	Gas Chromatograph
G-M	Geiger-Mueller
GPS	Global Positioning System
GSR	Gamma Stereotactic Radiosurgery
Gy	Gray
HAZMAT	Hazardous Material

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HDR	High Dose-Rate
Hr	Hour
HVL	Half Value Layer
I-125	Iodine-125
I-131	Iodine-131
ICRP	International Commission on Radiological Protection
IDHS	Indiana Department of Homeland Security
IMC	Inspection Manual Chapter
IN	Nuclear Regulatory Commission Information Notice
IP	Inspection Procedure
Ir-192	Iridium-192
IRB	Institutional Review Board
L/C	License Condition
LDR	Low Dose-Rate
LLD	Lower Limit of Detection
LLEA	Local Law Enforcement Agency
LLW	Low-Level radioactive Waste
LVS	License Verification System
LSA	Low Specific Activity
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDA	Minimum Detectable Activity
MDC	Minimum Detectable Concentration
MeV	Million electron Volts
μCi	microcurie
mCi	millicurie
mGy	milligray
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m	meter
MOU	Memorandum of Understanding
Mo-99	Molybedenum-99
mrem	millirem
mR	milliroentgen
MSHA	Mine Safety and Health Administration
N/A	Not Applicable
NaI	Sodium Iodide
NCRP	National Council on Radiation Protection and Measurements
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NMED	Nuclear Materials Event Database
NMSS	Office of Nuclear Material Safety and Safeguards
NOV	Notice of Violation
NRC	United States Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Report
NVLAP	National Voluntary Laboratory Accreditation Program
PG	United States Nuclear Regulatory Commission Policy and Guidance Directives
OSL	Optically Stimulated Luminescence Dosimeter
OSHA	United States Occupational Safety and Health Administration
000	Official Use Only
P-32	Phosphorous-32
PET	Positron Emission Tomography
PII	Personally Identifiable Information

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Q	Quality Factor
QA	Quality Assurance
QC	Quality Control
R	Roentgen
RAI	Request for Additional Information
Ra-226	Radium-226
Ru-82	Rubidium-82
RMCP	Radioactive Materials Control Program
RMCPP	Radioactive Materials Control Program Procedure
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSRM	Risk Significant Radioactive Material
SDE	Shallow Dose Equivalent
SI	International System of Units
SNM	Special Nuclear Material
SRI	Security Related Information
SSD	Sealed Source and Device [registration certificate]
SSDR	Sealed Source and Device Registry
Std	Standard
Sv	Sievert
TAR	Technical Assistance Request
ТВq	Terabecquerel
Tc-99m	Technietium-99m
т	Time
TEDE	Total Effective Dose Equivalent
TI	Transport Index
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TLD	Thermo-Luminescent Dosimeter
U.S.C	United States Code
WBL	Web Based Licensing
WD	Written Directive
Wk	Week
XRF	X-ray Fluorescence
Yr	Year

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

This section of the application provides technical procedures that address radiation safety issues necessary for the safe and secure storage, possession, and use of licensed materials. These documents include standard review plans, checklists, and licensing guides.

They address:

- Assessment of the applicant's facilities and safety equipment, training, and experience in the use of the materials for the purpose requested and proposed managerial controls.
- Security requirements for radioactive materials in quantities of concern, including requirements for pre-licensing visits for new entities that do not have an existing Agreement State or NRC license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license.
- Information exchange between the program's inspection staff and licensing staff; and
- The specific required qualification of license reviewers within the staff qualification plan.

They also provide guidance for the evaluation of technical issues in license applications including places and conditions of storage, places, and conditions of use, and decommissioning of facilities and equipment. In addition, the procedures address environmental considerations, security against unauthorized removal, and safety equipment. They address the qualification of users, licensee operating and emergency procedures, appropriate surveys, personnel monitoring under the close supervision of technically qualified individuals, and preparations for transport. 10 CFR 35.1000 Emerging Technology issues are addressed by utilizing the guidance provided on the NRC's "Medical Uses Licensee Toolkit" at

https://www.nrc.gov/materials/miau/med-use-toolkit.html

Procedures that address license fees, license file maintenance, and other materials program administrative issues are found in Section 4.3.5 and 4.3.6.

The U.S. Nuclear Regulatory Commission's (NRC) NUREG-1556 Series documents are used by the Indiana Department of Homeland Security Radioactive Materials Control Program Reviewers and Inspectors. The NUREG-1556 Series Volumes provide detailed instructions and examples for licensees and applicants in the preparation of their radioactive materials applications.

All administrative licensing action are to be performed with the guidance contained in NUREG-1556 Volume 20 "Guidance About Administrative Licensing Procedures," and the Indiana Department of Homeland Security Radioactive Materials Control Program Procedures (RMCPP) 1.1-1.4 and 4.1.

A tabulation of the applicable NUREG-1556 Volumes is provided below in Table 4.3-1

Table 4.3-1 NUREG-1556 Volumes

NOTE: The most up-to-date volumes can be found at: <u>https://www.nrc.gov/reading-rm/doc-</u> <u>collections/nuregs/staff/sr1556/index.html</u>

Volume No.	Volume Title
1	Program Specific Guidance About Portable Gauge Licenses
	https://www.nrc.gov/docs/ML1617/ML16175A375.pdf
2	Program Specific Guidance About Industrial Radiography Licenses
	http://www.nrc.gov/docs/ML1606/ML16062A091.pdf
3	Applications for Sealed Source and Device Evaluation and Registration
	http://www.nrc.gov/docs/ML1524/ML15246A317.pdf
4	Program Specific Guidance About Fixed Gauge Licenses
	http://www.nrc.gov/docs/ML1618/ML16188A048.pdf
5	Program Specific Guidance About Self-Shielded Irradiator Licenses
	http://www.nrc.gov/docs/ML1817/ML18176A007.pdf
7	Program Specific Guidance About Academic, Research and Development, and Other licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers
	http://www.nrc.gov/docs/ML1806/ML18065A006.pdf
8	Program Specific Guidance About Exempt Distribution Licenses
	http://www.nrc.gov/docs/ML1815/ML18158A165.pdf
	http://www.nrc.gov/docs/ML2125/ML21256A291.pdf
9	Program Specific Guidance About Medical Use Licenses
	https://www.nrc.gov/docs/ML1925/ML19256C219.pdf
11	Program Specific Guidance About Licenses of Broad Scope
	https://www.nrc.gov/docs/ML1705/ML17059D332.pdf

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12	Program Specific Guidance About Possession Licenses for Manufacturing and Distribution
	https://www.nrc.gov/docs/ML1813/ML18136A704.pdf
13	Program Specific Guidance About Commercial Radiopharmacy Licenses
	https://www.nrc.gov/docs/ML1907/ML19079A207.pdf
14	Program Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
	https://www.nrc.gov/docs/ML1812/ML18120A129.pdf
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
	https://www.nrc.gov/docs/ML1618/ML16181A003.pdf
16	Program Specific Guidance About Licenses Authorizing Distribution to General Licensees
	https://www.nrc.gov/docs/ML1818/ML18180A187.pdf
17	Program Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass
	https://www.nrc.gov/docs/ML1819/ML18190A207.pdf
18	Program Specific Guidance About Service Provider Licenses
	https://www.nrc.gov/docs/ML1724/ML17242A055.pdf
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non- Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
	https://www.nrc.gov/docs/ML1617/ML16175A107.pdf
20	Guidance About Administrative Licensing Procedures
	https://www.nrc.gov/docs/ML2031/ML20318A384.pdf

Program Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator
https://www.nrc.gov/docs/ML1814/ML18143A670.pdf

The NUREG-1556 Series documents contain directions for applicants and licensees on forms used to apply for a license, an amendment or renewal to an existing license, and communications with the Department. The table below provides the forms necessary when applying for a radioactive materials license. The forms and communications are to be sent to:

Indiana Department of Homeland Security:

Telephone:	ADD
Email Address:	ADD
Mailing Address:	302 West Washington, E-208
	Indianapolis, IN 46204
Attn:	Radioactive Materials Control Program

NRC Form	Department Form	Purpose
313	313	Application for a Radioactive Materials License
313A (RSO)	313A (RSO)	Radiation Safety Officer (Preceptor Attestation)
313A (AMP)	313A (AMP)	Authorized Medical Physicists (Preceptor Attestation)
313A (ANP)	313A (ANP)	Authorized Nuclear Pharmacist (Preceptor Attestation)
313A (AUD)	313A (AUD)	Authorized User-Diagnostic (Preceptor Attestation) No WD
313A (AUS)	313A (AUS)	Authorized User Therapy (Preceptor Attestation)
313A (AUT)	313A (AUT)	Authorized User Written Directive Required (Preceptor Attestation)
314	314	Disposition of Materials
3	3	Notice to Employees
4	4	Cumulative Occupational Dose History
5	5	Occupational Dose Records for a Monitoring Period
241	241	Reciprocity Application

Table 4.3-2: NRC and Department Forms

4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources or Devices and Registration for Distribution – Not Applicable

> The State of Indiana is not applying for authority to regulate the evaluation of radiation safety information on sealed sources or devices nor registration for distribution. As such, there are no procedures in this section of the application.

4.3.3 Procedures for Conducting the Technical Evaluation of a Proposed License for a Low-Level Radioactive Waste Land Disposal Site – Not Applicable

> The State of Indiana is not applying for regulatory authority to conduct the technical evaluation of a proposed license for a low-level radioactive waste land disposal site. As such, there are no procedures in this section of the application.

4.3.4 Procedures for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material Including Uranium or Thorium Mining Facilities – Not Applicable

> The State of Indiana is not applying for authority to conduct the evaluation of a regulatory program for 11e.(2) byproduct material including uranium or thorium mining facilities. As such, there are no procedures in this section of the application.

4.3.5 Procedures for Assuring the Technical quality of Licenses

Indiana Department of Homeland Security Radioactive Materials Control Program staff will utilize RMCPP 1.1 "Review of an Initial Application for License or an Amendment" to provide means by which the technical quality of licenses is assured. The elements included primary review, secondary review by two different qualified license reviewers, and a supervisory review. The primary and secondary review are documented using the **RMCPP 1.1 Attachment 1.1-4 Licensing Review Job Aid** and the supervisory review is documented using the **RMCPP 1.1 Attachment 1.1-5 Administrative Qualitative Checklist**. These three reviews are used for all new licenses, license amendments, license renewals, and license terminations to help assure the quality of licensing actions. All licensing procedures and their attachments are found in the Application Section 4.3.6 Administrative Licensing Procedures.

4.3.6 Administrative Licensing Procedures

Administrative licensing procedures describe the administrative processing steps useful to assure all procedural requirements are completed in licensing activities. There are five administrative procedures for licensing: RMCPP 1.1 *Review of Initial Application for License or an Amendment Request*, RMCPP 1.2 *Renewal of Licenses*, RMCPP 1.3 *License Termination/Revocation*, RMCPP 1.4 *NRC Licenses Affected by Agreement States*, and RMCPP 4.1 *Renewal Notices, Receipt, and Tracking of Licensing Actions*. Copies of the procedures follow in this order.

Indiana Department of Homeland Security Radioactive Materials Control Program Radioactive Materials Control Program Procedure 1.1, Revision 0



Review of an Initial Application for License or an Amendment Request		
Prepared By:	Date:	
Reviewed by:	Date:	
Approved By:	Date:	
Effective Date:		
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Revision	Date	Description of Changes
0		

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Attachment 1.1-4 License Review Job Aid

- Attachment 1.1-5 Administrative Qualitative Checklist
- Attachment 1.1-6 Program Codes by License
- Attachment 1.1-7 Department Form 313 Application for Radioactive Materials License

*These are maintained separately as Security-Related Materials

1.0 PURPOSE

1.1 Applicability

- 1.1.1 The purpose of this procedure is to define the process for reviewing all types of specific license requests and license amendments (refer to Attachment 1.1-6 for Program Codes for each license type) received by the Indiana Department of Homeland Security Radioactive Materials Program (Department) and those transferred to the Department from the Nuclear Regulatory Commission (NRC). Applications for license renewal are covered by RMCPP 1.2 *Renewal of Licenses* and termination is covered by RMCPP 1.3 *License Termination/Revocation*.
- 1.1.2 Appropriate NUREG-1556 checklists and procedures that shall be used during the review process will be identified.
- 1.1.3 The process for issuing a specific license or an amendment to a license and standard license conditions will be provided after a thorough and equitable evaluation of the application.
- 1.1.4 The process for denying (state's initiative) or abandoning (applicant's or state's initiative) a request for licensing action shall be defined.
- 1.1.5 This procedure does not address the qualifications required to review a specific license of each type; refer to RMCPP
 5.1 Qualifications and Training for these guidelines. For this procedure, qualification of the license reviewer for a specific license type is verified by the Radiation Control Program Director prior to determining the reviewer.

1.2 References

- 1.2.1 290 IAC 3
- 1.2.2 NUREG-1556, "Consolidated Guidance About Materials Licenses".
- 1.2.3 Title 10 of the Code of Federal Regulations (10 CFR)

1.3 Files

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- 1.3.1 Specific License
- 1.3.2 License Application and/or Amendment Request Submittal
- 1.3.3 Any Deficiency Letters
- 1.3.4 License Transmittal Letter
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1.4 Definitions

- 1.4.1 Department: Means Department of Homeland Security as established by I.C. 10-19-2-1.
- 1.4.2 Amendment (License Amendment): Any change to any of the content of a radioactive materials license once issued by the Department constitutes an amendment.
- 1.4.3 Application Request: A request for an application for a license from a prospective applicant on NRC Form 313 or equivalent.
- 1.4.4 Denying with Prejudice: Denial on the basis that the applicant for license is not qualified and shall not reapply for a license unless there has been a material change to the circumstances and substance of the license application, e.g., a minor applying for a license to possess and use radioactive material or a non-medical qualified individual applying for a license to use radioactive material in the diagnosis and/or treatment of humans will have their licenses denied with prejudice and may only reapply if and when the applicants meet the age and medical qualifications, respectively.
- 1.4.5 Denying Without Prejudice: Denial on the basis that the application for license was deficient and denied, but that the applicant may reapply after correcting the deficiencies.
- 1.4.6 License Review: The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.
- 1.4.7 License Reviewer: A Radioactive Materials Control Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.
- 1.4.8 Licensing Action: A request or application received from an applicant, or a licensee as follows:

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- An application for a license to receive, possess, and use licensed material;
- An application for renewal of a license;
- An amendment request to a license, e.g., change in administrations, authorized use, and/or user(s), Radiation Safety Officer (RSO), quantity of material, isotopes, facilities, etc.; and/or,
- A request for termination of a license
- 1.4.9 Manufacturing and Distribution (M&D): Refers to licenses for manufacturing and distribution of byproduct, source, and/or special nuclear material.
- 1.4.10 Possession Only License: A license issued by the Indiana Department of Homeland Security Radioactive Material Control Program that authorizes the licensee to possess specific radioactive material but does not authorize its use. A possession only license is issued for a licensee that has ceased principal operations which used radioactive material and has begun or is preparing to decommission its storage and usage facilities and dispose of, or transfer remaining radioactive material to an authorized recipient, or as shielding material (depleted uranium) used for medical therapy linear accelerators and technetium-molybdenum generators.
- 1.4.11 Primary Review: A primary review is that conducted initially for a licensing action by a qualified license reviewer. It is conducted using RMCPP 1.1, or other relevant RMCPPs, and relevant content from NUREG 1556 and is documented on the **License Review Job Aid.**
- 1.4.12 Pre-Licensing Checklist: The purpose of this checklist is to provide a basis for confidence that a new applicant (i.e., an entity that has never had a license or is unknown) requesting a specific license, or a licensee requesting transfer of control to a new applicant or unknown entity will store and use radioactive materials at locations as specified and under the authorization of the license.
- 1.4.13 Pre-Licensing Site Visit: A site visit and face-to-face meeting with an entity with the purpose of providing a basis for confidence that radioactive material will be used as specified. Staff should use the Pre-Licensing Checklist

to determine which applicants require visits. The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-Licensing Checklist. At a minimum, all storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application. Prelicensing site visits must be completed before the issuance of a license.

- 1.4.14 Regulatory Guide: Guidance published by the NRC or the Indiana Radioactive Materials Control Program, in which each guide defines an acceptable program or part of a program, for the possession and specific use of radioactive materials. An applicant is not obligated to follow one of these guidance documents when developing their program and applying for a license or amendment; however, if not followed, the applicant must demonstrate that the proposed program is at least equivalent to the one described in the guidance document.
- 1.4.15 Risk Significant Radioactive Material (RSRM): RSRM refers to the values in 10 CFR 37 Appendix A.
- 1.4.16 Secondary Review: A secondary review is conducted by a qualified license reviewer as a quality control activity. It is meant to assure the license review conducted by the primary reviewer is complete and accurate. The secondary reviewer must be a qualified license reviewer other than the person conducting the primary review. It is done using RMCPP1.1, other RMCPPs as appropriate, and applicable guidance from NUREG 1556. It is documented using the **License Review Job Aid**.
- 1.4.17 Supervisory Review: This is the final required review of licensing activity.
- 1.4.18 Tie-down: A license commitment that is additional to the standard license conditions stated on the license.
- 1.4.19 Written Directive: An authorized user's written order for the administration of byproduct material or radiation

from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 May serve as primary reviewer of license applications and amendments for licenses for which qualified. Through review, the HP receives, logs, and saves licensing action information and makes requests for additional information from the applicant/licensee.
- 2.1.2 May also serve as secondary reviewer, though not for license applications and amendments for which the HP was primary reviewer.
- 2.1.3 Maintains the computer-based and other files and tracks the application for a license during processing.
- 2.1.4 Responds to requests for license applications and amendments by transmitting an application (NRC Form 313), internet address of the regulations, and a copy of, or reference to, specific guidance within 30 days of the licensing actions.
- 2.1.5 Reviews the application or amendment, determines if it is complete, requests additional information as needed, and prepares the license or amendment for secondary review and license or amendment approval by the Radiation Control Program Director (RCPD) or designee.
- 2.1.6 The suggested time to complete all licensing actions (i.e., new license applications and existing license amendments, renewals, and terminations) is:

Priority	Goal Time Increment	Licensing Action
R - Rush	As Soon As Possible	Assigned by S/HP
		License Termination
		License Expiration
H – High	90 days	New RSO
		New Authorized User
		New Use*
		Possible Violations

M - Medium	180 days	Initial License Renewal – In Entirety New Equipment
		New Change Practice
L – Low	180 days	Delete AU or RSO

- 2.1.7 Recommends whether an application is deficient and should be denied either with or without prejudice.
- 2.1.8 Provides findings during the primary or secondary review of license applications and amendments to the Senior Health Physicist or RCPD as appropriate.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Generally, manages the Radioactive Materials Control Program and for license applications and amendments, assigns the licensing actions to a qualified Health Physicist. This responsibility can be designated if necessary to the RCPD.
- 2.2.2 May perform primary or secondary reviews of license applications and amendments.
- 2.2.3 May initiate consultation with and seek concurrence of the IDHS General counsel on license application or amendment denials, with or without prejudice.
- 2.2.4 The responsibilities of the S/HP may be designated to the RCPD in the S/HP's absence.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Approves and signs licenses and license amendments. This responsibility may be designated to the S/HP in the absence of the RCPD.
- 2.3.2 May perform secondary license reviews if qualified as a license reviewer for the license type.
- 2.3.3 The responsibilities of the RCPD relative to the Radioactive Materials Control Program may be designated to the S/HP in the absence of the RCPD.

3.0 PROCEDURE

3.1 Receipt of a License Application or Request for a License Amendment

Upon receipt of an application for a license or a request for a license amendment the following shall be performed:

- 3.1.1 Timeliness of review Within 30 days of receipt of a request for a licensing action, the Department should perform an acceptance review of the licensing request and take the following actions:
 - 3.1.1.1 Issue an acknowledgement of receipt within 30 working days of the receipt and make an entry for such in Web-Based Licensing (WBL).
 - 3.1.1.2 Confirm that all necessary sections of the application (NRC Form 313) are completed, and the form has been signed by the applicant's certifying official.
 - 3.1.1.3 Confirm that attachments identified by the applicant are included in the submittal.
 - 3.1.1.4 Identify any requests for expedited review for safety-significant concerns (e.g., change in the Radiation Safety Officer or amendment requests resulting from identification of safety-significant violations) or business reasons (e.g., change of ownership).
- 3.1.2 After the acceptance review, send the applicant an acknowledgement letter that the license is under review and, if applicable, the current license will remain in effect until the licensing action is complete.
- 3.1.3 Note any administrative deficiencies or omissions that were identified during the primary review that could delay the technical review of the licensee's action.
- 3.1.4 Once issues and deficiencies have been identified in an application, the license reviewer should use the most efficient process available to fully communicate issues to the licensees, thereby reducing reliance on formal letters.

- 3.1.5 Ensure that each requested item for additional information is clear (i.e., provide a description of the deficiency and a statement of what is needed); is essential to protect safety; and is limited to Department regulatory requirements and NUREG-1556 and other guidance.
- 3.1.6 Any significant or complex deficiencies in an application for either a new license or license amendment should be described in a deficiency letter to the applicant. Deficiency letters can be sent by regular mail, e-mail, or facsimile. The letter to the applicant should contain a statement that specifies that the Department will assume the applicant does not intend to pursue its application if the Department does not receive a reply within 30 calendar days from the date of the letter.
- 3.1.7 If a response to the deficiency letter is received within 35 calendar days from the date of the letter, proceed with review of the response.
- 3.1.8 If a response to the deficiency letter is not received within 35 calendar days from the date of the letter, the application can be considered abandoned for failure to provide the requested information. This abandonment is without prejudice to the resubmission of the application. Prompt action (5 working days) should be taken to void the application. The voiding of this application should be closely coordinated with the IDHS General Counsel.
- 3.1.9 Inform the applicant or licensee that the technical review may identify additional omissions in the submittal and technical issues that require additional information.
- 3.1.10 Provide the applicant or licensee with an estimated time for completion of the licensing action. These are only estimates based on the specific type of licensing action. The estimated time for completion should account for any expedited review.
- 3.1.11 Inform the applicants that they are subject to Department licensing fees as outlined in NRC Form 313 or equivalent (Attachment 1.1-1.7).
- 3.1.12 Priority: An action priority shall be assigned to the application or request in accordance with the priority schedule here in RMCPP 1.1 and with the concurrence of the S/HP.

- 3.1.13 Assignment of Reviewer: The processing and review of an application or amendment request shall be assigned to a Health Physicist qualified to conduct such a review.
- 3.1.14 Follow-Up on Mail Returned from Licensees: Mail that is returned to the Department may indicate several problems, ranging from clerical errors to the loss of control of licensed material. The steps below must be followed in such situations:
 - Mail returned to the Department as undeliverable should be checked to ensure that the address is the same as on the application/license.
 - Any pending application related to the license should be checked for the correct mailing address.
 - For mail returned to the Department for any reason other than a Department clerical error, the procedure will be the same as for an expired license (RMCPP 1.3).
 - When the licensee cannot be located, send a certified letter to the address in the licensee file requesting clarification.
 - Determine if the applicant has made any deliveries or has made any shipments of radioactive materials.
 - <u>Under no circumstances will a license be</u> <u>issued if the location of use and mailing</u> <u>address is incorrect.</u>

As with new licensees, applicants requesting quantities of radioactive materials in excess of 10 CFR 37 Appendix A Category 1 and Category 2 quantities, shall have an initial inspection within one year of the application issue date. The first inspection date is entered in WBL and the licensee file as a reminder.

3.2 Processing an Application for License

3.2.1 The application and all appended and referenced material shall be reviewed. State of Indiana rules, policies, procedures, NUREG-1556 applicable volumes, and

applicable parts of 10 CFR shall be used, as appropriate, by the reviewer to evaluate the applicant and the application.

- 3.2.1.1 The **Pre-Licensing Checklist** (Attachment 1.1-1) shall be used on all new license applications as well as transfer of control (change of ownership) applications. Note that change of ownership or transfer of control is generally considered a new application unless the entities are well known as would be the case if one medical licensee assumes ownership of or merges with another medical licensee. Once completed, the checklist must be placed in the licensing folder with the license.
- 3.2.1.2 A checklist to address requests for **Risk-Significant Radioactive Material** (Attachment 1.1-2) must also be completed and placed in the licensing folder.
- 3.2.2 If additional information is needed, a Request for Additional Information (RAI) should be used. If the RAI is not addressed as necessary, a meeting with the applicant and/or a visit to the proposed facility(s) must be completed by the reviewer.
- 3.2.3 The reviewer shall use the **Licensing Job Aid** (Attachment 1.1-4) to verify all aspects of the licensing review have been completed and ensure that the review of the application includes the following commonly missed items:
 - Application signed by upper management;
 - Facility diagrams or sketches, including but not limited to, hoods, shielding, ventilation, work areas, storage areas, location of nearest occupied area, and physical security of radioactive material;
 - Number, type, and range of survey instruments including procedures for calibration, checks for operability, and maintenance;
 - Training and experience records for all Authorized Users (AUs);
 - Preceptor and attestation statements for all new AUs, RSOs, and Authorized Medical Physicists (AMPs);

- Training and experience records, duties, responsibilities, and the availability of the RSO;
- Training and experience records for the Radiation Safety Committee Chair, if appropriate;
- Records to be retained and responsibility for records retention assigned;
- Frequently missed records include training for new employees, annual refresher training, survey instrument calibrations and source checks, and dose calibrator constancy, accuracy, linearity, and geometric variation checks for medical licenses;
- Procedures for receipt of radioactive material, especially to include off-hours and weekends.
- 3.2.4 Following this primary review, a secondary review will be conducted for quality assurance purposes by a qualified license reviewer other than the person doing the primary review.
- 3.2.5 The secondary review must also be conducted using the Licensing Job Aid and include a thorough evaluation of the completeness and accuracy of the licensing action file contents including the Pre-licensing Checklist and the Risk-Significant Radioactive Materials Checklist.
- 3.2.6 Upon completion of the primary and secondary review of the application and any supplemental material requested by the reviewer, a recommendation to issue a license or deny the application shall be made to the RCPD who will conduct the Administrative Qualitative Checklist and approve or deny the license application or amendment.
- 3.2.7 If the RCPD approves issuance of the license or license amendment, the prepared license will be signed by the RCPD or designee.
- 3.2.8 All submitted and referenced information shall be tieddown. A tie-down license condition is used for procedures, radiation detection equipment, use locations, etc., that are not already specifically identified on the license.
- 3.2.9 If the recommendation is to deny the application and the IDHS General Counsel concurs, the primary reviewer, S/HP

or RCPD, in concert with the IDHS General counsel shall prepare a notification to the applicant. The notification shall state the reason for denial and if a new application would be accepted from the applicant.

3.3 Pre-licensing Site Visit

- 3.3.1 The purpose of a Pre-licensing site visit is to establish a basis for confidence that radioactive materials will be used as specified.
- 3.3.2 Pre-licensing site visits are conducted for new entities that do not have an existing NRC or Agreement State license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license. They are also used to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up per the guidance in the **Pre-licensing Checklist** (Attachment 1.1-1).
- 3.3.3 By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis for confidence that the applicant will use the radioactive materials as specified in its license application.

3.4 Processing a Request for License Amendment

- 3.4.1 A request for an amendment to a specific license must be submitted using NRC Form 313 or equivalent. The request should be accompanied with a letter on company letterhead plus attachments. The request shall be signed by the individual in the position, or higher, that signed the application for license or the request shall be returned for proper signature. Alternatively, the licensing action request may be signed by an individual delegated by the person who signed the application or higher.
- 3.4.2 The primary review of the request for amendment shall determine if the request is so broad that it should be processed as a rewrite of the current license or as a new license. If it is determined that either a rewrite or a new license is appropriate and the S/HP concurs, the request

shall be returned to the licensee and an appropriate application shall be requested.

- 3.4.3 A request from a medical licensee to add a qualified Authorized User to their license shall be accompanied by records of the individual's training and qualifications. Records of training shall be signed by the preceptor and shall not be just a letter stating that these procedures had been performed at another licensed facility.
- 3.4.4 A request to add an Authorized User to a license shall be accompanied by records of the individual's training and qualifications, especially as related to the AU's uses of radioactive materials.
- 3.4.5 A request to delete an Authorized User must require an evaluation to determine that the authorized material and uses are approved for other Authorized Users on the license.
- 3.4.6 A request to add or replace a Radiation Safety Officer (RSO) or Chair of the Radiation Safety Committee (RSC) shall include training and experience records and duties, responsibilities, and if appropriate, availability and delegation of authority.
- 3.4.7 A request to add isotopes, quantities, physical form, use, facilities, instrumentation, or the authorized place of use shall be reviewed in the same way as a request for a partial specific license for that activity.
- 3.4.8 A checklist to address requests for **Risk-Significant Radioactive Material**, (Attachment 1.1-2), must also be completed when the amendment includes any radioisotope listed in the Ris-Significant Radioactive Material Table in Attachment 1.1-2 and the checklist must be placed in the licensing folder.
- 3.4.9 A license is normally amended in its entirety and includes new tie-down license conditions as appropriate. The RCPD shall sign to approve the amendment.

3.5 Processing a Request for Possession Only License (License Termination)

3.5.1 A Possession Only License is a license that authorizes the licensee to possess specific radioactive material but does not authorize its use. A Possession Only License is issued

for a licensee that has ceased principal operations using radioactive material and has begun or is preparing to decommission its storage and usage facilities and dispose of or transfer the remaining radioactive material to an authorized recipient. It may also be issued for shielding material (depleted uranium) used for medical therapy linear accelerators and technetium-molybdenum generators.

- 3.5.2 If a licensee requests that its license be converted to possession-only status, determine whether the licensee has permanently ceased operation. If the licensee has permanently ceased operation, the licensee is required to begin decommissioning pursuant to 10 CFR 30.36(d), 40.42(d), and 70.38(d). Determine whether the licensee can proceed with decommissioning.
- 3.5.3 If the licensee can proceed with decommissioning, instruct the licensee to proceed with decommissioning and license termination. Do not amend the license to authorize possession only. (Expired licenses do not need to be amended because by rule, decommissioning is the only activity authorized.) If decommissioning is the only activity authorized, change the program code to DECOMMISSIONING.

NOTE: Reviewers should coordinate with inspection and decommissioning staff concerning site reviews and inspection activities before the program code is changed.

3.5.4 If the licensee cannot proceed with decommissioning (e.g., demonstrates that all reasonable options for radioactive waste disposal have been exhausted), review the licensee's application using the checklist in Enclosure (1) from NRC's Policy and Guidance Directive PG 1-27 "Reviewing Requests to Convert Active Licenses to Possession-Only Licenses." When each item on the checklist has been adequately addressed, issue a possession-only license and change the program code to POSSESSION-ONLY: PERMANENT. Change the authorized use condition on the license to read, "Possession and storage only until termination of the license." The license should have a two-year expiration date and may be renewed if the licensee continues to demonstrate that it cannot divest itself of the radioactive material, although it has taken all reasonable actions within its ability to dispose of the material.

3.6 Handling of Information

3.6.1 A reviewer may receive information from an applicant or licensee that is marked as "proprietary," "confidential," "restricted," or "is the express property of Company X." The reviewer will need to determine whether the information is necessary to the licensing action. If the information is not necessary, it should be returned to the applicant. If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request for withholding the information (Attachment 1.1-3 **Checklist for Requests to Withhold Information from Public Disclosure)**. The reviewer evaluates the applicant's request for withholding the information. If the request is denied, in whole or in part, the applicant is given the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer notifies the applicant in writing that the request for withholding information from the public has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Documents that contain personally identifiable information, security-related confidential information, and/or proprietary information should be protected from public disclosure. Licensees and other entities should have sufficient internal controls to prevent release of information to limit the risk that personal, confidential, and proprietary information could be released to someone with malevolent intent. Methods to prevent the inadvertent release of confidential information include (1) restricting access to electronic recordkeeping systems that contain such information, (2) controlling the reproduction, distribution, and destruction of potentially confidential records, and (3) releasing confidential information only to those individuals who have a need to know the information to perform their jobs and who are made aware of the security-related nature of the information.

- 3.6.2 If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request for withholding the information in accordance with I.C.§## that includes the following guidance:
 - 3.6.2.1 The applicant shall request withholding at the time the document is submitted and shall comply with the document marking and affidavit requirements set forth below. The Department has no obligation to review documents not so marked to determine whether they contain information eligible for withholding.
 - 3.6.2.2 The applicant shall ensure that the document containing information sought to be withheld is marked as follows:
 - The first page of the document, and each successive page containing such information, must be marked to be readily visible, at the top, or by electronic watermark or other suitable marking on the body of the page, with language substantially similar to : "confidential information submitted under I.C. § ## "withhold from public disclosure under I.C. § #", or "proprietary", to indicate that it contains information the applicant seeks to have withheld.
 - Each document or page, as appropriate, containing information sought to be withheld from public disclosure must indicate, adjacent to the information, the basis (i.e., trade secret, personal privacy, etc.) for proposing that the information be withheld

from public disclosure under paragraph 3.6.2 of this section.

- 3.6.2.3 The Department may waive the affidavit requirements on request, or on its own initiative, or in circumstances when the Department, in its discretion, deems it appropriate. Otherwise, except for personal privacy information, which is not subject to the affidavit requirement, the request for withholding must be accompanied by an affidavit that:
 - Identifies the document or part sought to be withheld;
 - Identifies the official position of the person making the affidavit;
 - Declares the basis for proposing the information withheld, encompassing considerations set forth in I.C. § #.
 - Includes a specific statement of the harm that would result if the information sought to be withheld is disclosed to the public; and
 - Indicates the location(s) in the document of all information sought to be withheld.
- 3.6.2.4 Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with I.C. § # and the applicant should be notified in writing that the Department plans to honor the request; however, the notification needs to inform the applicant that the Department may have cause to review the determination in the future, for example, if the scope of a records request is in accordance with Indiana's Access to Public Records and Documents law I.C. §§

3.7 Assuring the Technical Quality of Licensing Actions

3.7.1 All license applications, license amendments, license renewals, and license terminations shall be provided a

primary, secondary, and supervisory review prior to the licensing action being signed and approved utilizing the **License Review Job Aid** for the primary and secondary review and the **Administrative Qualitative Checklist** for supervisory review (Attachment 1.1-4 and 1.1-5).

- 3.7.2 Upon completion of the primary review, the primary license reviewer will notify the Senior Health Physicist for secondary review assignment. This may be assigned to any qualified radioactive materials program license reviewer. The secondary review will utilize Attachment 1.1.-4 License Review Job Aid.
- 3.7.3 License reviewers should compare similar Indiana radioactive materials licenses as a means to provide an additional quality check to ensure completeness.
- 3.7.4 The final review to assure the technical quality of licensing actions is the supervisory review. It is conducted by the Radiation Control Program Director before signing the approving the licensing action.

4.0 Records

4.1 Records to be Maintained

- 4.1.1 Applications for license plus attachments are kept in the license file and are maintained by the Radioactive Materials Program Staff in a secure electronic environment accessible to Indiana Department of Homeland Security Radioactive Materials Control Program personnel only.
- 4.1.2 Requests for amendments are maintained in the appropriate specific license file.

4.2 Records Retention

- 4.2.1 Web Based Licensing is the primary electronic file repository.
- 4.2.2 Records may also be kept in other secure electronic forms with access only to RMCP staff.

5.0 Attachments to RMCPP 1.1

- 1.1-1 Pre-Licensing Checklist*
- 1.1-2 Risk-Significant Radioactive Material Checklist*
- 1.1-3 Checklist for Requests to Withhold Information from Public Disclosure
- 1.1-4 License Review Job Aid
- 1.1-5 Administrative Qualitative Checklist
- 1.1-6 Program Codes
- 1.1-7 NRC Form 313 Application for Radioactive Materials License

*These are maintained separately as Security-Related Materials



ATTACHMENT 1.1-1 to RMCPP 1.1, Revision 0: PRE-LICENSING CHECKLIST

This document is maintained separately as security-related materials



ATTACHMENT 1.1-2 to RMCPP 1.1, Revision 0: RISK-SIGNIFICANT RADIOACTIVE MATERIAL CHECKLIST

This document is maintained separately as security-related materials



ATTACHMENT 1.1-3 to RMCPP 1.1, Revision 0: CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE

Nar	me: License Number:			
	request that the Department withhold information contained in an			
	plication form public disclosure, the applicant must submit the information			
	application, including an affidavit, in accordance with I.C. #. The applicant			
	ould submit all the following:			
	A proprietary copy of the information. Brackets should be placed			
	around the material considered to be proprietary. This copy should be			
	marked as proprietary.			
	A non-proprietary copy of the information. Applicants should white			
	out or black out the proprietary portions (i.e., those in the brackets),			
	leaving the non-proprietary portions intact. This copy should not be			
	marked as proprietary. An affidavit that:			
	Is notarized.			
	Clearly identifies (such as by name or title and date) the document to be			
	withheld.			
	Clearly identifies the position of the person executing the affidavit. This			
	person must be an officer or upper-level management official who has			
	been delegated the function of reviewing the information sought to be			
	withheld and authorized to apply for withholding on behalf of the company.			
	States that the company submitting the information is the owner of the			
	information or is required, by agreement with the owner of the			
	information, to treat the information as proprietary.			
	Provides a rational basis for holding the information in confidence.			
	A letter that fully address the following issues:			
	• Is the information submitted to, and received by, the Department in			
	confidence?			
	Provide details.			
	Does the applicant customarily treat this information, or this type of			
	information, as confidential? Explain why.			
	 Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so 			
	substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of			
	the information to your company, amount of effort or money			
	expended in developing the information, and the ease or difficulty of			
	others to acquire the information.			



ATTACHMENT 1.1-4 to RMCPP 1.1, Revision 0: LICENSE REVIEW JOB AID

- **1.** Review submittal within 30 days of receipt of application.
- **2.** Review using applicable guidance to ensure the licensee submitted all required information from:
 - a. NUREG-1556 Consolidated Guidance About Materials Licenses;
 - NUREG-1757 Volume 1 & 2 Consolidated Decommissioning Guidance;
 - c. NUREG-1757 Volume 3 for Financial Assurance, Recordkeeping, and Timeliness;
 - d. RMCPP 1.1-1.4 and RMCPP 4.1; and
 - e. NRC Medical License Toolkit https://www.nrc.gov/materials/miau/med-use-toolkit.html
- **3.** Determine if subject to:
 - a. Financial Assurance;
 - b. Emergency Plan;
 - c. Environmental Assessment; or
 - d. Change of Ownership (References: 10 CFR 30.34(b), 40.26, 70.25, and NUREG-1556 Volume 15 for change of ownership).
- **4.** For amendments and renewals, compare with previous license and markup to show changes. Review licensee inspection/enforcement history.
- **5.** For new licenses and change of ownership, ensure that the Prelicensing Checklist has been completed.
- **6.** For all license action, ensure that the Risk Significant Radioactive Material (RSRM) Checklist has been completed.
- **7.** Review list of escalated enforcement actions for licensees and individuals. Go to:

https://www.nrc.gov/reading-rm/doccollections/enforcement/actions/materials/s.html

https://www.nrc.gov/reading-rm/doccollections/enforcement/actions/individuals/index.html

- **8.** Review license tie downs and inspection documentation.
- **9.** For license terminations:
 - a. Account for all radioactive material and locations of use and/or storage;
 - b. Confirm all materials have been properly transferred or disposed, that a thoroughly documented survey for the presence of radioactive materials (contamination or radiation) has been performed, and the site can be released for unrestricted use;
 - c. Determine if any incidents (spills/contamination) have occurred and the records of remediation and/or disposition of the radioactive materials (NRC Form 314) are completed if applicable; and
 - d. Ensure licensee has submitted records in accordance with 10 CFR 30.36(k)(4), 40.61, and 70.51.
- **10.** Notify the Radiation Control Program Director immediately with concerns and/or violations identified during the review.
- **11.** Ensure completed NRC forms are included and signed by licensee management:
 - a. NRC form 313 New Licenses (required)
 - b. NRC form 313 License Renewal (or equivalent); and
 - c. NRC form 314 License Termination (or equivalent)
- **12.** Ensure that sealed source model numbers are registered.
- **13.** Complete security related information and mark as appropriate.
- **14.** Obtain second reviewer concurrence.
- **15.** Ensure the document will be properly delivered through the mail.
- **16.** Draft license following license generation forms and compare with sample licenses.
- **17.** Update license expiration date on license.

- **18.** Confirm proper program code and inspection priority.
- **19.** Draft cover letter and print letter and license.
- **20.** Use Administrative Quality Checklist for Licensing Actions for QA/QC review of letter and license.



ATTACHMENT 1.1-5 to RMCPP 1.1, Revision 0: ADMINISTRATIVE QUALITATIVE CHECKLIST

- **1.** Spell check has been run. Spelling of names on cover letter and license are consistent.
- **2.** Issue date on the license and cover letter match.
- **3.** Cover letter and license contain proper "Official Use Only-Security Related Information (OUO-SRI)" banner, as required.
- **4.** Mailing address identified on cover letter matches address in item 2 of the license.
- **5.** License contains correct page numbers and amendment number. All initial licenses will be Amendment 0.
- **6.** License conditions are correctly numbered on the license.
- Document(s) are added to the tie-down conditions of the license, such as licensee commitments. Dates for all licensee commitments are correctly referenced in the tie down conditions of the license.
- **8.** Cover letter has the correct license numbers, date specified, and signatures.
- **9.** Licensing worksheets (checklists) are completed prior to Web Based Licensing processing. All electronic signatures (reviewer and supervisor) are completed.
- **10.** All information on the Web Based Licensing (WBL) worksheet is filled out and correct (Program Codes, Contact, RSO, Address, etc.).
- 11. Error reduction techniques are utilized, such as: reread/proofread/secondary review after printing which ensures that the printed license matches the screen and is appropriate prior to mailing the license.



ATTACHMENT 1.1-6 to RMCPP 1.1, Revision 0: INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES From US NRC Inspection Manual 2800 Enclosure 1

Program Code	Priority Code	Category Title
1000	Vary-	RSRM Licensee
1100	3	Academic Type A Broad
1110	5	Academic Type B Broad
1120	5	Academic Type C Broad
2110	2	Medical Institution Broad
2120	3	Medical Institution Written Directive (WD) Required
2121	5	Medical Institutions WD Not Required
2200	3	Medical Private Practice WD Required
2201	5	Medical Private Practice WD Not Required
2210	3	Eye Application Strontium-90
2220	3	Mobile Medical Service WD Not Required
2230	2	High-Dose Rate Remote After loader HDR
2231	2	Mobile Medical Service WD Required
2240	2	Medical Therapy Other Emerging Technology
2300	5	Teletherapy
2310	2	Gamma Stereotactic Radiosurgery
2400	5	Veterinary Non-human Subjects
2410	5	in-Vitro Testing Laboratories
2500	2	Nuclear Pharmacies
2511	5	Medical Product Distribution - 32.72 Prepared Radiopharmaceuticals
2513	5	Medical Product orstribution- 32.74- Sources and Devices
2600		Production or PET Radioactive Drugs - 30.320) (Secondary Code)
2700	5	Radium-226 luminous Products & Sources up to 10 Times 31.12(a)(4) & 151
2710	3	Radium-226 Luminous Products & Sources Greater Than 10 Times 31.12(a)(4) & 151
3110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources
3111	3	Well Logging Byproduct and/or SNM Sealed Sources Only

3112	3	Well Logging Byproduct Only - Tracers Only
3113	3	Field Flooding Studies
3120	5	Measuring Systems Fixed Gauges
3121	5	Measuring Systems Portable Gauges
3122	T	Measuring Systems Analytical Instruments
3123	Т	Measuring Systems Gas Chromatographs
3124	Т	Measuring Systems Other
3130	5	Inspection Systems
3210	2	Radionuclide Production Using an Accelerator
3211	2	Manufacturing and Distribution Broad Type A
3212	5	Manufacturing and Distribution Broad Type B
3213	5	Manufacturing and Distribution Broad Type C
03214	5	Manufacturing and Distribution Other
3215	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226
3218	3	Nuclear Laundry
3219	3	Decontamination Services
3220	Т	Leak Test Service Only
3221	5	Instrument Calibration Services Only - Sources Less than Or Equal To 100 Curies
03222	5	Instrument Calibration Services Only - Source Greater than 100 Curies
03225	5	Other Services - Source Less Than or Equal to 100 Curies
3226	2	Other Services - Source Greater Than 100 Curies
3231	2	Waste Disposal Burial
3232	3	Waste Disposal Service Prepackaged Only
3233	2	Waste Disposal Service Incineration
3234	2	Waste Disposal Service Processing and/or Repackaging
3235		Incineration, Non-commercial
3236	2	Waste Treatment Service (Other Than Compaction)

3240	5	General License Distribution - 32.51
3241	5	General License Distribution - 32.53
3242	5	General License Distribution - 32.57
3243	5	General License Distribution - 32.61
3244	5	General License Distribution - 32.71
3250	5	Exempt Distribution - 32.11: Exempt Concentrations and Items
3251	5	Exempt Distribution- 32.14: Certain Items
3252	5	Exempt Distribution - 32.17: Resins
3253	5	Exempt Distribution- 32.18: Small Quantities
3254	5	Exempt Distribution - 32.22: Self-luminous Products
3255	5	Exempt Distribution - 32.26: Smoke Detectors
3256	5	Exempt Distribution - 32.21 Carbon-14 Urea Capsules
3310	2	Industrial Radiography Fixed Location
3311	2	Industrial Diagnostic Systems
3320	1	Industrial Radiography Temporary Job Sites
3510	5	Irradiators Self Shielded less Than Or Equal To 10,000 Curies
3511	5	Irradiators Other less Than Or Equal To 10.000 Curies
3520	5	Irradiators tors Self Shielded Greater Than 10,000 Curies
3521	2	Irradiators - Other Greater than 10,000 Curies
3610	3	Research and Development Broad - Type A
3611	5	Research and Development Broad - Type B
3612	5	Research and Development Broad - Type C
3613	2	Research and Development Broad - Multisite - Multiregional
3620	5	Research and Development Other
3710	5	Civil Defense

3800	3	Byproduct Material Possession Only - Permanent Shutdown
3810	3	Byproduct Material Standby - No Operations
3900	D'	Decommissioning of Byproduct Material Facilities
11200	5	Source Material Other Less than 150 Kilograms
11210	Т	Source Material Shielding
11220	5	Source Material Military Munitions
11221	5	Source Material Military Munitions Outdoor Testing
11230	5	Source Material General License Distribution - 40.34
11300	5	Source Material Other Greater than 150 Kilograms
11700	5	Rare Earth Extraction and Processing
11800	2	Source Material Possession Only- Permanent Shutdown
11810	2	Source Material Standby- No Operations
11900	D	Decommissioning of Source Material Facilities
21310	5	Critical Mass Material - University
21320	5	Critical Mass Material - Other Than Universities
21325	D	Decommissioning of Critical Mass - Other Than Fuel Fabrication
22110	3	Special Nuclear Material Plutonium - Unsealed, Less than Critical Mass
22111	3	Special Nuclear Material, U-235 and/or U-233 - Unsealed, Less than a Critical Mass
22120	5	SNM Plutonium - Sealed Neutron Sources Less than 200 Grams
22130	Т	Power Sources with Byproduct and/or Special Nuclear Material
22140	5	Special Nuclear Material Plutonium - Sealed Sources in Devices
22150	5	Special Nuclear Material Plutonium - Sealed Sources Less than a Critical Mass
22151	5	Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass

22160	т	Pacemaker-Byproduct, and/or Special Nuclear Material - Medical Institution
22161	Т	Pacemaker - Byproduct, and/or Special Nuclear Material - Individual



ATTACHMENT 1.1-7 to RMCPP 1.1, Revision 0: APPLICATION FOR RADIOACTIVE MATERIALS LICENSE – NRC FORM 313

INSTRUCTIONS

See the appropriate **NUREG-1556** Consolidated Guidance <u>https://www.nrc.gov/reading-rm/doc-</u>

<u>collections/nuregs/staff/sr1556/index.html</u>, for detailed instructions for completing the application. Please also read the instructions below before completing this form. Type or print legibly and attach any additional information. You may submit electronic copies of the application and additional information.

Guidance for items 1 through 11 in this application is contained in each of the volumes of the NUREG-1556 Series. Different volumes exist for different activities. The applicant must follow the specific volume to complete items 1 through 11. The NUREG-1556 Guidance volumes are found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html

Fees: Applicants should refer to the RMCP website for the appropriate fee schedule.

Certification: The certifying individual must be a company senior officer, who has signature authority, and is responsible for the safe use of radioactive material in the State of Indiana.

Retain a copy and submit this application in duplicate to:

Indiana Department of Homeland Security Radioactive Materials Control Program 302 W. Washington Street, Room E-208 Indianapolis, IN 46204-2739

If this is an application for a NEW license, it must include remittance for the appropriate annual fee.

NRC Form 313 can be found at: <u>https://www.nrc.gov/reading-</u> rm/doc-collections/forms/nrc313info.html Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 1.2, Revision 0 Renewal of Licenses

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
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1.0 PURPOSE

1.1 Applicability

- 1.1.1 The purpose of this procedure is to define the steps required for renewal of a specific license under Indiana Department of Homeland Security Radioactive Materials Control Program (RMCP) authority, including those transferred from the Nuclear Regulatory Commission (NRC). This procedure also defines when an expedited renewal form is allowed rather than renewal in entirety. Timely and untimely applications for renewal are also discussed.
- 1.1.2 For the purpose of this procedure, qualification of the license reviewer for a specific license type is verified by the Radiation Control Program Director (RCPD) prior to determining the reviewer.

1.2 References

- 1.2.1 NUREG-1556 Series, "Consolidated Guidance About Materials Licenses".
- 1.2.2 Title 10 of the Code of Federal Regulation (10 CFR).
- 1.2.3 290 IAC 3

1.3 Files

The following records will be maintained by the Radioactive Materials Control Program, primarily in an electronic format for each licensee:

- 1.3.1 Specific License;
- 1.3.2 License Application and;/or Amendment Request Submittal;
- 1.3.3 Deficiency Letter;
- 1.3.4 License Transmittal Letter;
- 1.3.5 Requests for Additional Information; and
- 1.3.6 Financial assurance documents

1.4 Definitions

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- 1.4.1 Renewal in Entirety: Based on the review of the application, the inspection history, the current license, or a significant change in the applicable rule, the preparation of a total license revision is warranted. An example is a license that has been amended numerous times since the last renewal, such that the scope of the program has changed.
- 1.4.2 Expedited Renewal: The renewal of a license where the application, the inspection history, and the current license demonstrate that there has not been a significant change in the scope of the licensed program.
- 1.4.3 License Review: License review is the processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities primary review and secondary review.
- 1.4.4 License Reviewer: A Health Physicist or other Radioactive Materials Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform review for any category of license for which they are not qualified.
- 1.4.5 Timely Renewal: The receipt of an application for renewal of a license that has been postmarked 30 days or more before the license's expiration date. The license remains in effect until processing of the application for renewal has been completed.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Notifies a licensee that their license(s) will expire in 90 days and sends appropriate guidance document(s).
- 2.1.2 Informs the Senior Health Physicist (S/HP) or designee of licensees that have not submitted renewal applications at least 30 days prior to expiration and of any licenses that have expired.

- 2.1.3 Receives, logs, and acknowledges the receipt of an application for license renewal and informs the applicant that the application is considered to be timely if that is the case.
- 2.1.4 Sends the applicant for license renewal a request for additional information (RAI) and reviews the information submitted by the applicant in response to the RAI.
- 2.1.5 Maintains the records file with renewal documentation.
- 2.1.6 Completes the license renewal review in the time frame specified in RMCPP 1.1.
- 2.1.7 Provides information of important findings in the renewal application to the Senior Health Physicist (S/HP) or the Radiation Control Program Director (RCPD) in the absence of the S/HP.
- 2.1.8 Performs secondary reviews of license renewal applications as needed, but only of license renewals for which not a primary reviewer. Secondary review is documented using the **Licensing Job Aid** (Attachment 1.1-4 in RMCPP 1.1)

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Assigns a licensing action for processing to a qualified Health Physicist.
- 2.2.2 Reviews the renewal application to see if it is valid and processes the renewal application, as assigned.
- 2.2.3 Recommends whether a renewal application is deficient and should be denied either with or without prejudice. Denial with prejudice requires additional consultation with IDHS leadership and legal counsel.
- 2.2.4 Provides information of important findings in the renewal application to the Radiation Control Program Director.
- 2.2.5 Performs primary and secondary reviews of license renewal applications as needed.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Reviews, approves, and signs licenses. This responsibility can be delegated to the S/HP in the RCPD's absence.

- 2.3.2 Performs primary and secondary reviews of license renewal applications for licenses for which qualified as a license reviewer as needed.
- 2.3.3 Following consultation with, and concurrence of, the IDHS General Counsel, denies, with or without prejudice, a renewal application for license.

3.0 PROCEDURE

The review of an application for renewal of a specific license shall be conducted by a Health Physicist qualified to conduct such a review. All applications will have a secondary independent review performed by a qualified RMCP license reviewer prior to submission for approval.

3.1 License Expiration

- 3.1.1 Ninety (90) days prior to a license's expiration date, the licensee shall be notified of the pending expiration date using Attachment 1.2-2 and that if an application for renewal is postmarked at least 30 days prior to the expiration date, the application will be timely.
- 3.1.2 If the renewal application is postmarked less than 30 days prior, but not after the expiration date, the S/HP shall determine if the application should be considered timely.
- 3.1.3 If the application is found to be timely, the licensee if informed by letter that activities authorized by the current license may continue until processing of the renewal has been completed. This letter (Attachment 1.2-3) must be issued within 30 working days of the receipt.
- 3.1.4 If a timely application is not received by the expiration date, the licensee is informed that the license is considered to be expired. Any activity using licensed radioactive material shall cease and all licensed radioactive material shall be placed in storage or be disposed. The license will also be revised to become a possession only license. See sample letter as Attachment 1.2-1.
- 3.1.5 The Radiation Control Program Director must approve continued operation under the authority of any license for

which the renewal application was submitted after the license's expiration date.

3.1.6 Processing of terminated licenses is covered in RMCPP 1.3, License Termination/Revocation.

3.2 License Renewal

- 3.2.1 Radioactive Materials Control Program staff must review all license renewals in their entirety. One of the principal reasons for renewing a license in its entirety is to eliminate the confusion that can be caused by multiple amendments to the license and numerous tie-down conditions.
- 3.2.2 License renewal requests are conducted similarly to new license application (RMCPP 1.1 *Review of Initial Application for License or an Amendment Request*). The time frame for conducting license renewals from RMCPP 1.1 is 180 days.
- 3.2.3 The license renewal should contain all information that would be included in an initial license of the same program code(s) including tie-down license conditions that are based on any and all referenced license amendments.
- 3.2.4 Expedited renewals are conducted when a request is made by the licensee for new users or uses, such as a new medical modality (e.g., boron neutron capture therapy) or a new Radiation Safety Officer (RSO).
- 3.2.5 Expedited renewals are conducted on an as needed basis and should be completed in a timely manner depending on the scope of the request. They are granted only by the RCPD or S/HP in the absence of the RCPD.

4.0 RECORDS

4.1 Records to be Maintained

4.1.1 The application for license renewal plus attachments are maintained in the licensee's file as well as any deficiency letters, requests for additional information, and license transmittal letters generated.

4.2 Record Retention

- 4.2.1 Web Based Licensing (WBL) is the primary electronic file repository.
- 4.2.2 Records may also be kept in other secure electronic forms with access only to RMCP staff.

5.0 ATTACHMENTS TO RMCPP 1.2

- 1.2-1 Sample Letter for Expired License
- 1.2-2 Sample Renewal Letter for 90-day Notification
- 1.2-3 Sample Letter for Receipt of Renewal Application-Timely Filed

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 1.2-1 LICENSE EXPIRATION LETTER

<CITY, STATE, ZIP>

SUBJECT: EXPIRED LICENSE

Dear <NAME>,

Indiana Department of Homeland Security Radioactive Materials Control Program (Department) records show that Indiana Radioactive Materials License No. <**LICENSE NO.**> expired on <**DATE**>. A letter was sent on <**DATE**> (copy enclosed) informing you that your license would expire on <**DATE**>.

As of the date of this letter, no renewal application has been filed as per <**INSERT IN REGULATION**>. The license has been amended by the Indiana Department of Homeland Security Radioactive Materials Control Program to be a possession-only license allowing only the storage of the licensed material pending its transfer to a person authorized to receive it by a license issued by the NRC or an Agreement State.

Any use of the licensed material is in violation of the Indiana Department of Homeland Security Radioactive Materials Control Program regulations. If you wish to resume use of the licensed material, you may apply for a new Indiana Radioactive Material License.

Report to the Indiana Department of Homeland Security Radioactive Materials Control Program in writing of the steps taken to transfer all licensed material in your possession. Your report on NRC Form 314 Certificate of Disposition of Materials must be received no later than **<INSERT DATE 30 days from date of letter**>.

If you have decided not to possess radioactive materials and to discontinue your program, immediately transfer all radioactive material formerly authorized by the license to an authorized recipient. You must verify that the recipient's license authorizes the receipt of the isotope(s), type, form, and quantity of radioactive material to be transferred.

Send copies of the transfer records, a separate written request for termination of the license and appropriate attachments (i.e., decommissioning surveys of the facility, leak tests, et.) to the Department within 30 days of the date of this letter. Complete NRC Form 314

Send your response to the following address:

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Indiana Department of Homeland Security Radioactive Materials Control Program 302 W. Washington Street, Room E-208 Indianapolis, IN 46204-2739

Sincerely,

Senior Health Physicist

IDHS RMCP: Send certified mail to ensure receipt.

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 1.2-2 LICENSE RENEWAL LETTER

[DATE]

{LICENSEE NAME}

{ADDRESS}

{CITY, STATE, ZIP CODE}

SUBJECT: NOTIFICATION TO RENEW INDIANA AGREEMENT STATE LICENSE

Dear {SALUTATION, LAST NAME}:

Your Indiana Radioactive Materials License No. **{LICENSE NO.}** expires on **{DATE}**.

If you wish to renew, please submit a new application with NRC Form 313. It must include any and all information or documents previously submitted with the original application and any amendments. Please consult the Department if you wish to reference previously submitted information. Your license will be amended in its entirety utilizing the latest wording on the conditions of your license. These action s should help keep your license as complete and up-to-date as possible. If you do not wish to renew, you must complete NRC Form 314 Certificate of Disposition of Radioactive Materials. It is available at our web site:

ADD Hyperlink to web site

Below is a link to the Nuclear Regulatory Commission Regulatory Guide **(NUREG-1556)** that you should use in preparing the application. All items in the guide must be addressed.

Please complete the application, retain a copy, and submit all renewal requests to the following address:

Indiana Department of Homeland Security Radioactive Materials Control Program 302 W. Washington Street, Room E-208 Indianapolis, IN 46204-2739

If your application is submitted at least 30 days before the license expiration date, your license will remain in effect until the application has been finally determined by the Indiana Department of Homeland Security Radioactive

Materials Control program. You will be sent a Timely Renewal letter stating this.

If you have any questions concerning your license or the renewal process, please contact **{NAME}** at the Department at **{PHONE NUMBER}** or **{email address}**.

Sincerely,

{NAME}

Senior Health Physicist

Enclosures: Copy of License to be Renewed

Link to NUREG-1556 Series of Licensing Guidance:

https://www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr1556/index.html Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 1.2-3

Letter for Receipt of Renewal Application-Timely Filed

<DATE>

<LICENSEE NAME>

<CONTACT NAME, TITLE>

<ADDRESS>

<CITY, STATE, ZIP>

Attention: **<CONTACT NAME>** Radiation Safety Officer

SUBJECT: RENEWAL DEEMED TIMELY

Dear **<CONTACT NAME>**:

This acknowledges receipt of your application for renewal of Indiana Radioactive Material License No. **<NUMBER>**. Your license renewal request has been deemed timely filed and shall not expire until the application has been fully determined by this office.

If you have any questions concerning your license or the renewal process, please contact the Department at **<PHONE>** or **<EMAIL address>**.

Sincerely,

<NAME, SIGNATURE AND DATE>

Health Physicist

<NAME, SIGNATURE AND DATE>

Senior Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 1.3, Revision 0 License Termination/Revocation

Prepared By:	Date:
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- 4.2 Records Retention

5.0 ATTACHMENTS TO RMCPP 1.3

1.3-1 NRC Form 314 Certificate of Disposition of Materials

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure defines the process for terminating a license granted by the Indiana Department of Homeland Security Radioactive Materials Control Program (Department) to possess, use, store and, dispose of licensed radioactive material.
- 1.1.2 This procedure applies to the disposal of licensed material, decommissioning of the site and facilities, and surveys adequate to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

1.2 References

- 1.2.1 290 IAC 3
- 1.2.2 Title 10 Code of Federal Regulations, Part 20, Subpart E Radiological Criteria for License Termination.
- 1.2.3 NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM).
- 1.2.4 NUREG-1757, "Consolidated Decommissioning Guidance" Volumes 1, 2, and 3 Revision 2.
- 1.2.5 The various RESRAD programs: (e.g., Dose Modeling Code (Soil Concentration Levels); RESRAD-Build, Dose Modeling Code (Buildings); RESRAD-OFFSITE)
- 1.2.6 The DandD Code for screening analyses for license termination and decommissioning. It automates the definition and development of the scenarios, exposure pathways, models, mathematical formulations, assumptions, and justifications of parameter selections documented in Volumes 1 and 3 of NUREG/CR-5512

1.3 Files

The following records will be maintained by the Radioactive Materials Control Program, primarily in an electronic format, for each licensee:

- 1.3.1 Specific license.
- 1.3.2 License termination request document.
- 1.3.3 License termination letter.
- 1.3.4 Requests for Additional Information (RAI)

1.3.5 NRC Form 314 Certificate of Disposition of Materials

1.4 Definitions

- 1.4.1 ALARA. Acronym for "as low as is reasonably achievable," which means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken, and taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to the benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest (see 10 CFR 20.1003).
- 1.4.2 Background Radiation: Radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material and including global fallout as it exists in the environment form the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of a licensee or registrant. Background radiation does not include sources of radiation from radioactive materials regulated by the Department.
- 1.4.3 Certification Amount of Financial Assurance. See prescribed amount of financial assurance.
- 1.4.4 Certification of Financial Assurance. The document submitted to certify that financial assurance has been provided as required by regulation.
- 1.4.5 Characterization survey. A type of survey that includes facility or site sampling, monitoring, and analysis activities to determine the extent and nature of residual

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radioactivity. Characterization surveys provide the basis for acquiring necessary technical information to develop, analyze, and select appropriate cleanup techniques.

- 1.4.6 Cleanup. See decontamination.
- 1.4.7 Closeout Inspection. An inspection performed by NRC, or its contractor, to determine if a licensee has adequately decommissioned its facility. Typically, a closeout inspection is performed after the licensee has demonstrated that its facility is suitable for release in accordance with NRC requirements.
- 1.4.8 Confirmatory Survey. A survey conducted by NRC, or its contractor, to verify the results of the licensee's final status survey. Typically, confirmatory surveys consist of measurements at a fraction of the locations previously surveyed by the licensee, to determine whether the licensee's results are valid and reproducible.
- 1.4.9 Critical Group: The group of individuals reasonably expected to receive the greatest exposure to radiation for any applicable set of circumstances.
- 1.4.10 DandD code. The Decontamination and Decommissioning (DandD) software package, developed by NRC, that addresses compliance with the dose criteria of 10 CFR 20, Subpart #. Specifically, DandD embodies NRC's guidance on screening dose assessments to allow licensees to perform simple estimates of the annual dose from residual radioactivity in soils and on building surfaces.
- 1.4.11 Decommission: To remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.
- 1.4.12 Decommission Funding Plan (DFP). A document that contains a site-specific cost estimate for decommissioning, describes the method for assuring funds for decommissioning, describes the means for adjusting both the cost estimate and funding level over the life of the facility, and contains the certification of financial assurance and the signed originals of the financial instruments provided as financial assurance.

- 1.4.13 Decommissioning Groups. For the purposes of this guidance document, the categories of decommissioning activities that depend on the type of operation and the residual radioactivity.
- 1.4.14 Decommissioning Plan (DP). A detailed description of the activities that the licensee intends to use to assess the radiological status of its facility, to remove radioactivity attributable to licensed operations at its facility to levels that permit release of the site in accordance with NRC's regulations and termination of the license, and to demonstrate that the facility meets NRC's requirements for release. A DP typically consists of several interrelated components, including (1) site characterization information; (2) a remediation plan that has several components, including a description of remediation tasks, a health and safety plan, and a quality assurance plan; (3) site-specific cost estimates for the decommissioning; and (4) a final status survey plan (see 10 CFR 30.36(g)(4).
- 1.4.15 Decontamination. The removal of undesired residual radioactivity from facilities, soils, or equipment prior to the release of a site or facility and termination of a license. Also known as remediation, remedial action, and cleanup.
- 1.4.16 Derived Concentration Guideline Levels (DCGLs). Radionuclide-specific concentration limits used by the licensee during decommissioning to achieve the regulatory dose standard that permits the release of the property and termination of the license. The DCGL applicable to the average concentration over a survey unit is called the DCGLW. The DCGL applicable to limited areas of elevated concentrations within a survey unit is called the DCGLEMC.
- 1.4.17 Distinguishable from Background: The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or in the case of structures, in

similar materials using adequate measurement technology, survey, and statistical techniques.

- 1.4.18 Dose (or radiation dose). A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of 10 CFR 20.1003 (see 10 CFR 20.1003). In this NUREG report, dose generally refers to total effective dose equivalent (TEDE).
- 1.4.19 Effluent. Material discharged into the environment from licensed operations.
- 1.4.20 Environmental Monitoring. The process of sampling and analyzing environmental media in and around a facility (1) to confirm compliance with performance objectives and (2) to detect radioactive material entering the environment to facilitate timely remedial action.
- 1.4.21 Exposure Pathway. The route by which radioactivity travels through the environment to eventually cause radiation exposure to a person or group.
- 1.4.22 Exposure Scenario. A description of the future land uses, human activities, and behavior of the natural system as related to a future human receptor's interaction with (and therefore exposure to) residual radioactivity. In particular, the exposure scenario describes where humans may be exposed to residual radioactivity in the environment, what exposure group habits determine exposure, and how residual radioactivity moves through the environment.
- 1.4.23 External Dose. That portion of the dose equivalent received from radiation sources outside the body (see 10 CFR 20.1003).
- 1.4.24 Final Status Survey (FSS). Measurements and sampling to describe the radiological conditions of a site or facility, following completion of decontamination activities (if any) and in preparation for release of the site or facility.
- 1.4.25 Final Status Survey Plan (FSSP). The description of the final status survey design.

- 1.4.26 Final Status Survey Report (FSSP). The description of the final status survey design.
- 1.4.27 Financial Assurance. A guarantee or other financial arrangement provided by a licensee that funds for decommissioning will be available when needed. This is in addition to the licensee's regulatory obligation to decommission its facilities.
- 1.4.28 Financial Assurance Mechanism. Financial instruments used to provide financial assurance for decommissioning.
- 1.4.29 Ground Water. Water contained in pores or fractures in either the unsaturated or saturated zones below ground level.
- 1.4.30 Hydraulic Conductivity. The volume of water that will move through a medium in a unit of time under a unit hydraulic gradient through a unit area measured perpendicular to the direction of flow.
- 1.4.31 Hydrology. Study of the properties, distribution, and circulation of water on the surface of the land, in the soil and underlying rocks, and in the atmosphere.
- 1.4.32 Impact. The positive or negative effect of an action (past, present, or future) on the natural environment (land use, air quality, water resources, geological resources, ecological resources, aesthetic and scenic resources) and the human environment (infrastructure, economics, social, and cultural).
- 1.4.33 Impacted Areas. The areas with some reasonable potential for residual radioactivity in excess of natural background or fallout levels (see 10 CFR 50.2).
- 1.4.34 Inactive Outdoor Area. The outdoor portion of a site not used for licensed activities or materials for 24 months or more.
- 1.4.35 Infiltration. The process of water entering the soil at the ground surface. Infiltration becomes percolation when water has moved below the depth at which it can be removed (to return to the atmosphere) by evaporation or transpiration.
- 1.4.36 Institutional Controls. Measures to control access to a site and minimize disturbances to engineered measures

established by the licensee to control the residual radioactivity. Institutional controls include administrative mechanisms (e.g., land use restrictions) and may include, but are not limited to, physical controls (e.g., signs, markers, landscaping, and fences).

- 1.4.37 Karst. A type of topography that is formed over limestone, dolomite, or gypsum by dissolution, characterized by sinkholes, caves, and underground drainage.
- 1.4.38 Leak Test. A test for leakage of radioactivity from sealed radioactive sources. These tests are made when the sealed source is received and on a regular schedule thereafter. The frequency is usually specified in the sealed source and device registration certificate and/or license.
- 1.4.39 License Termination Rule (LTR). The License Termination Rule refers to the final rule on "Radiological Criteria for License Termination," published by NRC as Subpart E to 10 CFR 20 on July 21, 1997 (62 FR 39058).
- 1.4.40 Licensee. A person who possesses a license, or a person who possesses licensable material, who the RMCP could require to obtain a license.
- 1.4.41 License Review: The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.
- 1.4.42 License Reviewer: A Health Physicist or other Radioactive Materials Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.
- 1.4.43 License Revocation: A license is revoked during its effective validity period for cause, usually for failure to comply with licensing requirements and applicable regulations. NOTE: The Department must take formal action in order to revoke a license under I.C §10-19-12, 10 CFR 30.61, 10 CFR 40.71, and 10 CFR 70.81.

- 1.4.44 License Expiration: When the licensee has allowed the license to expire, did not respond after being informed that the license had expired, and/or did not request that the license be renewed, then the Department will issue a possession-only license.
- 1.4.45 MARSSIM. The Multi-Agency Radiation Site Survey and Investigation Manual (NUREG-1575) is a multi-agency consensus manual that provides information on planning, conducting, evaluating, and documenting building surface and surface soil final status radiological surveys for demonstrating compliance with dose- or risk-based regulations or standards.
- 1.4.46 Model. A simplified representation of an object or natural phenomenon. The model can be in many possible forms, such as a set of equations or a physical, miniature version of an object or system constructed to allow estimates of the behavior of the actual object or phenomenon when the values of certain variables are changed. Important environmental models include those estimating the transport, dispersion, and fate of chemicals in the environment.
- 1.4.47 Monitoring. Monitoring (radiation monitoring, radiation protection monitoring) is the measurement of radiation levels, concentrations, surface area concentration, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses (see 10 CFR 20.1003).
- 1.4.48 mrem/y (millirem per year). One one-thousandth (0.001) of a rem per year. (See also sievert.).
- 1.4.49 Naturally Occurring Radioactive Material (NORM). The natural radioactivity in rocks, soils, air and water. NORM generally refers to materials in which the radionuclide concentrations have not been enhanced by or as a result of human practices. NORM does not include uranium or thorium in source material.
- 1.4.50 Non-impacted Areas. The areas with no reasonable potential for residual radioactivity in excess of natural background or fallout levels.

- 1.4.51 Pathway. See exposure pathway.
- 1.4.52 Performance-Based Approach. Regulatory decisionmaking that relies upon measurable or calculable outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes.
- 1.4.53 Permeability. The ability of a material to transmit fluid through its pores when subjected to a difference in head (pressure gradient). Permeability depends on the substance transmitted (oil, air, water, and so forth) and on the size and shape of the pores, joints, and fractures in the medium and the manner in which they are interconnected.
- 1.4.54 Porosity. The ratio of openings, or voids, to the total volume of a soil or rock expressed as a decimal fraction or as a percentage.
- 1.4.55 Potentiometric Surface. The two-dimensional surface that describes the elevation of the water table. In an unconfined aquifer, the potentiometric surface is at the top of the water level. In a confined aquifer, the potentiometric surface is above the top of the water level because the water is under confining pressure.
- 1.4.56 Prescribed Amount of Financial Assurance. An amount of financial assurance based on the authorized possession limits of the RMCP license. As specified in 10 CFR 30.35(d), 40.36(b), or 70.25(d).
- 1.4.57 Principal Activities. Activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities (see 10 CFR 30.4).
- 1.4.58 Probabilistic. Refers to computer codes or analyses that use a random sampling method to select parameter values from a distribution. Results of the calculations are also in the form of a distribution of values. The results of

the calculation do not typically include the probability of the scenario occurring.

- 1.4.59 Reasonable Alternatives. Those alternatives that are practical or feasible from a technical and economic standpoint.
- 1.4.60 Reasonably foreseeable land use. Land use scenarios that are likely within 100 years, considering advice from land use planners and stakeholders on land use plans and trends.
- 1.4.61 rem. The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert) (see 10 CFR 20.1004).
- 1.4.62 Remedial Action. See decontamination.
- 1.4.63 Remediation. See decontamination.
- 1.4.64 Residual Radioactivity: Radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental release of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provision of 10 CFR 20.2001.
- 1.4.65 RESRAD Code. A computer code developed by the U.S. Department of Energy and designed to estimate radiation doses and risks from RESidual RADioactive materials in soils.
- 1.4.66 RESRAD-BUILD Code. A computer code developed by the U.S. Department of Energy and designed to estimate radiation doses and risks from RESidual RADioactive materials in BUILDings.
- 1.4.67 Restricted Area. Any area to which access is limited by a licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials (see 10 CFR 20.1003).

- 1.4.68 Risk. Defined by the "risk triplet" of a scenario (a combination of events and/or conditions that could occur) or set of scenarios, the probability that the scenario could occur, and the consequence (e.g., dose to an individual) if the scenario were to occur.
- 1.4.69 Risk-Based Approach. Regulatory decision making that is based solely on the numerical results of a risk assessment. (Note that the Commission does not endorse a risk-based regulatory approach.)
- 1.4.70 Risk-Informed Approach. Regulatory decision making that represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety.
- 1.4.71 Risk Insight. Results and findings that come from risk assessments.
- 1.4.72 Robust engineered barrier. A man-made structure that is designed to mitigate the effect of natural processes or human uses that may initiate or accelerate release of residual radioactivity through environmental pathways. The structure is designed so that the radiological criteria for license termination (10 CFR 20, Subpart E) can be met. Robust engineered barriers are designed to be more substantial, reliable, and sustainable for the time period needed without reliance on active ongoing maintenance.
- 1.4.73 Saturated Zone. That part of the earth's crust beneath the regional water table in which all voids, large and small, are ideally filled with water under pressure greater than atmospheric.
- 1.4.74 Scoping Survey. A type of survey that is conducted to identify (1) radionuclide contaminants, (2) relative radionuclide ratios, and (3) general levels and extent of residual radioactivity.
- 1.4.75 Screening Approach/Methodology/Process. The use of (1) predetermined building surface concentration and surface soil concentration values, or (2) a predetermined

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methodology (e.g., use of the DandD code) that meets the radiological decommissioning criteria without further analysis, to simplify decommissioning in cases where low levels of residual radioactivity are achievable.

- 1.4.76 Sealed Source. Any special nuclear material or byproduct material encased in a capsule designed to prevent leakage or escape of the material.
- 1.4.77 Sievert (Sv). The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 sievert = 100 rem) (see 10 CFR 20.1004).
- 1.4.78 Site. The area of land, along with structures and other facilities, as described int the original Department license application, plus any property outside the originally licensed boundary added for the purpose of receiving, possessing, or using radioactive material at any time during the term of the license, as well as any property where radioactive material was used or possessed that has been released prior to license termination.
- 1.4.79 Site Characterization. Studies that enable the licensee to sufficiently describe the conditions of the site, separate building, or outdoor area to evaluate the acceptability of the decommissioning plan.
- 1.4.80 Site Characterization Survey. See characterization survey.
- 1.4.81 Site-Specific Dose Analysis. Any dose analysis that is done other than by using the default screening tools.
- 1.4.82 Smear. A radiation survey technique which is used to determine levels of removable surface contamination. A medium (typically filter paper) is rubbed over a surface (typically of area 100 cm²), followed by a quantification of the activity on the medium. Also known as a swipe.
- 1.4.83 Source Material. Uranium or thorium, or any combination of uranium and thorium, in any physical or chemical form, or ores that contain by weight onetwentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and

thorium. Source material does not include special nuclear material (see 10 CFR 20.1003).

- 1.4.84 Source Term. A conceptual representation of the residual radioactivity at a site or facility.
- 1.4.85 Special Nuclear material. (1) Plutonium, uranium-233 (U-233), uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material (see CFR 20.1003).
- 1.4.86 Specific Licenses. Licenses issued to a named person who has filed an application for the license under the provisions of 10 CFR Parts 30, 32 through 36, 39, 40, 61, and 70. Examples of specific licenses are industrial radiography, medical use, irradiators, and well logging.
- 1.4.87 Survey. An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present (see 10 CFR 20.1003).
- 1.4.88 Survey Unit. A geographical area consisting of structures or land areas of specified size and shape at a site for which a separate decision will be made as to whether or not the unit attains the site-specific reference-based cleanup standard for the designated pollution parameter. Survey units are generally formed by grouping contiguous site areas with similar use histories and having the same contamination potential (classification). Survey units are established to facilitate the survey process and the statistical analysis of survey data.
- 1.4.89 Technologically Enhance Naturally Occurring Radioactive Material (TENORM). Naturally occurring radioactive

material with radionuclide concentrations increased by or as a result of past or present human practices. TENORM does not include background radioactive material or the natural radioactivity of rocks and soils. TENORM does not include uranium or thorium in source material.

- 1.4.90 Timeliness. Specific time periods stated in NRC regulations for decommissioning unused portions of operating nuclear materials facilities and for decommissioning the entire site upon termination of operations.
- 1.4.91 Total Effective Dose Equivalent (TEDE). The sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (CEDE) (for internal exposures) (see 10 CFR 20.1003).
- 1.4.92 Transmissivity. The rate of flow of water through a vertical strip of aquifer which is one unit wide and which extends the full saturated depth of the aquifer.
- 1.4.93 Unrestricted Area. An area, access to which is neither limited nor controlled by the licensee (see 10 CFR 20.1003).
- 1.4.94 Unsaturated Zone. The subsurface zone in which the geological material contains both water and air in pore spaces. The top of the unsaturated zone typically is at the land surface, otherwise known as the vadose zone.
- 1.4.95 Vadose Zone. See unsaturated zone.
- 1.4.96 Voluntary Termination: A licensee has requested that a license be terminated.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Identifies licenses that have expired or are about to expire and notifies licensee and the Senior Health Physicist (S/HP) within 30 days of the license expiration date.
- 2.1.2 Issues acknowledgment letters for receipt of termination requests within 30 days of receipt of the request for termination.

- 2.1.3 Maintains computer-based and other licensing files.
- 2.1.4 Begins to process requests for license termination or expired licenses as assigned within a 15-day period, upon the notification of the license expiration date.
- 2.1.5 When required, performs closeout surveys to verify that the licensee survey data is accurate and supports the finding that the license can be terminated when a licensee is decommissioning their facility.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Assigns a request for license termination or an expired license to a Health Physicist (HP) for processing. The S/HP will instruct the HP in the required scope of the termination or expired license process, i.e., whether the licensee is required to submit a Decommissioning Plan.
- 2.2.2 In concert with the IDHS General Counsel, initiates a petition for revocation of the license or other sanction, when deemed necessary to protect the public health and the environment.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Reviews, concurs or does not concur, with the petition for revocation of the license or other sanctions after consultation with the IDHS Executive Director and IDHS General Counsel.
- 2.3.2 Reviews, approves, and signs terminated license letters.
- 2.3.3 Approves the implementation of a revocation action and signs the final order.

3.0 PROCEDURE

3.1 General Provisions

3.1.1 The criteria for termination of a license are listed in 10 CFR 30.36, 40.42, and 70.38 as well as the Indiana

Department of Homeland Security Radioactive Materials Control Program Rule.

3.2 Request for Termination

- 3.2.1 Within 15 working days following the receipt of the request for license termination, the notice is placed in the licensee file and the reviewer should prepare a termination letter and inform the licensee that the Radioactive Materials Control Program may request additional information.
- 3.2.2 Following the receipt of a request for termination, a determination of the potential for residual radioactive contamination of the facility shall be made. The license and inspection history shall be reviewed to determine the potential risk of residual radioactive contamination.
- 3.2.3 The highest risk would be licensees that utilize significant quantities of unsealed radioactive material with half-lives greater than 120 days such as, but not limited to, nuclear pharmacies; waste disposal processing and repackaging services; manufacturing and distribution; nuclear laundries; academic or medical Type A Broad; and research and development, Type A Broad licenses. The lowest risk would be licensees that utilize radioactive materials only in the form of sealed sources. Unless there has been a significant leak of a sealed source, the probability of residual contamination is essentially zero. (NOTE: However, there have been a number of cases of residual contamination resulting from melting sealed sources contained in measuring gauges.)
- 3.2.4 For licenses that authorize both sealed and unsealed sources of radioactive material, the highest risk use shall dictate the decommissioning process.

3.3 License Termination – Sealed Sources

3.3.1 Determine which decommissioning group applies and follow the guidance in NUREG-1757 Volume 1.

3.4 License Termination – Unsealed Sources

3.4.1 Determine which decommissioning group applies and follow the guidance in NUREG-1747 Volume 1.

3.5 Expired Licenses

- 3.5.1 Licensee Contacted.
 - 3.5.1.1 Within fifteen (15) working days following the expiration date of a license without the receipt of a request for license termination or license renewal, the licensee shall be contacted by telephone or in person and informed that the license has expired. The licensee shall be informed, in writing, that any activity using radioactive material under the license shall cease, the licensed material shall be placed in storage or disposed of, and an application for license termination shall be submitted within 30 days.
 - 3.5.1.2 If the licensee intends to continue licensed operations and states that the failure to submit an application for license renewal was an oversight, the licensee shall be informed that operations shall cease and that an application for license renewal should be submitted as soon as possible. The licensee shall be informed that operation without a current *valid* license constitutes noncompliance and that appropriate enforcement action will result.
 - 3.5.1.3 The licensee shall be informed that only the S/HP may authorize continued use of radioactive material without a current license.
 - 3.5.1.4 The notice to cease licensed activities shall be recorded and transmitted to the licensee by registered mail, return receipt requested (attachment 1.2-1 **Sample Letter for Expired License** of RMCPP 1.2 Renewal of Licenses). This notification to the licensee transmits the

requirements for the proper disposition of radioactive materials with a **NRC Form 314** (Attachment 1.3-1) attached.

- 3.5.2 Licensee Not Contacted.
 - 3.5.2.1 Returned, undeliverable mail to licensees must trigger an immediate follow-up. The follow-up must include a telephone call, email, or site visit to the licensee to verify the licensee's physical address.
 - 3.5.2.2 If the licensee cannot be contacted either by telephone, visit to the address on the license, or all other reasonable efforts, the authorized place of use shall be inspected and surveyed. All possible means must be taken to establish the facts associated with the loss of contact, including interviews of related parties like landlords, neighboring parties or vendors. A survey for radiation and radioactive materials must also be conducted of premises left abandoned. If no radioactive materials are found and the survey indicates the facility is free of radioactive contamination, necessary legal action must proceed in order to revoke the license.
 - 3.5.2.3 If residual contamination is discovered, the facility shall be restricted from unauthorized access and decontaminated to acceptable levels and the license revoked in accordance with I.C.§ 10-19-12
 All legal efforts to require this of the licensee shall be exhausted before taking other actions. Consult with IDHS General Counsel about these and all other steps.
 - 3.5.2.4 If there was an emergency, the RMCP could use I.C.§ 10-19-12 to mitigate or force the mitigation of the hazard. If the RMCP incurred any cost as a result of this action, it has the authority to seek the recovery of costs under our civil enforcement statute I.C.#.

4.0 RECORDS

4.1 Records to be Maintained

- 4.1.1 Terminated License File.
- 4.1.2 Licensee Correspondence Requesting Termination.
- 4.1.3 Transfer the decommissioning records discussed in 10 CFR 30.35, 30.36, and 30.51; 40.36, 40.42, and 40.61; 70.25, 70.38, and 70.51; or 72.80, as appropriate, or affirm that they are not required to retain or transfer the records.
- 4.1.4 License Termination Letter.

4.1.5 NRC Form 314 Certificate of Disposition of Materials.

4.2 Records Retention

- 4.2.1 Web Based Licensing (WBL) is the primary electronic file repository.
- 4.2.2 Records may also be kept in other secure electronic forms with access only to RMCP staff.

5.0 ATTACHMENTS TO RMCPP 1.3

1.3-1 NRC Form 314 Certificate of Disposition of Materials

Attachment 1.3-1 NRC Form 314 Certificate of Disposition of Materials

NRC Form 314 can be found at:

https://www.nrc.gov/docs/ML1308/ML13083A079.pdf

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 1.4, Revision 0 NRC Licenses Affected by Agreement State

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
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5.0 Attachments to RMCPP 1.4

None

1.0 PURPOSE

1.1 Applicability

- 1.1.1 The purpose of this procedure is to define the process for licenses transferred to the State of Indiana under the Agreement with the Nuclear Regulatory Commission (NRC) at the time the Agreement takes effect.
- 1.1.2 Implementation of this procedure will ensure that each licensing action will be processed in a timely and efficient manner and ensure the continued validity of the NRC licenses affected by the Agreement.

1.2 References

1.2.1 290 IAC 3

1.3 Files

- 1.3.1 Files received from the NRC;
- 1.3.2 Older files exist only on paper. They will be maintained in that form until they can be converted to electronic records

1.4 Definitions

- 1.4.1 License Review: The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.
- 1.4.2 License Reviewer: A Health Physicist or other Radioactive Materials Control Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.
- 1.4.3 Licensing action: A request or application received from an applicant, or a licensee as follows:
 - An application for a license to receive, possess, and use licensed radioactive material;
 - An application for renewal of a license;

- An amendment request to a license, e.g., change in administration, authorized use and/or users, RSO, quantity of material, add isotopes, facilities, etc.; and/or
- A request for termination of a license(s).

2.0 **RESPONSIBILITIES**

- 2.1 Maintains the records, letters, forms, and report files and updates the files and WBL, as necessary.
- 2.2 Transfers information from the NRC files to the secure state files located within the Radioactive Materials Control Program and inputs any required information into the WBL and electronic data files.

3.0 PROCEDURE

3.1 Receipt of Files from the Nuclear Regulatory Commission (NRC):

Upon receipt of files from the NRC, each file will be stored, and all licensees shall be regulated as Indiana Department of Homeland Security (Department) licensees.

3.2 Licensing Actions

- 3.2.1 Following receipt of the licensing files from the NRC, each licensing action appropriate to those licenses obtained from the NRC will be prioritized and processed in accordance with RMCPP 1.1 *Review of Initial Application for License or an Amendment Request*.
- 3.2.2 All renewals will be processed in accordance with RMCPP 1.2 *Renewal of Licenses*.
- 3.2.3 In the event of a request for a termination of one of the licenses acquired from a file transferred by the NRC, RMCPP 1.3, *License Termination/Revocation will be implemented*.

4.0 Records

4.1 Records to be Maintained:

- 4.1.1 Licensee files sent by the NRC to become state files.
- 4.1.2 Applications for license, license renewal, license amendment, or license termination are maintained in applicable files.

4.2 **Records Retention:**

- 4.2.1 Web Based Licensing is the primary electronic file repository.
- 4.2.2 Records may also be kept in other secure electronic forms with access only to RMCPP staff.

5.0 Attachments to RMCPP 1.4

None

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 4.1, Revision 0 Renewal Notices, Receipt and Tracking of Licensing Actions

Prepared By:	Date:
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4.0 RECORDS

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5.0 ATTACHMENTS TO RMCPP 4.1

None

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to all records related to license applications, renewals, amendments, and terminations including renewal notices, receipt of licensing actions, acknowledgment letters, and tracking of licensing actions.
- 1.1.2 Licensing actions shall be tracked from their receipt until a licensing action is completed or a determination is made to dent the request.

1.2 References

- 1.2.1 290 IAC 3
- 1.2.2 NRC Form 313 filed in Indiana license file.
- 1.2.3 Department Letter filed in Indiana license file.
- 1.2.4 License file in Indiana license file.

1.3 Files

TBD

1.4 Definitions

- 1.4.1 Request for Additional Information (RAI): A communication with the applicant that documents a request for additional information needed to process the licensing request. Problems with the submission, the rule or regulatory guidance that is applicable, and the specific action requested of the licensee or applicant must be clearly stated.
- 1.4.2 License Reviewer: A Health Physicist qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a secondary review for any category of license for which they are not qualified.

- 1.4.3 Licensing Action: A request or application received from an applicant or a licensee as follows:
 - 1.4.3.1 An application for a license to receive, possess, store, and use licensed radioactive materials;
 - 1.4.3.2 An application for renewal of a license;
 - 1.4.3.3 An amendment request to a license, e.g., change in administration, authorized use and/or user(s), RSO, quantity of material, add isotopes, facilities, etc.; and/or,
 - 1.4.3.4 A request for termination of a license.
- 1.4.4 Processing: Reviewing the application for license or amendment, requesting additional information if appropriate, and either issuing or denying, with or without prejudice, the requested license or amendment.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Responds to requests for license applications and uses the schedule in RMCPP 1.1 *Review of Initial Application for License or an Amendment Request* for prioritization of license reviews.
- 2.1.2 Receives, logs, and acknowledges the receipt of an application, including application fee, for a new license in the licensee/applicant file.
- 2.1.3 Prepares the renewal letter to notify the licensee that the license will expire in 90 days.
- 2.1.4 Records dates as provided for receipt and tracking of all licensing actions, including transmittal of timely filed letters for renewals.
- 2.1.5 Sends out acknowledgment letters for receipt of termination requests in a timely fashion (if possible, within 15 working days).
- 2.1.6 Assigns due date (90 or 180 days) for each licensing action based on type of action (see RMCPP 1.1) and enters this information into Web-Based Licensing (WBL) in

consultation with the Senior Health Physicist (S/HP), as needed.

- 2.1.7 Prepares a list for the Senior Health Physicist that shows the status of each licensing action.
- 2.1.8 Performs secondary review of licenses prepared by other Department licensing staff members.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Responds to requests for license applications and uses RMCPP 1.1 for prioritization of license reviews.
- 2.2.2 Conducts license review or secondary reviews as assigned by the Radiation Control Program Director.
- 2.2.3 Conducts completeness review for renewals and signs deemed timely filed letter for renewals as assigned by the Radiation Control Program Director.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Provides guidance to S/HP on Prioritizing and reviewing licensing actions.
- 2.3.2 Assigns licensing actions and completeness reviews to Health Physicists for secondary review of license applications.

3.0 PROCEDURE

3.1 Receipt of Licensing Action

- 3.1.1 Upon receipt of a licensing action, the primary reviewer will determine the type of licensing action (i.e., new application, renewal, amendment request, or termination request) and based on the prioritization schedule in RMCPP 1.1, identifies a priority and due date. The S/HP will provide additional guidance in prioritization as needed.
- 3.1.2 If the application is for a renewal or new application or significant amendment, a more detailed review is required.
- 3.1.3 All primary (and secondary) reviews are documented using RMCPP 1.1, Attachment 1.1-4 License Review Job Aid.

- 3.1.4 Acknowledgement letters shall be sent for new applications and termination requests.
- 3.1.5 A fee must accompany the initial application.

3.2 Assignment of License Reviewer

The S/HP or designee will assign licensing action to qualified license reviewers based on workloads, experience levels, and the priority assigned to the licensing action.

3.3 Secondary Review

- 3.3.1 A secondary review must be performed for all licensing actions to identify and deficiencies in the license application, renewal amendment, or termination documentation before the licensing review can proceed to supervisory review and RCPD approval.
- 3.3.2 A secondary review using the guidance in RMCPP 1.1-4 **License Review Job Aid** is to verify the licensee used appropriate regulatory guidance and forms to complete the application.
- 3.3.3 A secondary review determines if additional information is required (e.g., emergency response procedures, attestation, training and experience, leak test results, etc.), and if the application was signed by a duly authorized representative of the company or institution.
- 3.3.4 Timely filed letters shall be sent for renewal applications that are deemed to be complete.

3.4 Receipt of Additional Information or Missed Deadline

- 3.4.1 The qualified reviewers shall review the licensing action request and determine if additional information is needed.
- 3.4.2 Requests for additional information will be handled with a letter or a documented telephone call to the licensee or applicant that indicates a due date for submittal of the information within 30 days or less.

- 3.4.3 A due date for the additional information shall be entered into WBL.
- **Note:** If the information needed is not extensive, the request may be communicated by telephone or email and the licensee or applicant may submit via fax as long as the fax is signed. The license reviewer will need to document the telephone call in the license file.

3.5 Receipt of Additional Information or Missed Deadline

- 3.5.1 Once the requested information is received, the receipt of the information shall be logged into WBL.
- 3.5.2 On a weekly basis, each qualified reviewer shall be responsible for checking his/her pending licensing actions to determine the current status.
- 3.5.3 In the event that a deadline is missed by a licensee or applicant, the license reviewer shall, in a timely fashion (if possible, within 5 working days), follow up with the licensee or applicant to determine the status of the requested information.
- 3.5.4 If no response is received within 60 days, the licensing request may be considered abandoned and any relevant information documented in WBL.
- 3.5.5 The license reviewer will prepare an abandonment letter for signature of the RCPD and send it to the licensee notifying them of the action taken.

3.6 Writing the License, Secondary Review, and Documentation

- 3.6.1 <u>Writing the License</u>: The qualified license reviewer shall write the license action using the standard license conditions and license template to develop or modify the license. The initial Department issued license will not have an Amendment Number.
- 3.6.2 <u>Secondary Review</u>: The primary reviewer shall forward the licensing action file with the draft license to the S/HP or designee to assign or make a secondary review. The

secondary reviewer will discuss any issues of concern with the initial license reviewer and make the necessary corrections.

- 3.6.3 <u>Supervisory Review</u>: Before a licensing action is signed and approved by the RCPD, the RCPD must make a supervisory review as documented on the Administrative Qualitative Checklist (Attachment 1.1-5).
- 3.6.4 <u>Documentation</u>: When all issues are satisfactorily resolved, the secondary reviewer documents agreement with the proposed licensing action.

3.7 Signing the License and File Documentation

- 3.7.1 <u>Signing Approval of the Licensing Action</u>: The license can be signed by the RCPD or by an individual designated by the RCPD after the secondary review and the supervisory review.
- 3.7.2 <u>File Documentation:</u> The licensing action is assigned to a qualified license reviewer for logging the completion of the licensing activity, inserting the licensing request, and deficiency letters, response(s), transmittal letter, and licensing actions into WBL.

4.0 RECORDS

4.1 Records to be Maintained

- 4.1.1 License Application (NRC Form 313) filed in Indiana license file.
- 4.1.2 Request for Additional Information filed in Indiana file.
- 4.1.3 License filed in Indiana license file.

4.2 Records Retention

- 4.2.1 Web Based Licensing is the primary electronic file repository.
- 4.2.2 Records may also be kept in other secure electronic forms with access only to RMCP staff.

5.0 ATTACHMENTS TO RMCPP 4.1

None

4.4 Inspection Program Elements

The State of Indiana, through the Indiana Department of Homeland Security (Department) Radioactive Materials Control Program (RMCP) (*hereafter* "RMCP" or "the program") will conduct inspections of radioactive materials licensees following the guidance in the NRC's specific Inspection Procedures, NUREG-1556 Safety Audits and relevant related documents for the various license types in Indiana. The program will also use the broader inspection guidance found in the NRC's Inspection Manual Chapters and relevant related documents. For the administration of the inspection program, Indiana has written administrative procedures, the Radioactive Materials Control Program Procedures (RMCPPs). The RMCPPs apply broadly to all inspection activities. A table of inspection related RMCPPs is below.

RMCPP No	Title
RMCPP 2.1	Scheduling of Inspections
RMCPP 2.2	Inspection Preparations
RMCPP 2.3	Performance-Based Inspections
RMCPP 2.4	Documentation of Inspection Results
RMCPP 2.5	Enforcement, Escalated Enforcement and
	Administrative Actions
RMCPP 2.6	Materials Inspection Checklist and Definitions
RMCPP 2.7	Assuring the Technical Quality of Inspections
RMCPP 4.2	Tracking Inspections

In application section 4.4.1 Procedures for Inspecting Facilities Where Radioactive Material is Stored or Used, the RMCP plans to use the NRC Inspection Manual Chapters, applicable NUREG-1556 Safety Audits, and Inspection Procedures. This section also briefly describes RMCPP 2.1 through 2.6 which are written to guide the scheduling of inspections, preparations for an effective inspection for compliance and the methods to conduct, document and respond to the finding of radioactive materials licensee inspections.

RMCPP 2.7 Assuring the Technical Quality of Inspections is described in application section 4.4.2. The key tenets of the process are checklist-guided

initial inspections, secondary review of the inspection report by another qualified inspector and annual supervisory accompaniment of inspectors as they conduct performance-based inspections.

The administrative procedures appropriate for all inspections as required for Handbook Section 4.4.3 are copied into the concluding section of 4.4 with the exception of RMCPP 2.5 *Enforcement, Escalated Enforcement and Administrative Action*. While significantly related to inspection activities, it is described and found in application section 4.5 Enforcement Program Elements.

4.4.1 Procedures for Inspecting Facilities Where Radioactive Material Is Stored or Used

This table is copied into the licensing administrative procedure RMCPP 1.1 *Review of an Initial Application for License or an Amendment Request*.

The format and guidance for inspection reports; performance of inspections, including performance-based criteria; and notifications to licensees of results and whether or not the licensee is in compliance.

The format and guidance for inspection reports, instructions for performing inspections and the documentation of inspections including notification of the licensee of the inspection results, especially as related to compliance, are found in RMCPP 2.1 *Scheduling of Inspections*, RMCPP 2.2 *Inspection Preparations*, RMCPP2.3 *Performance-Based Inspections*, RMCPP 2.4 *Documentation of Inspection Results*, RMCPP 2.6 *Materials Inspection Checklists and Definitions* and, RMCPP 4.2 *Tracking inspections*. Each of these RMCPPs is copied into Section 4.4.3 of this Application.

Rather than recreate inspection procedures and checklists for the specific types of licenses that will be issued in Indiana, the Indiana Department of Homeland Security Radioactive Materials Control Program will incorporate by reference certain Nuclear Regulatory Commission (NRC) Inspection Manual Chapters (IMC), NUREG-1556 Safety Audits and Inspection Procedures. The Department will use only those NUREGS, IMC chapters and inspection procedures relevant to Indiana's Radioactive Materials Control Program.

The Inspection Manual Chapters are found at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manualchapter/index.html. The NUREG-1556 "Consolidated Guidance About Materials Licenses" are found at https://www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr1556/index.html The specific NRC Inspection Manual Chapters, NUREG-1556 Audits, and Inspection Procedures to be used in Indiana at the time of this Application are listed in Table 4.4-1 below.

Table 4.4-1

	Inspection Manual Chapters and Titles
0610	Nuclear Material Safety and Safeguards Inspection Reports
0620	Inspection Documents and Records
1220	Processing of NRC Form 241 and Inspection of Agreement State
	Licensees Operating Under 10 CFR 150.20
1248 App A	Materials Health Physics License Review Qualification Journal
1248 Арр В	Materials Health Physics Inspector Qualification Journal
1301	Response to Radioactive Material Incidents That Do Not Require
	Activation of the NRC Incident Response Plan.
1302	Follow-up Actions and Action Levels for Radiation Exposures
	Associated with Materials Incidents Involving Members of the Public
1303	Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)
1330	Response to Transportation Accidents Involving Radioactive Materials
2602	Decommissioning Oversight and Inspection Program for Fuel Cycle
	Facilities and Materials Licensees
2800	Materials Inspection Program
	Inspection Procedures and Titles84850
83822	Radiation Protection
83890	Closeout Inspection and Survey
84850	Radioactive Waste Management – Inspection of Waste Generator
	Requirements of 10 CFR Part 20 and 10 CFR Part 61.
84900	Low-Level Radioactive Waste Storage
86730	Transportation of Radioactive Materials

NRC Documents Serving as Model Guidance for Indiana

86740	Inspection of Transportation Activities
87102	Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)
87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87104	Decommissioning Inspection Procedure for Materials Licensees
87121	Industrial Radiography Programs
87122	Irradiator Programs
87123	Well Logging Programs
87124	Fixed and Portable Gauge Programs
87125	Materials Processor/Manufacturer Programs
87126	Industrial/Academic/Research Programs
87127	Radiopharmacy Programs
87130	Nuclear Medicine Programs Written Directive Not Required
87131	Nuclear Medicine Programs Written Directive Required
87132	Brachytherapy Programs
87133	Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
87134	Medical Broad-Scope Programs
87137	10 CFR Part 37 Materials Security Programs
87250	Locating Missing Materials Licensees
NUREG 1757	Consolidated Decommissioning Guidance

NUREG	Volume 1, Appendix E- Portable Gauge Audit Checklist
1556	Volume 2, Appendix G- Industrial Radiography Radiation Safety Audit Checklist
	Volume 4, Appendix E – Fixed Gauge Audit Checklist

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Volume 5, Appendix I- Self-Shielded Irradiator Audit Checklist
Volume 6, Appendix G- 10 CFR Part 36 Irradiators Suggested Audit Checklist
Volume 7, Appendix H- Academic, Research and Development, and Other licenses of Limited Scope Sample Audit Program Checklist
Volume 9, Appendix L- Medical Licenses Model Medical License Audit Checklist
Volume 12, Appendix G- Sample Audit Program Possession Licenses for Manufacturing and Distribution Checklist
Volume 13, Appendix I- Suggested Commercial Radiopharmacy Licenses Audit Checklist
Volume 17, Appendix E- Suggested Audit Checklist Special Nuclear material of Less than Critical Mass
10 CFR Part 37 Checklist
RMCPP 1.1 Attachment 1.1-1 Pre-Licensing Checklist
RMCPP 1.1 Attachment 1.1-2 Risk Significant Radioactive Materials Checklist
NRC Enforcement Manual
STP SA-102 "Reviewing the Common Performance Indicator, Technical Quality of Inspections"
NRC Enforcement Policy

These documents are strictly for guidance only

State field instrumentation and laboratory analysis capabilities, including calibration and quality assurance.

To facilitate effective inspections, for radiation protection purposes and for emergency preparedness, the RMCP possesses and maintains numerous radiological instruments. These instruments are capable of measuring exposure rates from x- and gamma radiation, absorbed dose rates from beta radiation, and count rates from alpha, beta, beta-gamma, gamma and neutron radiation-emitting radioactive materials of a wide range of energies. Some filed instruments are capable of isotopic identification. As we do now, the Radioactive Materials Control Program will maintain sufficient instruments for the above purposes in good working order. They will be calibrated annually by a facility licensed for such.

Most portable instrument calibrations are and will be conducted by the State of Ohio. Occasionally other licensed facilities are used, including those of our instrument manufacturers, especially if the instrument also needs repair or other services beyond calibration.

The services of the Indiana Department of Health Laboratories Radiochemistry laboratories can be used for radiochemical analysis. Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.2, Revision 0 Inspection Preparation

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

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Revision	Date	Description of Changes
0		

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2.2-1 Radioactive Materials Control Program Guidelines for Completing an Inspection Plan.

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to an inspector preparing for the performance of an inspection.
- 1.1.2 Preparation for conducting initial, routine, special, reactive, and reduced frequency is covered.

1.2 References

- 1.2.1 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program"
- 1.2.2 290 IAC 3

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Provides a list on a monthly basis, using Web-Based Licensing for the Senior Health Physicist (S/HP) of inspections due for the next 6 months. These are in accordance with their Priority Code and documented on the *Inspections Due for the Next 6 Months-By Priority Report*.
- 2.1.2 Maintains the files and WBL current with letters, forms, and reports.
- 2.1.3 Updates files
- 2.1.4 Properly prepares for each inspection by following the guidance in Section 3 below.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 May assign inspections to a qualified member of the inspection staff. This duty maybe delegated to the RCPD. Maintains the *Inspections Due for the Next 6 Months-By Priority Report*.
- 2.2.2 Discusses with inspection staff any items from previous inspection and their proposed inspection plan, if required.
- 2.2.3 Approves inspection plans if required, before the inspection begins.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Assigns inspections to a qualified member of the inspection staff, in the absence of the S/HP.
- 2.3.2 Approves travel plans as necessary.

3.0 PROCEDURE

3.1 General Inspection Process

- 3.1.1 This procedure is designed to provide guidance that is applicable to all types of licensed programs.
 - 3.1.1.1 General inspection preparation should be completed in accordance with this procedure and other applicable RMCPPs.
 - 3.1.1.2 It is expected that inspectors understand and use the unique individual requirements for each type of inspection, such as use of an appropriate NRC Licensing Guide (NUREG-1556) Safety Audit or the appropriate Inspection Checklist and Inspection Procedure for the inspection type.
 - 3.1.1.3 Scheduling of inspections is in accordance with RMCPP 2.1 *Scheduling of Inspections*.
 - 3.1.1.4 Inspections of licensees shall be conducted per RMCPP 2.3 *Performance-Based Inspections*.
 - 3.1.1.5 Checklists for the different inspections by licensee type are in the applicable NUREG 1556 series checklist. Inspections should be conducted following these checklists and procedures.
 - 3.1.1.6 RMCPP 2.7 Assuring the Technical Quality of Inspections provides detailed guidance on inspections and their reports.
 - 3.1.1.7 Any new Regulatory Issue Summaries or Information Notices that may be applicable to the licensee since the last inspection.
- 3.1.2 It is not necessary for the inspector to review all the current licensing documents and procedures from the licensee file. However, to adequately prepare, an inspector shall review:
 - 3.1.2.1 The license to determine:
 - 3.1.2.1.1 If an unusual license conditions or tie-down commitments exist that would affect the approach to the inspection, i.e. authorization

for non-routine maintenance, use of material at temporary job sites,

- 3.1.2.1.2 If the licensee is authorized for activities at temporary job sites, prepare to make every reasonable attempt to include an unannounced inspection of licensed activities at any temporary jobsite(s).
- 3.1.2.2 The licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items, and to determine whether any events have been reported by the licensee during the current inspection cycle. Older issues preceding the last inspection should be reviewed, if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.
- 3.1.2.3 The Nuclear Material Events Database (NMED) to determine if any incidents have occurred since the last inspection.
- 3.1.2.4 Any commitments made by the licensee or restrictions imposed by the Department as a result of an order or other enforcement action issued since the last inspection.
- 3.1.2.5 Any information regarding special inspection emphasis, i.e., license reviewer's request for an inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of amendment.
- 3.1.2.6 Any allegation trends and a follow-up of the licensee's evaluations and response to the allegation.
- 3.1.2.7 Any changes to the Regulatory Requirements since the last inspection that affect the licensee's program.
- 3.1.2.8 A copy of the applicable Sealed Source and Device Registration Certificates.
- 3.1.3 For a reactive inspection, the inspector should review specific information as determined by the S/HP on a case-by-case basis.
- 3.1.4 Inspectors should anticipate whether or not they will encounter protected information during an inspection of a licensee and be prepared to provide the minimum handling requirements for confidential information.
- 3.1.5 Anticipate security requirements, guidance, questions, and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief and final Department determinations).

- 3.1.6 If the licensee is authorized to possess risk significant radioactive material (RSRM), request the National Source Tracking System (NSTS) inventory record at least two days in advance.
- 3.1.7 The inspector should identify the location of the licensee, make travel arrangements, and discuss special aspects of the inspection with the S/HP, as necessary.
- 3.1.8 The inspector should prepare questions for interviews and consider the focus areas or focus elements in the applicable NRC inspection procedure.
- 3.1.9 If necessary, methods for determining if licensed activities have been performed effectively may include contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee.
- 3.1.10 The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Staff must also wear their assigned dosimetry and appropriate personal protective equipment (safety shoes, glasses, hearing protection and hard hats).
- 3.1.11 The inspector should obtain the appropriate inspection reports, select appropriate and calibrated radiation detection instrumentation, and use the appropriate Inspection Procedure(s) and safety audits from the NUREG 1556 series for the inspection and obtain any other documentation that may be useful.
- 3.1.12 Radiation detection instruments are assigned to all RMCP staff in order to ensure appropriate instrumentation for potential surveys as related to the licensed activities being inspected. There are alpha, beta, gamma survey instruments, contamination and exposure rate instruments and radioisotope identification available.

3.2 Initial Inspections

The licensee is informed to report the first receipt of licensed material to the Department. Initial inspections are conducted within six months following receipt of the notice from the licensee that licensed material has been received or one year following the issuance of the license whichever occurs first. All initial inspections of a new licensee, or any existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy – Other Emerging Technology) are to be announced. Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.

3.3 Routine Inspections

- 3.3.1 All routine inspections are unannounced unless specific instruction are received from the S/HP that an inspection is to be announce.
- 3.3.2 Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.
- 3.3.3 Routine inspection frequency is as determined by RMCPP 2.1 Scheduling of Inspections and Attachment **1.1-6 Inspection Priority Codes Assigned to Program Codes** in RMCPP 1.1 Review of Initial License Application or an Amendment Request.
- 3.3.4 While encouraged for use, an inspection plan is not required.

3.4 Reactive Inspections

- 3.4.1 Reactive Inspections focus on limited issues, often related to specific incidents, that are not within the scope of preparation for a routine inspection. If the reactive inspection does not cover the activities normally reviewed during a routine inspection, then the scheduling window still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.
- 3.4.2 The S/HP shall promptly assess the preliminary information received concerning the incident to determine if a reactive inspection is necessary.
- 3.4.3 The S/HP will notify a Health Physicist of the incident and if an inspection is required.
- 3.4.4 The inspector will review appropriate specific information to prepare for a reactive inspection.
- 3.4.5 The inspector should also prepare for issues of compliance, which will generally be addressed after all safety issues and program weaknesses are identified and clearly understood.
- 3.4.6 **Reactive Inspection for Incidents.** The emphasis while preparing for reactive inspection is response to incidents is the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.
- 3.4.7 **Reactive Inspection for Allegations.** Preparation for inspections of allegations shall be processed in accordance with RMCPP 3.1 *Management of Allegations*.

3.5 Special Inspections

Special inspections (i.e., reciprocity, security, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections may be under the supervision of the S/HP. Preparing for reciprocity inspections should be completed in accordance with this procedure and all applicable RMCPP. Narrative reports shall be prepared, if required by the S/HP, for special inspection. Inspection frequencies for special inspections are defined in RMCPP 2.1 *Scheduling of Inspections*.

- 3.5.1 **Reciprocity Inspections.** The inspector should prepare for an unannounced inspection of actual field work and review appropriate information to use during inspection.
- 3.5.2 **Temporary Job Site and Permanent Field Office Inspections.** The inspector should prepare to perform an unannounced inspection of licensed activities at these location(s). Preparation for temporary job site and permanent field office inspection should be conducted in accordance with Section 3.1 and other applicable guides.

3.5.3 Abandoned, Expired and Terminated License and Decommissioning Activities.

Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

- 3.5.3.1 Emphasis should be placed on security and control of radioactive materials while preparing for an inspection at these types of facilities.
- 3.5.3.2 Prepare to review the licensee's transfer, disposal, and closeout survey data; and/or prepare to perform confirmatory surveys.
- 3.5.3.3 Prepare to review records of radioactive material disposals and public dose that may be required to be submitted to the Department.
- 3.5.3.4 Prepare to verify that the licensee is complying with regulations for timely decontamination and decommissioning and meeting the required schedules for licensee action.

- 3.5.3.5 Abandoned licensed activities indicated by returned mail, unreturned telephone calls or email, disconnected telephone messages or unoccupied or abandoned spaces found upon site visit need to be investigated to the degree determined by the S/HP and RCPD in consultation with Department leadership and legal counsel with particular attention to any potential for health and safety risk.
- 3.5.4 Team Inspections

Team inspections will be conducted on an as-needed basis.

- 3.5.4.1 At the S/HP's discretion, inspection plans may be developed for all team inspections.
- 3.5.4.2 Inspection plans should be considered for team inspections of major, broad scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the Department (other than NRC or other Agreement State radiation control agencies) are involved.
- 3.5.5 Reduced Inspections

Reduced inspections may be performed for a variety of reasons as determined by the Radioactive Material Program Director.

- 3.5.5.1 The most common reason is due to poor licensee performance. All other reasons will be addressed with the Health Physicist assigned to the inspection by the Radiation Control Program Director
- 3.5.5.2 Poor Performance History: The focus should be on the areas of poor performance and only other areas of the radiation safety program as time allows.
- 3.5.5.3 The inspection should be unannounced unless specific individuals and/or activities need to be reviewed that are not available or performed on a routine basis by the licensee.
- 3.5.5.4 All other preparations should be conducted in accordance with RMCPP 3.1 and other applicable guides.
- 3.5.6 Inspections After Escalated Enforcement

If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on the licensee's

corrective actions in response to Severity Level III or above violation(s) shall be scheduled and conducted within 12 months of the issuance of the escalated enforcement action (Severity Level III or above).

3.6 Inspection Preparation Plan

See Attachment 2.2-1 **Inspection Plan** for completion of the inspection plan. The following items should be reviewed:

- 3.6.1 License: Differences between the license and the application, if any; and "tie-down" commitments and information submitted by the licensee that is not a "tie-down" condition in the license.
- 3.6.2 License File: Determine if the license has been amended since the last inspection. Note differences such as increased scope of operations, changes in principal staff, new/different facilities, new "tie-down" commitments or other special license conditions.
- 3.6.3 Regulatory Requirements: Determine changes in regulatory requirements since the last inspection that affect the licensee's program.
- 3.6.4 Results of Last Inspection: Review the results of the last inspection. If any enforcement action was taken, or if clear inspection form with minor noncompliance items was issued, note the items that the licensee committed to correct.
- 3.6.5 Guidance: Use appropriate Indiana guidance to determine specific requirements that should be reviewed during the inspection. [NOTE: This should include a review of the appropriate Inspection Procedures.]
- 3.6.6 Notices: Review the Department's and NRC's Information Notices and Regulatory Issue Summaries files and NRC's Office of Nuclear Materials Safety and Safeguards Letters to determine if there have been any recent issues concerning this type of licensee that should be reviewed during this inspection.
- 3.6.7 Nuclear Material Events Database (NMED): Review NMED for licensee events.
- 3.6.8 Allegations, if appropriate. If there was an allegation, the next inspection should address the issue.
- 3.6.9 Sealed source and device registration should also be reviewed.
- 3.6.10 NRC and State RMCP letters: Review the variety of STC, NMSS, RCPD and other NRC or State RMCP letters for issues of relevance to the licensee.

4.0 Records

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4.1 Files

- 4.1.1 Records are primarily filed electronically and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.
- 4.1.2 The completed inspection reports and any necessary correspondence mailed to and/or received from the licensee are placed in the licensees electronic and paper files.

5.0 Attachments to RMCPP 2.2

2.2-1 Inspection Plan

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.2-1 Inspection Plan

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Attachment 2.2-1: Inspection Plan

DIRECTIONS:

The following guidelines are provided to help complete the inspection plan and prepare for the inspection.

DEFINITIONS:

- Area: The components of the licensee's program being inspected. Example areas include industrial radiography-field operations and Medical Licensee-Radiopharmaceutical Therapy or Radiation Therapy.
- Activity: Tasks performed by an individual within an area. Example activities are industrial radiography surveys, milking the generator, administration of I-131, or Gamma Knife patient treatment.
- **Element:** Observable aspects of an activity. Example elements are surveys of camera after source crank-in; use of shielded container, time, gloves, syringe shield, or survey meter.

LICENSEE ACTIVITY SELECTION GUIDELINES

- A. Identify high priority areas and activities
- B. Activities in progress are preferred

C. Identify medium and low priority activities that can be inspected concurrently

D. Give preference to high priority elements

INSPECTION METHOD

The preferred method is direct observation. Acceptable alternatives include:

- A. Walk-through or demonstration
- B. Review of activity documents
- C. Interview selected licensee personnel

Radioactive Materials Control Program

Inspection Plan

iness email, a	and Telephone	e)
Priority		
This Inspection Date		
Initial	Special	
Routi	ne	Re-inspection
	Priority This Inspect Initial	This Inspection Date

Performance-Based Inspection Plan

1. Identify the higher priority areas and activities to be reviewed. Note lower priority areas that may be reviewed concurrently.

2. Indicate the major element to be observed. List individuals/positions to be interviewed.

3. Check the documents that were reviewed during inspection preparation.

Previous Inspection Report

Reading File

NRC Inspection Procedure(s)

License Condition/Tie-downs

SSD Sheets

NUREG-1556

Information Notices/Regulatory Issue Summaries

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NMED and allegation file, if appropriate

4. List survey meters that will be used on the inspection.

Acknowledgement

Inspector Signature Date Date

Approval Signature

(Senior Health Physicist)

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.3, Revision 0 Performance-Based Inspection

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

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Revision	Date	Description of Changes
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None

1.0 PURPOSE

1.1 Applicability

- 1.1.1 Inspections conducted by the Indiana Radioactive Materials Control Program (RMCP) are to be performance-based, meaning the inspector evaluates the licensee performing activities for which they are licensed.
- 1.1.2 This procedure describes how an RMCP inspector is to conduct performance-based inspections. Inspection Manual 2800 is to be used along with the additional guidance found in:
 - 1.1.2.1 RMCPP 2.1 Scheduling of Inspections
 - 1.1.2.2 RMCPP 2.2 Inspection Preparations
 - 1.1.2.3 RMCPP 2.4 Documentation of Inspection Results
 - 1.1.2.4 RMCPP 2.6 *Materials Inspections Checklists and Definitions*
 - 1.1.2.5 RMCPP 2.7 Assuring the Technical Quality of Inspections
 - 1.1.2.6 RMCPP 4.2 *Tracking Inspections*
 - 1.1.2.7 NRC Inspection Procedures
- 1.1.3 A review of a licensee's program documentation or a walk-down (tour) of a facility is not a performance-based inspection.
- 1.1.4 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.
- 1.1.5 This procedure helps the inspector identify and prioritize those activities that impact on a licensee's performance.

1.2 References

- 1.2.1 NUREG-1556 Volume 19, Revision 1, "Guidance for Agreement State Licensee About NRC Form 241 'Report of proposed Activities in Non-Agreement States, Area of exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement States Jurisdiction (Reciprocity)."
- 1.2.2 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."

- 1.2.3 NRC Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- 1.2.4 NRC Inspection Procedure 87103, "Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing."
- 1.2.5 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program."
- 1.2.6 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."
- 1.2.7 290 IAC 3

1.3 Files

- 1.3.1 Current Department and NRC Information Notices & Regulatory Issue Summaries.
- 1.3.2 Licensee File
- 1.3.3 Records are primarily filed electronically and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 For each initial, routine core and non-core inspection:
 - 2.1.1.1 Reviews, as appropriate, application, license and inspection reports, and Department and NRC Information Notices.
 - 2.1.1.2 Determines instruments needed to conduct independent measurements.
 - 2.1.1.3 Conduct performance-based inspections by observing licensed activities in progress.
 - 2.1.1.4 Reviews the inspection findings with the Senior Health Physicist (S/HP) and/or Radiation Control Program Director (RCPD), as necessary.
- 2.1.2 For each reactive, reduced, or special inspection:
 - 2.1.2.1 Reviews relevant information based upon the required scope of the inspection.
 - 2.1.2.2 Conducts an inspection with a focus on the required scope by observing licensed activities in progress.

- 2.1.2.3 Reviews the inspection finding with the S/HP and/or RCPD, as necessary.
- 2.1.2.4 Informs the licensee of pending initial inspection and reactive inspections, if necessary.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Within one week of submission, reviews the inspection findings with the assigned inspector(s), as necessary.
- 2.2.2 Determines if a reactive or special inspection is warranted, if it should be performed promptly or if it can be included in the next routine inspection. Assigns an inspector or team of inspectors to perform the inspection.
- 2.2.3 Provides inspection statistics to the RCPD quarterly. These may be generated using WBL.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Performs an annual accompaniment inspection with each Health Physicist and documents the results. [See Appendix B in SA-102 for template.]
- 2.3.2 May perform duties of the HP or S/HP in their absence.

3.0 PROCEDURE

3.1 General

- 3.1.1 An inspection will be considered to have been performed if:
 - 3.1.1.1 The inspection involves a licensee that possesses or has possessed licensed material since the last inspection, or that is performing or has performed licensed activities since the last inspection;
 - 3.1.1.2 The inspection is an initial inspection that has been performed in accordance with this procedure;
 - 3.1.1.3 Where inspection of temporary job site activities were not available to the inspector at the time of the inspection, this inspection should be recorded as an inspection of the main office and the inspection documentation should make note of this.
 - 3.1.1.4 An inspection for licenses that have expired or are being processed for termination.

- 3.1.2 An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector should determine when another attempt will be made to inspect the licensee, document the attempted inspection in accordance with RMCPP 2.4 Documentation of Inspection Results.
- 3.1.3 Performing inspections should be completed in accordance with this procedure. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection that may be found in other Department or NRC guidance documents. All routine inspections are unannounced unless specific instructions are received from the S/HP or other factors (i.e., initial inspections and mobile unit at different locations) require that an inspection is to be announce.
- 3.1.4 Focus elements or focus areas in the NRC inspection procedures are selected as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus elements or focus areas.
- 3.1.5 If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus element, the inspection effort expended in reviewing that particular focus element will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus element, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.
- 3.1.6 The inspector should use a performance-based approach to evaluate the focus elements. A determination regarding safety and compliance with Department requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by the Department, independent measurements of radiological condition at the licensee's facility, and, where appropriate, a review of selected records. Emphasis should be place on observing licensee performance as it relates to staff

training, equipment operation and adequacy, overall management of the licensed program and integration of safety and security.

- 3.1.7 In reviewing the licensee performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.
- 3.1.8 The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments) prior to beginning the performance-based inspection.
- 3.1.9 Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. The inspector shall not under any circumstances knowingly allow an unsafe work practice which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.
- 3.1.10 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the information reviewed or gathered has been declared as proprietary information by the licensee.
- 3.1.11 Proprietary and/or patient information should not be taken from the licensee unless confidential, security-related or personally identifiable information has been removed. In the case of a medical incident only the information relevant to the incident should be included. Personally identifiable patient information such as name, medical record and social security numbers are examples of Personally Identifiable Information (PII).
- 3.1.12 In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete. Inspectors shall ensure that the licensee

understands that the retained record will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding the information.

3.1.13 The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensee's understanding and agreement that an apparent violation occurred, preferably before leaving the site. The inspector shall also take the time to discuss any recommendations.

- 3.1.14 The inspector should keep the S/HP informed of significant findings (i.e., safety hazards, willfulness, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate Department guidance under such circumstances.
- 3.1.15 The inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns).

3.2 Inspection Preparation

Preparation for inspections is defined in RMCPP 2.2 *Inspection Preparation*. Attachment 2.2-1 is an example of an inspection plan.

3.3 Performance-based Inspections

- 3.3.1 <u>Entrance Meeting</u>: The inspection begins with a meeting with appropriate licensee personnel. The inspector shall assure that licensee management (signer of the application for license or appropriate senior management) will be made aware of the inspection. In certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observation of licensed activities currently in progress.
 - 3.3.1.1 The inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This is often an opportune

time for the inspector to identify personnel to be interviewed.

- 3.3.1.2 The licensee representative should be asked to identify any recent problems related to the licensed program.
- 3.3.1.3 When an inspection is likely to involve proprietary information, Personally Identifiable Information (PII) and patient information, the inspector should discuss how the information will be handled during the inspection.
- 3.3.1.4 If appropriate, the exit meeting should be scheduled during the entrance meeting.
- 3.3.1.5 The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary, PII or patient related. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.
- 3.3.1.6 In all cases where licensee documents are retained beyond inspection, inspectors should follow the requirements of IMC 0620 "Inspection Documents and Records." Inspectors shall ensure that the licensee understands that the retained records will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding of the information.
- 3.3.2 <u>Follow-up on Previous Items</u>: Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took corrective actions as described in the licensee's response to the Notice of Violation (NOV) and followed up on safety concerns and unresolved issues identified during the previous inspection. Inspectors should ensure that corrective actions implemented from previous inspections are being followed to prevent recurrence of the violation by:
 - 3.3.2.1 Review of the original NOV in the original inspection report and verify the licensee instituted sufficient corrective actions to prevent recurrence and are in accordance with the disposition of the NOV.
 - 3.3.2.2 Determine whether the violation will be closed during the current inspection and obtain information necessary to close the unresolved item.

- 3.3.2.3 Document the results of the follow-up inspection activity in an inspection report.
- 3.3.3 <u>General Overview</u>: The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.
 - 3.3.3.1 Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection.
 - 3.3.3.2 Identify the reporting relationship and management structure between the licensee's executive management, the RSO, and, if applicable, the chairperson and other members of the Radiation Safety Committee (RSC).
 - 3.3.3.3 Interview cognizant personnel to determine the types, quantities, and use of radioactive material, frequency of use, staff size, etc., and anticipated changes in the radiation use program.
 - 3.3.3.4 Determine if the licensee possesses material in accordance with a general license.
- 3.3.4 <u>The Inspection</u>: The inspector should observe licensee operations, interview staff and conduct document review to complement and support observations. Perform radiation surveys to obtain independent and confirmatory measurements.
 - 3.3.4.1 Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety. In performance-based inspection, a problem with licensee performance leads the inspector to identify programs or procedures for evaluation. If there is no opportunity to observe work in progress that involves Department regulated activities, the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites.
 - 3.3.4.2 If an activity results in significant problems, licensee management should be informed as soon as possible. This will allow the licensee sufficient time to begin root cause analysis and possibly determine a corrective action prior to the exit meeting.
 - 3.3.4.3 Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. The walk-

through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.

- 3.3.4.4 Conduct inspections of principal activities that are a potentially significant contributor to dose, regardless of shift.
- 3.3.4.5 Perform routine inspections, when applicable, at times of high use of licensed material.
- 3.3.4.6 Make direct observations of radiation safety systems and practices used.
- 3.3.4.7 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of records should occur only if the current records are out of compliance and it is necessary to determine the presence of a prevalent or persistent problem.
- 3.3.5 <u>Independent and Confirmatory Measurements</u>: Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.
 - 3.3.5.1 The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility.
 - 3.3.5.2 Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e., inspector's detection equipment malfunctions during an inspection trip).
 - 3.3.5.3 Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.
 - 3.3.5.4 Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.
 - 3.3.5.5 The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation. However, the inspector must use IDHS instrumentation for independent verification of the licensee's measurements.

- 3.3.6 <u>Special License Conditions</u>: If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that that licensee understands the additional requirements and maintains compliance with the special license conditions.
- 3.3.7 <u>Exit Meeting</u>: The inspection concludes with an exit meeting with licensee management. If a senior management representative is unavailable for the exit meeting, the inspector should hold an exit meeting with appropriate staff onsite. Dependent on the results of the inspection, the inspector may hold another exit meeting directly with a senior management representative and the licensee's RSO. This meeting involving the licensee's management and RSO can be held by telephone. 3.3.7.1 When appropriate, the inspector should prepare NRC
 - Form 591M Safety Inspection Report and Compliance Inspection before the exit meeting so that the form can be properly executed during the exit meeting. IDHS RMCP form 591M may be issued while still in the field for:
 - 3.3.7.1.1 An inspection that results in no findings.
 - 3.3.7.1.2 To document a non-cited violation (NCV); or
 - 3.3.7.1.3 To document a Severity Level IV (health and safety only) that does not require an amendment to the license to correct and is not willful or repetitive in nature. The Severity Level IV violation being documented in this manner must be corrected while the inspector is present or can be easily corrected within 30 days of the date of the inspection. Any corrective actions must be listed on IDHS RMCP Form 591M Part 1.
 - 3.3.7.2 When NRC Form 591M is used to document the results of an inspection, NRC Form 591M Part 3 must also be completed. The inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or non-cited violation and the facts necessary to demonstrate that a requirement was not met; reference to the regulation, license condition or other legally binding requirement that was violated; and a description of the licensee's corrective action.
 - 3.3.7.3 The results of the inspection and any unresolved items will be discussed with the licensee. During the

meeting, the inspector shall explain any violation of Department requirements and the inspector's understanding of the licensee's corrective action plan for each violation. The inspector should explain safetyrelated concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

- 3.3.7.4 Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated, or the licensee has made a commitment to initiate corrective actions. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, the S/HP should be notified immediately.
- 3.3.7.5 Although deficiencies identified in some areas (e.g., a worker's knowledge of radiation protection regulations) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report of Notice of Violation (NOV).
- 3.3.7.6 At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature, including PII and patient information. If so, the inspector should assure proper handling of the information.
- 3.3.8 Evaluating Inspection Results: After returning from an inspection trip, the inspector shall discuss, either through verbal or written manner, the results of the inspection(s) with the S/HP. The inspector should make an accurate determination of the actual condition of the activities inspected. The technical basis or root causes of identified problems must be emphasized, not just the symptoms or administrative indications. The reliability of both equipment and workers should be evaluated with respect to safety. Inspection findings should be evaluated for generic health and safety problems. Performance conditions should also be evaluated to predict their impact on future operations. Documentation for inspection Results.

3.4 Initial Inspections

- 3.4.1 Initial inspections of a new licensee shall be announced and completed within 12 months of the date the new license or amendment was issued by the Department; however, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months of license issuance. Scheduling initial inspections are determined in RMCPP 2.1 Scheduling of Inspections. If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:
 - 3.4.1.1 Determine the licensee's plans for future possession of license material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities, personnel and equipment are in place to safely handle licensed material, as described in the license application
 - 3.4.1.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions and give the licensee an opportunity to ask any regulatory questions.
 - 3.4.1.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of licensed operations, as required by license condition. Document the contact and enter the record into the file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.
 - 3.4.1.4 Ensure that the due date is set for 18 months from license issuance.
- 3.4.2 Performing initial inspections. During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed.

Methods for determining if principal activities have been performed include but are not limited to the following: performing a site tour, performing independent measurements, and/or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with this procedure and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

- 3.4.2.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.
- 3.4.2.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.
- 3.4.2.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.
- 3.4.2.4 Remind the licensee of the requirements in 10 CFR 30.36(d) to provide written notification to the Department within 60 days if no principal activities under the license have been conducted for a period of 24 months.
- 3.4.2.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.
- 3.4.2.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by \pm 6 months.
- 3.4.3 Document the onsite inspection by completing a **NRC Form 591M Safety Inspection and Compliance Inspection** for the exit interview or complete other inspection reports as described in RMCPP 2.4 *Documentation of Inspection Results*. The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.

- 3.4.4 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by \pm 6 months.
- 3.4.5 New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.
- 3.4.6 New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
 - 3.4.6.1 The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);
 - 3.4.6.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
 - 3.4.6.3 The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);
 - 3.4.6.4 The licensee significantly increases the number of authorized users; or
 - 3.4.6.5 The new license authorizes on or more new facilities
- 3.4.7 If none of these conditions applies, the "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.
- 3.4.8 New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

3.5 Routine Inspections

- 3.5.1 Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority as defined in RMCPP 2.1 *Scheduling of Inspections*.
- 3.5.2 If the licensee has possessed material or performed principal activities since the last inspection, the inspector should perform

a routine inspection of the facility as defined in the programspecific inspection procedure using a performance-based inspection as discussed in Section 3.3.

3.5.3 If the licensee has not possessed material or performed principal activities since the last inspection, the inspector should follow the instruction in Section 3.4.

Team inspections will be conducted on an as-needed basis.

- 3.5.4 Inspectors should plan to conduct routine inspections close to the due date. However, to achieve the goals of cost saving and efficient use of staff time and travel, routine inspections may be scheduled within a window around their inspection due dates. Inspection of licensees in Priority Codes 1 and 2 may vary around their due date by \pm 50 percent. Routine inspections of Priority Codes 3 and 5 licensees may vary around their due dates by \pm 1 year.
- 3.5.5 Inspections will not be considered "overdue" until they exceed the scheduling window. In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, inspections may be scheduled before their window if the Department receives information that warrants earlier inspection. The bases for scheduling the inspection before the window should be documented in the inspection records and signed by the inspector's immediate supervisor and place in the licensee file and in WBL.

3.6 Reactive Inspections

- 3.6.1 Reactive Inspections focus on limited issues that are not within the scope of a routine inspection. Inspections performed to follow up on incidents (i.e., medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. The S/HP shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary.
- 3.6.2 Preparation for these inspections shall be under the direction of the S/HP. Narrative reports shall be prepared, if required, by the S/HP. The inspection frequencies for reactive inspections are defined in RMCPP 2.1 *Scheduling of Inspections*. Performing

reactive inspections should be completed in accordance with RMCPP 3.1 *Management of Allegations* and/or RMCPP 3.2 *Incident Response*.

- 3.6.3 The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.
- 3.6.4 Issues of compliance will generally be addressed after all safety issues and program weaknesses are identified and understood.
- 3.6.5 It is particularly important that the inspector keep the S/HP informed of the inspection details and explain the exit meeting strategy before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's and inspector's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to the S/HP. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the S/HP. The licensee's next opportunity to discuss the finding will be after the S/HP has reviewed these matters.
- 3.6.6 If a narrative inspection report is required, the report will include a discussion of inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident.
 - 3.6.6.1 <u>Incidents</u>: Inspections of reportable incidents (e.g., medical events, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. All reactive inspections will be performed using the guidance in RMCPP 3.2 *Incident Response*. Reactive inspections of incidents will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy.

- 3.6.6.2 <u>Medical Events</u>: Inspection of medical events shall be conducted in accordance with the guidance in RMCPP 3.2 *Incident Response*. Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program."
- 3.6.6.3 Allegations: Allegations shall be processed in accordance with RMCPP 3.1 *Management of Allegations*.

3.7 Special Inspections

- 3.7.1 Special inspections (i.e., reciprocity, temporary job site, team, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections shall be under the direction of the S/HP. Narrative reports shall be prepared, if required by the S/HP, for special inspections. Inspection frequencies for special inspections are defined in RMCPP 2.1 Scheduling of Inspections.
- 3.7.2 For a licensee authorized to work at a temporary job site, the inspector shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).
 - 3.7.2.1 <u>Reciprocity Inspection</u>: Performing reciprocity inspections should be completed in accordance with RMCPP 2.2 *Inspection Preparations*, IMC 2800 "Materials Inspection Program" and IMC 1220 "Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore waters", and Inspection of Agreement State Licenses under 10 CFR 150.20.
 - 3.7.2.2 <u>Temporary Job Site Inspections</u>: For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).
 - 3.7.2.2.1 During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).
 - 3.7.2.2.2 The inspector may contact the licensee's customer to schedule the temporary job site

inspection. The licensee's customer should be requested not to notify the licensee of the inspection.

- 3.7.2.2.3 If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).
- 3.7.2.2.4 If a temporary job site inspection not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" data element in Web-Based Licensing may indicate a reduced inspection interval.
- 3.7.2.3 <u>Permanent Field Offices</u>: If the license does not authorized licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities. If an inspection identifies significant program weaknesses (indicative of poor program management/oversight), the S/HP should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.
 - 3.7.2.3.1 If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or two field offices), only one location must be inspected at the interval specified in this procedure for the type of license.
 - 3.7.2.3.2 If the license authorized licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this procedure for the type of license.
 - 3.7.2.3.3 It the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected.
 - 3.7.2.3.4 Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

- 3.7.2.3.5 If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.
- 3.7.2.3.6 If an inspection identifies significant program weaknesses (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the license reviewer should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.
- 3.7.2.4 Expired and Terminated Licenses and Decommissioning Activities: Notification that a license has expired or is being terminated (and an inspection is required in accordance with RMCPP 1.3, License Termination/Revocation), requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.
 - 3.7.2.4.1 Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys.
 - 3.7.2.4.2 The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the Department of termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.
 - 3.7.2.4.3 If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule.

- 3.7.2.5 <u>Abandonment of Licensed Activities</u>: Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.
- 3.7.2.6 <u>Inspection After Escalate Enforcement</u>: If escalated enforcement action has taken place for a particular licensee, a special inspection follow-up shall be scheduled and conducted within 6 months of the last inspection or sooner after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous Severity Level III or above violations. The Department may perform this follow-up inspection as a part of a routine inspection. In determining when to conduct the follow-up inspection, the Department should consider the risksignificance, number, and severity level of the violations.
- 3.7.2.7 <u>Significantly Expanded Programs</u>: During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license review may request a near-term onsite inspection for a significant licensing actin that was recently completed. Both the inspector and the reviewer should make their supervisors aware of the following changes in a licensee's scope of work. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:
 - 3.7.2.7.1 The licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of risk significant radioactive material (RSRM);
 - 3.7.2.7.2 The licensee authorized a physical move of a facility or a new use at a temporary jobsite;
 - 3.7.2.7.3 The licensee authorizes new (i.e., since the previous inspection) satellite facilities where licensed materials will be used or stored;

- 3.7.2.7.4 The licensee has increased the types of uses or disposal (i.e., incineration or decay-instorage) of radioactive material;
- 3.7.2.7.5 The number of authorized users has significantly increased or decreased; and
- 3.7.2.7.6 The licensee has ceased activities at the entire site or in any building area as defined in 10 CFR 30.36(d).

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded, or activities have ceased. See the six points in the preceding paragraph. If during the licensee will possess RSRM, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff, should add Program Code 01000. An onsite inspection must be performed to verify that the applicant has implemented the security requirements before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.

3.8 Reduced Inspections

- 3.8.1 The inspection interval shall not be extended beyond that specified by the priority system indicated in RMCPP 2.1 *Scheduling of Inspections*. The interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. If there was a reduction in inspection frequency, ensure that frequencies are reduced as discussed in RMCPP 2.1 *Scheduling of Inspections*. The inspection should be performed in accordance with this procedure; However, special attention should be focused on the areas of poor performance. Other aspects of the program should only be focused on as time and opportunity allows.
- 3.8.2 At the discretion of the **S/HP**, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing

the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent a timely inspection from being complete. The bases for altering the scheduling of inspections should be documented in the inspection records and signed by S/HP and placed in the license file and WBL.

3.9 Team Inspections

- 3.9.1 The Department shall schedule and conduct team inspections of major licensees within Indiana on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside IDHS shall be made by the S/HP and RCPD.
- 3.9.2 Examples of situations where team inspections may be appropriate are:
 - 3.9.2.1 Routine inspections of major licensees (i.e., broadscope academic, broad-scope medical licensees, and large processor/manufacturers). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.
 - 3.9.2.2 Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).
 - 3.9.2.3 Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess a licensee's strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, prelicensing visits are not considered inspections, and team inspections should not take the place of prelicensing visits.

3.10 Coordination with Other Agencies

- 3.10.1 The Department does not conduct inspections of licensee compliance with the requirements of other local, state, or federal agencies, except the U.S. Department of Transportation (DOT). However, a Health Physicist (HP) may identify concerns that are within another agency's regulatory authority.
 - 3.10.1.1 If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the S/HP should inform the appropriate liaisons within the other agency about the concerns.
 - 3.10.1.2 Except for DOT regulations, it is important that all HP's recognize and understand that they are not to make decisions regarding activities under the purview of other agencies.
 - 3.10.1.3 Thus, in discussing the concerns with the licensee, HP are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations but are to point out concerns to heighten licensee awareness. For example, if an HP identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation.
 - 3.10.1.4 The HP should also advise the licensee of the obligation to inform the S/HP who may coordinate the information with the other lead agency.

3.11 Security Inspections

- 3.11.1 The requirements of 10 CFR Part 37 apply only to licensees in possession of aggregated category 1 and 2 quantities of radioactive materials, including sealed and unsealed sources.
- 3.11.2 Affected licensees may include manufacturers and distributors, self-shielded irradiators, open-air beam calibrators, pool-type irradiators, medical facilities with blood irradiators and/or gamma-ray stereotactic radiosurgery (gamma knife), radiopharmacies, industrial radiographers, and licensees transporting category 1 and 2 quantities of radioactive material
- 3.11.3 The focus of this inspection is the security inspections of those licensed under 10 CFR Part 30, subject to Part 37 requirements when possessing certain aggregated category 1

and 2 quantities of radioactive material. (See Inspection Procedure 87137 for additional details.)

3.12 Pre-Licensing Site Visits

- 3.12.1 The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-licensing Checklist.
- 3.12.2 At a minimum, all storage and use locations must be visited.
- 3.12.3 By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application.
- 3.12.4 Pre-licensing visits must be completed before the issuance of a license.

4.0 Records

- **4.1** Letter with Notice of Violation or Department Letter or clear inspection form.
- **4.2** Inspection Report maintained in file and WBL.
- **4.3** Records are primarily filed electronically, and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 Attachments to RMCPP 2.3

None

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.4, Revision 0 Documentation of Inspection Results

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	
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1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure is designed to ensure that reports of inspections clearly communicate significant inspection results to licensees, licensing staff, and the public. It is the Department's goal that all Radioactive Materials Control Program staff should be qualified in both licensing and inspections of all uses of radioactive materials in the State of Indiana. Significant findings in the inspection reports will be reviewed during the program staff meetings conducted by the Radiation Control Program Director (RCPD) and attended by all program staff.
- 1.1.2 This procedure will ensure that reports of inspections provide conclusions about the effectiveness of the program(s) and/or principal activities inspected. The depth and scope of the documented conclusions should be commensurate with the depth and scope of the inspection.
- 1.1.3 The documentation described in this procedure will provide a basis for enforcement action.

1.2 References

- 1.2.1 NRC Inspection Manual, Chapter 0610, "Nuclear Material Safety and Safeguards Inspection Reports."
- 1.2.2 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."
- 1.2.3 NRC Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- 1.2.4 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program."
- 1.2.5 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."
- 1.2.6 290 IAC 3
- 1.2.7 NRC Enforcement Manual

1.3 Files

1.3.1 Letter with Notice of Violation Letter, Clean Inspection Report, and NRC Form 591M.

- 1.3.2 Other elements of inspection reports maintained in the licensee file.
- 1.3.3 Records are primarily filed electronically, and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Maintains files, records, letters, forms, and other records related to inspections.
- 2.1.2 Prepares the inspection documentation issued within 30 days of completing the inspection.
- 2.1.3 Prepares a Department letter transmitting the inspection findings to the licensee.
- 2.1.4 Tracks the inspection documentation until completed.
- 2.1.5 Updates the inspection history record and enters next inspection date in Web-Based Licensing (WBL).

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Updates the data in WBL. Once the inspection is completed, record the inspection date, licensee name, license number, lead inspector, and accompanying inspector(s) in WBL.
- 2.2.2 Reviews a report of inspection findings and recommended enforcement action. If warranted due to the severity of the inspection findings, notifies the Radiation Control Program Director, as soon as possible.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Concurs with the inspector's and/or S/HP's findings and recommendations or prescribes alternative actions.
- 2.3.2 Reviews and approves the narrative report of the inspection findings and transmittal letter, as necessary.
- 2.3.3 Signs all correspondence to the licensee related to the inspection report.

3.0 PROCEDURE

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Review RMCPP 2.3 *Performance-Based Inspection*, to determine if an inspection was performed. If an attempt was made, but the inspection was not performed, this needs to be documented to note the attempt in the license file. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection documentation. Documentation of inspections should be completed in accordance with this procedure and other applicable IDHS RMCP and NRC Guidance

3.1 Methods of Documenting Inspection Results

- 3.1.1 Results of inspections are reported to the licensee with a **NRC Form 591M Safety Inspection and Compliance Inspection** (Attachment 2.4-1) and may be followed up with additional documentation.
- 3.1.2 They may also be documented with a department letter as described in RMCPP 2.7 *Assuring the Technical Quality of Inspections*
- 3.1.3 The content of an inspection report should include that found in Attachment 2.4-2 **Inspection Report Content**.
- 3.1.4 Inspection Reports should also include either an Attachment 2.4-3 Notice of Violation Letter or Attachment 2.4-4 Clean Inspection Report.
- 3.1.5 Notes taken during the course of the inspection shall not be official documentation of the inspection performance. The S/HP may make an exception to this if the notes are determined by the S/HP to be sufficient documentation. If so, the notes will be place in the licensee file and WBL.

3.2 Inspection Reports

- 3.2.1 Upon completion of an inspection for a licensee, a narrative report or an inspection memo shall be generated on NRC Form
 591M Safety Inspection and Compliance Inspection.
- 3.2.2 Inspection reports should be completed within 15 working days following the completion of the on-site portion of the inspection.
- 3.2.3 Narrative reports shall contain:
 - 3.2.3.1 Sufficient detail to describe the inspection that was conducted including operations observed to document the performance-based part of the inspection;
 - 3.2.3.2 Compliance status of topics;
 - 3.2.3.3 The status of follow-up items involving prior enforcement or reported licensee events;

- 3.2.3.4 Sufficient information to support cited violations, noncited violations, and closed violations identified during a previous inspection;
- 3.2.3.5 Description of completed or anticipated corrective actions to any identified minor violations cited in NRC Form 591M;
- 3.2.3.6 Sufficient description of the scope of the licensee's program for the S/HP, license reviewers, and other inspectors to evaluate the licensee's overall safety program; and
- 3.2.3.7 For inspections that include a review of Part 37 requirements with no violations, the inspector should include in a non-publicly available inspection record (e.g., Form 591M Part 3) describing the licensee's implementation of security requirements. This form is Attachment 2.4-5 NRC Form 591M Security-Related.
- 3.2.4 An inspection report shall contain sufficient information to provide a general overview of the current status of the licensee's radioactive material program, including but not limited to, use of licensed material, staff size and hours, any changes from information previously noted in a narrative report, and any other information deemed relevant by the inspector.

3.3 Report to Licensees

- 3.3.1 Inspection findings shall be reported to the licensee upon acceptance of the inspection report by the S/HP or RCPD. Inspection findings should be sent to the licensee through a department letter unless a NRC Form 591M was provided to the licensee at the conclusion of the inspection and that is deemed sufficient by the S/HP or RCPD. Any Form 591M completed in the field must be signed by a supervisor when the inspector returns to the office. The form does not need to be reissued unless the characterization of any findings changes during supervisory review.
- 3.3.2 NRC Form 591M Safety Inspection and Compliance Inspection shall be used to document clear inspections and inspections resulting in non-cited violations (Severity Level IV violations that are neither willful nor repetitive and that can be corrected while the inspector is present, or that the licensee agrees to correct).
- 3.3.3 The inspector will present NRC Form 591M Part 1 to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with Department management is necessary,

the inspector may transmit NRC Form 591M Part 1 from the Department office

- 3.3.3.1 The NRC Form 591M, "Safety Inspection Report and Compliance Inspection," shall include the name of the responsible inspector.
- 3.3.3.2 The inspector shall sign the completed NRC Form 591M Part 1. Supervisory review is required, but is not necessary prior to issuance of NRC Form 591M Part 1, to the licensee.
- 3.3.3.3 If no changes are needed after supervisory review, the supervisor will sign the final signature block and the completed form will be put in WBL (only one form is maintained since it provides record of both the finding communicated to the licensee, and the final approved action).
- 3.3.3.4 If changes are needed after supervisory review, NRC Form 591M Part 1 will be reissued to the licensee, and both the original Part 1 and the revised completed form will be put in WBL (both versions are maintained in order to provide record of both the initial finding communicated to the licensee and the final approved action).
- 3.3.4 NRC Form 591M Part 1 may not be used to transmit non-cited or cited security-related violations.
- 3.3.5 The inspector must document findings with enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement (use titles only, names should be avoided, if possible), and when it was violated (including dates, or period of time of non-compliance, if known). If the licensee provides immediate or long term corrective action for the violation, this information should also be included as part of the inspection record.
- 3.3.6 When NRC Form 591M is used to document the results of an inspection, the inspector must ensure that for each cited violation, the form includes:
 - 3.3.6.1 A brief statement of the circumstances, including the date(s) of the violation or the period of time of the non-compliance;
 - 3.3.6.2 The facts necessary to demonstrate that a requirement was not met; and
 - 3.3.6.3 The reference to the regulation, license condition or legally binding requirement that was violated.
- 3.3.7 The Severity Level IV violation being documented in this manner must be corrected while the inspector is present or can be easily

corrected within 30 days of the date of the inspection. Any corrective actions must be listed on the Form 591M Part 1.

- 3.3.8 Following are examples of cited violations on NRC Form 591M:
 - 3.3.8.1 10 CFR 20.1101 requires the licensee to annually review the content and implementation of the radiation protection program. During years 2010 and 2011, the licensee did not complete the review. The licensee will complete the review in October 2012 for the period of January 2010 through September 2012. The licensee intends to complete future reviews in October of each year by completing NUREG-1556 Volume 9, Revision 2 Appendix L, Suggested Medical License Audit.
 - 3.3.8.2 As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2010 to October 24, 2010 to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system to notify the Radiation Safety Officer to perform the inventories.

Note: Attachment 2.5-1 of RMCPP 2.5 contains examples of violations that may be cited on NRC Form 591M

- 3.3.8.3 NRC Form 591M shall include the name of the responsible inspector. The inspector shall sign the completed NRC Form 591M. The inspector will present the NRC Form 591M to the licensee at the conclusion of the exit interview or, as necessary, by facsimile, mail, or electronic mail in accordance with State requirements.
- 3.3.9 <u>Department Letters</u>. A letter, signed by the inspector and/or the S/HP, shall be used if a NRC Form 591M was not issued to documents a clear inspection. A Department letter shall be sent within 30 days of completion of the inspection if a NRC Form 591M has not been issued. Department letters shall be sent along with a Notice of Violation(s) if any of the following situation are found:
 - 3.3.9.1 Repetitive violations;
 - 3.3.9.2 Violations involving willfulness:
 - 3.3.9.3 Where an apparent Severity Level III or higher violation or problem is detected;
 - 3.3.9.4 When an enforcement conference or a management meeting is to be held;

- 3.3.9.5 Where the licensee needs to take extensive corrective action(s) or make programmatic changes to address the violation(s);
- 3.3.9.6 Where the licensee needs to perform further evaluations before taking corrective action;
- 3.3.9.7 Where the corrective action includes a request for an amendment to the license;
- 3.3.9.8 When a specific message should be provided to the licensee;
- 3.3.9.9 If the inspector questions the effectiveness of the licensee's planned action or the ability of the licensee to carry out the corrective action;
- 3.3.9.10 Where it is appropriate to request a written response to the violation.

3.4 Marking of Inspection Documentation

- 3.4.1 Information relative to the licensee's physical protection measures (security-related information) is confidential information and needs to be protected.
- 3.4.2 The inspector should ensure that the NOV, documentation of findings (i.e., Form 591M Part 3 or narrative inspection report), and any other separate enclosure are appropriately protected, handled and marked in accordance with the following security-related information guidance:
 - 3.4.2.1 Paper copies must be filed in the padlocked secure files cabinet and electronic files saved in the secure access only server folder.
 - 3.4.2.2 Files must be Marked: "THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC AND/OR PAPER FILES ONCE FILLED OUT."
 - 3.4.2.3 Files must be maintained under the visual and physical possession of the user when outside of the electronic or padlocked file storage area.
- 3.4.3 All cover letters to licensees will be publicly available and should not contain confidential information. Security-related information should not be made available to the public.

3.5 Reports for Special Inspections

A narrative report should be completed documenting all special inspections. Reports should be completed and issued within 30 working days of the completion of the on-site portion of the inspection.

- 3.5.1 <u>Escalated Cases</u>: For escalated cases, the report should address all areas covered in the inspection.
- 3.5.2 <u>Medical Events</u>: for medical events the report should follow the guidance in NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility".
- 3.5.3 <u>Allegations</u>: For allegations the report should follow the guidance in RMCPP 3.1 *Management of Allegations*.
- 3.5.4 <u>Reactive and Reduced Inspection</u>: A reactive and reduced inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

4.0 Records

- **4.1** Inspection reports and inspection transmittal letters in licensee's file.
- **4.2** Records are primarily filed electronically, and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 Attachments to RMCPP 2.2

- 2.4-1 NRC Form 591M Safety Inspection Report and Compliance
- 2.4-2 Inspection Report Content
- 2.4-3 Notice of Violation Letter
- 2.4-4 Clean Inspection Report
- 2.4-5 Security Related 591M Part 3

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.4-1 NRC Form 591M Safety Inspection Report and Compliance

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NRC Form 591M Safety Inspection Report and Compliance Inspection

INDHS RMCP

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

2. LICENSEE NUMBER:

DATE(S) OF INSPECTION

LICENSEE: The inspection was an examination of the activities conducted under you license as they relate to radiation safety and to compliance with the Indiana Department of Homeland Security Radioactive Materials Control Program (IDHS RMCP) rules and regulations and condition of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

1. Based on the finding, no violations were identified.

2. Previous violation(s) closed.

3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the IDHS RMCP enforcement procedure to exercise discretion, were satisfied

Non-cited violation(s) were discussed involving the following requirements:

4. During the inspection, certain of your activities, as described below and/or attached, were in violation of IDHS RMCP enforcement Policy. This form is a NOTICE OF VIOATION, which may be posted in accordance with 10 CFR 19.11 (Violation and corrective Actions)

Statement of Corrective Action

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of I.C § 10-19-12 (corrective steps already taken, corrective steps which will be taken date when full compliance will be achieved). I understand that no further written response to the IDHS RMCP will be required, unless specifically requested.

Title Printed Name Signature Date

LICENSEE		
REPRESENTATIVE		
IDHS RMCP		
INSPECTOR		
IDHS RMCP		
Radiation Control		
Program Director		

NRC FORM 591M PART 2 DEPARTMENT OF HOMELAND SECURITY MATERIALS CONTROL PROGRAM	INDIANA RADIOACTIVE
SAFETY INSPECTION AND COMPLI LICENSEE/LOCATION INSEPCTED:	ANCE INSPECTION
LICENSE NUMBER:	DATE(S) OF INSPECTION
(OBSERVATIONS)	

FORM 591 Part 3 Indiana Department of Homeland Security Radioactive Materials Control Program File Information SAFETY INSEPCTION AND COMPLIANCE INSPECTION				
1. LICENSEE/LOCATIONS INSPECTED	2. LICENSE NUMBER(S)			
3. DATES OF INSPECTION	4. TYPE OF INSPECTION			
5. INSPECTION PROCEDURES USED	6. INSPECTION FOCUS AREAS			

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODES	2. PRIORITY
3. LICENSEE CONTACT	4. TELEPHONE NUMBER

Inspector Information

Name:	Signature:
-------	------------

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Phone No.:	Email address:

Main Office Inspection

Next Inspection Date

Field Office Inspection

Temporary Job Site Inspection

Approve:

Radiation Control Program Director Signature/Date

Program Scope

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Conclusions

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.4-2 Inspection Report Content

The content for Radioactive Materials Control Program Inspection Reports should consist of the applicable elements on this list. Details about these elements are in RMCPP 2.4 Documentation of Inspection Results.

- Cover Letter on Department letterhead
 - □ Address, Date, Salutation
 - Subject
 - Introductory Paragraphs
 - □ Body
 - Closing
- •
- NRC Form 591M, Notice of Violation Letter or Clean Inspection Report (Attachments 2.4-1, 2.4-3, and 2.4-4)
- Report
 - Scope
 - Observations and Findings
 - Generic issues, if any
 - Violations, if any
 - Conclusions
 - Exit Meeting Summary
 - Absence of Proprietary Information
 - Characterization of Licensee Response
 - Oral statements and Regulatory Commitments
 - Report Attachments
 - Key Points of Contact
 - □ List of Items Opened, Closed and Discussed (optional)
 - List of Documents Reviewed
 - List of Acronyms

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.4-3 Notice of Violation Letter

Date:

Name of Licensee Attn: Licensee Contact Address Street Address City, State, Zip Code Dear [Insert salutation]:

This letter refers to the inspection conducted on [Insert Date] at your [Facility name] by [Inspector's name].

This inspection was an examination of the principal activities conducted under you Indiana Radioactive Materials [License number], a selective examination of procedures and representative records, observations, and interviews with personnel as they relate to radiation safety and to compliance with the Department's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities and interviews with personnel.

Based on the results of this inspection, the Department has determined that [Insert number of violations] of Department requirements occurred. The violation(s) is/are cited in the enclosed Notice of Violation (Notice).

You are required to respond to this letter within 30 days and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the Department should consider, you may provide it in your response to the Notice. The Department review of your response to the Notice will determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal, privacy, or proprietary information so that it can be made public without redaction.

If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earlier convenience.

[Insert Health Physicist Inspector name, phone number, and email]

NOTICE OF VIOLATION

[Licensee Name]

[License Number] Page|236 During an inspection conducted on XX/XX/XXXX, [INSERT DATE(S)] # [INSERT NUMBER] violations of Department requirements were identified. The violations are listed below:

[INSERT VIOLATIONS WITH REGULATION AS APPROPRIATE]

This is a Severity Level # [INSERT SEVERITY LEVEL] violation.

######## [INSERT LICENSEE] is hereby required to submit a written statement of explanation to the Indiana Department of Homeland Security Radioactive Materials Control Program ATTN: Radioactive Materials Control Program, [ADD VALID IDHS ADDRESS WE DECIDE ON], within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received with the time frame specified in this Notice, an order may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken.

If you contest this enforcement action, you should reply to Indiana Department of Homeland Security Radioactive Materials Control Program ATTN: [ADD VALID IDHS ADDRESS WE DECIDE ON].

To the extent possible your response should not include any personal privacy, proprietary information so that it can be made public without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire to not be placed in the public document and provide the legal basis to support your request for withholding the information from the public.

Dated:

Approved: Program Director **Radiation Control**

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Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.4-4 Clean Inspection Report

Date: Name of licensee Attn: Licensee Contact Address Street Address City, State, Zip Code

Dear [Insert salutation]

This letter refers to the inspection conducted on [INSERT DATE] at your facility.

This inspection was an examination of the activities conducted under your Indiana Department of Homeland Security Radioactive Materials Control Program [License Number], as they relate to public health and safety, and to confirm compliance with the Department's rules and regulations and the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the findings, no violations of Department rules or regulations were identified.

You are not required to respond to this letter; however, you should retain a copy for your records.

If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earliest convenience.

Sincerely,

Radiation Control Program Director

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.4-5 IDHS RMCP 591M Security-Related Part 3

Official Use Only – Security-Related information						
Initial Annou		Unannounced	l Routine	Spe	cial	Security
IDHS RMCPP FORM Indiana Departme 10 CFR 2.201 Radiation Material	nt of	Homeland See	curity			
1. LICENSEE/LOCATION INSPECTED:			Indiana De	2. INSPECTED BY: Indiana Department of Homeland Security Radioactive Materials Control		
REPORT NUMBER(S)			Program [ADD ADDRESS]			
3. DOCKET NUMBER(S):		LICENSE 1BER(S):				ON
6. INSPECTION PROCEDURES:	1	7. INSPECTIO	N AREAS:			
SUP	PLE	MENTAL INSPE	CTION INFOR	RMATI	ON	
1. PROGRAM CODE(S):	2. PRIORITY		3. LICENSEE CONTACT		4. TE NUMB	LEPHONE ER
Main Office Inspe		Next	Inspec	ction Date:		
Field Office Inspe Temporary Job Si						
IDHS RMCPP FORM 59		PROGRA				

Official Use Only – Security Related Information THIS DOCUMENT MUST BE KEPT IN SECURED Non-Public

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ELECTRONIC OR PAPER FILES ONCE FILLED OUT

Confidential-Security-Related Supervisory Review By Radiation Control Program Director (RCPD):

Non-Public

4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

RMCPP 2.7 Assuring the Technical Quality of Inspections provides guidance on quality assurance for inspection reports. It describes secondary peer review and supervisory review, as well as the content of inspecting reports. Significant detail is provided to help assure sound bases are documented for the findings of inspections. It is based upon guidance found in the NRC's SA-102 *Reviewing the Common Performance Indicator, Technical Quality of Inspections* and IMC 0610 *Nuclear material Safety and Safeguards Inspection Reports*. RMCPP 2.7 is copied below. Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.7, Revision 0:

Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

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Revision	Date	Description of Changes
0		

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- 2.0 Objectives
- 3.0 Responsibilities
- 4.0 Inspection Report Writing
- 5.0 Secondary Report Review And Concurrence
- 6.0 Inspection Report Content And Form
- 7.0 Notice Of Violation
- 8.0 Significance Of Observation
- 9.0 Minor Violations And Determining Whether To Document
- **10.0** Violations Identified As Part Of Licensee Self-Assessments
- **11.0** Thresholds Of Significance For Non-Enforcement-Related Issues
- **12.0** Determining The Significance Of Negative Findings
- **13.0** Determining The Significance Of Neutral Or Positive Findings
- **14.0** Findings Previously Covered In Licensee Self-Assessments
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- **16.0** Supervisory Accompaniments
- **17.0 Attachments**
 - 2.7-1 Inspection Report Quality Assurance (QA) Checklist

1.0 PURPOSE

The purpose of this Radioactive Materials Control Program Procedure (RMCPP) is to provide guidance to ensure the technical quality of inspections and that inspection reports are consistent with the NRC's criteria for secondary reviews of inspections and inspection reports (See STP SA-102 "Reviewing the Common Performance Indicator, Technical Quality of Inspections").

2.0 OBJECTIVES

- 2.1 To ensure that inspections of licensed activities focus on health, safety, and security issues utilizing NRC Inspection Manual Chapter 2800, "Materials Inspection Program" as guidance.
- 2.2 To ensure that inspection findings are well-founded and welldocumented in reports.
- 2.3 To verify that inspections are complete and reviewed by a second qualified inspector for technical quality.
- 2.4 To determine that procedures are in place and used to help identify incident root causes and poor licensee performance.
- 2.5 To confirm that follow-up inspections address previously identified open items and/or past violations.
- 2.6 To verify that inspection findings lead to appropriate and prompt regulatory action.
- 2.7 To confirm that supervisors conduct annual accompaniments of each inspector to assess performance and assure application of appropriate and consistent policies and guides.
- 2.8 To determine that inspection guides are consistent with NRC guidance, and that they are being used consistently by inspectors to assure uniform and complete inspection practices.

3.0 **RESPONSIBILITIES**

3.1 All department inspectors (Health Physicists) are required to prepare inspection reports in accordance with the guidance provided to prepare inspection reports in accordance with the guidance provided in this procedure. See Section 6.0.

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- 3.2 Each inspection should be performed in accordance with IMC 2800, the NRC Inspection Procedure for that license type and applicable NUREG 1556 Appendix audits and checklists. The checklists from the applicable NUREG Volumes provide for an objective evaluation of individual inspection tasks.
- 3.3 Each inspection of a license holder shall be documented. As a minimum a Department Form 591M Safety Inspection and Compliance Inspection (see Attachment 2.4-1 of RMCPP 2.4 Documentation of Inspection Reports) may be used for inspections without issues. A narrative inspection report as described in Section 6.0 through 15.0 of this procedure is required for a notice of violation or other enforcement or escalated enforcement action.
- 3.4 Each inspection report must be reviewed by a second qualified inspector for quality assurance purposes. The review is to assure compliance with this and other procedures of the Radioactive Materials Program and documented using Attachment 2.7-1 **Inspection Report Quality Assurance (QA) Checklist**.
- 3.5 The Radiation Control Program Director (RCDP) must annually complete an inspection accompaniment with each of the Health Physicists qualified as inspectors. These are documented using Appendix B of **NRC States Agreement Procedure SA-102 "Reviewing the Common Performance Indicator, Technical Quality of Inspections"**. See Section 16.0 of this procedure.
- 3.6 The Senior Health Physicist (S/HP) must also review each inspection report in a timely manner before final filing.

4.0 INSPECTION REPORT WRITING

- 4.1 Inspectors have the primary responsibility for ensuring that observations and findings are accurately reported, that referenced material is correctly characterized, and that the scope and depth of conclusions are adequately supported by documented observations and findings. Advice and recommendations are not to be included in inspection reports.
- 4.2 Inspectors are responsible for ensuring that the content and tone of the report, as issued, is consistent with the content and tone of the exit meeting presentation.

- 4.3 When the report differs significantly from the exit meeting, the individual conducting the inspection should discuss those differences with the licensee before the report is issued.
- 4.4 Inspectors must ensure that inspection reports follow the general format given in the procedure based on the type of inspection. Further guidance on inspection quality and performance is found in RMCPP 2.1 *Scheduling of Inspections*, RMCPP 2.2 *Inspection Preparations*, RMCPP 2.3 *Performance-Based Inspections*. Audits to aid in the quality of inspection performance are found in the applicable NUREG 1556 Safety Audit Appendices.

5.0 SECONDARY REPORT REVIEW AND CONCURRENCE

- 5.1 Before issuance, each inspection report must be reviewed by a different member of the Radioactive Materials Control Program qualified to conduct similar inspections. This secondary report review is designed to better ensure the quality of all inspections and their reports. This secondary review is documented on Attachment 2.7-1 Inspection Report Quality Assurance (QA) Checklist.
- 5.2 The secondary report reviewer should establish that conclusions are logically drawn and sufficiently supported by observations and findings and that the observations, findings, and conclusions are consistent with Radioactive Materials Program and other Department policies and requirements.
- 5.3 The secondary report reviewer should ensure that assessments made in the inspection report represent the requirements of the Radioactive Materials Program and established Department policy rather than the personal views of an individual inspector. This id documented on Attachment 2.7-1
- 5.4 The Department will maintain the Attachment 2.7-1 used for secondary report review with the original inspection report to provide a record of inspectors' and reviewers' concurrences. They should address how to ensure continued inspector concurrence when substantive changes are made to the report as originally submitted, and how to treat disagreements that occur during the review process. At a minimum, substantial changes should be discussed with the inspector or inspectors involved to ensure continued concurrence, and disagreements that cannot be resolved should be documented.

6.0 INSPECTION REPORT CONTENT AND FORM

6.1 Cover Letter

- 6.1.1 The purpose of the cover letter is to transmit the inspection report results to licensee senior management representative and/or RSO.
- 6.1.2 Inspection reports are transmitted using a cover letter with Indiana Department of Homeland Security letterhead and summarized the results of the inspection findings.
- 6.1.3 When the inspection findings reveal the licensee's program is adequate to provide for the security of licensed radioactive materials and the protection of workers and the public, then a **Department Form 591M Safety Inspection and Compliance Inspection** (Attachment 2.4-1 of RMCPP *Documentation of Inspection Results*) or Attachment 2.4-4 **Clean Inspection Report** follows the cover letter.
 - 6.1.3.1 The Department Form 591M may also be left at the licensee site upon conclusion of the inspection.
 - 6.1.3.2 The Clean Inspection Report is transmitted only with the cover letter and other elements of the inspection report.
- 6.1.4 When the inspection findings reveal a violation Attachment 2.4-3 Notice of Violation Letter of RMCPP 2.4 *Documentation of Inspection Results* follows the cover letter.
- 6.1.5 The cover letter is written to transmit the inspection report to the licensee's management, and to deliver the "big picture" message regarding the inspection. Because it is the highest-level document, it does not need to (and normally will not) detail all the items inspected, and the inspection procedures used. It will note the areas covered by the inspection.
- 6.1.6 The tone of the cover letter must have a correct balance. The Department focuses on performance issues. If a licensee performed some activity 100 times, and succeeded 99 times, the inspector will be most interested in the single failure. But that does not mean that the cover letter will make it appear that the licensee rarely succeeded. The safety and regulatory

significance of any licensee failure will be a primary consideration, above and beyond the numerical frequency of failure compared to success. Then identifying problem(s) in a cover letter, the nexus to safety and security will also be provided.

- 6.1.7 The cover letter must always be consistent with the inspection report. In addition, it must be consistent with the information that the inspector conveyed to the licensee managers at the exit meeting. If the inspector's understanding of the facts, or the perspective on the nature or significance of the findings changes after the exit meeting, the Department shall call the licensee and re-exit. There should never be any surprises in a cover letter to anyone who was present at the exit meeting.
- 6.1.8 The cover letter should not contain recommendations. There should not be any statements to the effect: "the licensee should...." If the licensee is not meeting safety or regulatory requirements, the statements should clearly state those facts. If the Department believes that a licensee cannot ensure the safety of its activities, then an order or some similar official action may be appropriate.
- 6.1.9 **Cover Letter Content.** Cover letter content varies somewhat depending on whether the inspection resulted in findings or not. In general, every cover letter has the same basic structure, as follow:
 - 6.1.9.1 Addresses, Date, and Salutation. At the top of the first page, the cover letter begins with the Department seal and address, followed by the date on which the report cover letter is signed and the report issued. In the upper left-hand corner above the principal's addressee's name, include the Nuclear materials Events Database (NMED) number, if applicable.
 - 6.1.9.2 Subject Line. The subject line of the letter should state the facility name (if it is not apparent from the addressee line) and inspection subject. The words "NOTICE OF VIOLATION" SHOULD BE INCLUDED IF SUCH A NOTICE ACCOMPANIES THE INSPECTION REPORT. The entire subject line should be capitalized.

- 6.1.9.3 **Introductory Paragraphs.** The first two paragraphs of the cover letter should give a brief introduction, including the type of inspection report.
- 6.1.9.4 **Body.** The body of the letter should discuss the most important topics first.
- 6.1.9.5 **Closing.** The final paragraph consists of standard legal language that varies depending on whether enforcement action is involved.

6.2 Inspection Report Entails

- 6.2.1 The detailed discussion in the report provides the information which forms the bases upon which the other sections of an inspection report are developed.
 - 6.2.1.1 In most cases, the detailed discussion will be organized into one or more section, each addressing an area of inspection.
 - 6.2.1.2 Each area will in turn be divided into three parts: scope, observations and findings, and conclusions.
 - 6.2.1.3 Generic issues, if any, must be discussed in detail (see below)
 - 6.2.1.4 Violations, if any, must be described in detail and with bases (see below).
- 6.2.2 Scope. Scope is the extent of, or the area dealt with, in the inspection. Elements documented in an inspection should cover all relevant areas of the inspection's scope. The "Scope" portion of each area inspected will describe what was inspected. In most cases, the approach that can be used in writing the scope should be consistent with the Inspection Procedure (IP) which was used in performing that portion. Much of the writeup can be extracted from the "Purpose" section(s) of the applicable IP. When describing the Scope, it is acceptable to state either what the inspector(s) did, or what the inspection accomplished.
- 6.2.3 **Observations and Findings.** The observations and findings are the foundation of every inspection report. They derive out

of performing inspections according to the applicable NRC inspection procedure(s).

- 6.2.3.1 There should always be a readily identifiable connection between the stated Scope and the reported observations and findings. Thus, if the Scope was the review of personnel dosimetry records, the observations and findings will not be about packaging and shipping.
- 6.2.3.2 Observations and findings will be descriptive and will be relatively detailed compared to the other parts of the report documentation package. The amount of detail will be as much as is needed to make clear what was found, and whether it was significant. The inspector should say what was observed or found in an unequivocal manner. If an inspector was looking to see if contamination was well controlled and it was the report should state: "Contamination was well controlled." If too small a sample was examined to reach an unequivocal conclusion, the qualifier should state what specifically was inspected. For example, the report should state that, "Contamination was well controlled in the areas examined by the inspectors."
- 6.2.3.3 If the inspector identifies no findings during an inspection (other than minor findings), the report should state "No findings of significance were identified." A sample letter for an inspection with no items of nonconformance is found in RMCPP 2.4 Documentation of Inspection Results as Attachment 2.4-4 Clean Inspection Report.
- 6.2.4 **Generic Issues.** Findings that are likely to have generic concerns e.g., product defects and software problems should include details such as the manufacturer's name and model number for components, specifications, and other names and technical data that identify the item of concern. A generic issue is a well-defined, discrete, radiological safety or environmental

(with respect to radiological health and safety) matter of which safety/risk significance has been adequately determined.

- 6.2.4.1 Generic issues have the potential to affect public health and safety, or the environment (with respect to radiological health and safety);
- 6.2.4.2 The generic issue applies to two or more facilities and/or licensees;
- 6.2.4.3 The issue is not being addressed using other regulatory programs and processes; existing regulations, policies, or guidance;
- 6.2.4.4 The issue can be resolved by new or revised regulation, policy, or guidance;
- 6.2.4.5 Resolution of the issue may involve review, analysis, or action by the affected licensees or holders of other regulatory approvals.
- 6.2.4.6 Upon discovery of a generic concern during an inspection of a licensee's facility, the Department will notify affected Indiana licensees of the issue. The Department will notify the NRC of the discovery of the generic concern and resolution, if applicable.
- 6.2.5 **Violations.** In the case of a finding that results in a Notice of Violation, it is critical that enough detailed information be given so that the reader can understand what the requirement was, and how it was not met. See Sections 7.0 through 15.0 of this procedure for important information about violations and other findings. After the details of what occurred are provide, two specific concluding statements should be constructed.
 - 6.2.5.1 The first statement will define what the requirement was, including any related regulation. For example, "10 CFR 20.1801 requires that licensees shall secure from unauthorized access or removal licensed materials that are stored in controlled or unrestricted areas."
 - 6.2.5.2 The second statement will describe (or refer to a preceding description) how the requirement was violated. For example, "Specifically, failure by the

licensee to secure the radiographic exposure device (manufacturer model and serial numbers) that contained the sealed source of iridium-192 (manufacturer model and serial numbers, activity, and date of activity) in storage, as described above, is considered a violation of 10 CFR 20.1801." Additional actions or responses by the licensee, if any, should be included to fully describe the violation.

- 6.2.6 **Conclusions.** The Conclusions are statements describing the quality of licensee performance in the area inspected. The report will discuss whether the licensee succeeded or failed, whether performance was good (or some other descriptor), and whether violations were identified. Every statement in a Conclusion section should have a basis (proof that it is correct) written in the observations and findings.
- 6.2.7 **Exit Meeting Summary.** The final section of each inspection report briefly summarizes the exit meeting, which is also described in the first paragraph of the cover letter and identifies the most senior licensee manager who attended the meeting, and includes the following information:
 - 6.2.7.1 **Absence of Proprietary Information.** At the exit meeting, the inspectors should verify that information which the inspector reviews during the meeting and intends to include in the report is not proprietary. If the licensee does not identify any material as proprietary, the exit meeting summary or some other element of the inspection report should include a sentence to that effect.
 - 6.2.7.2 **Subsequent Contacts or Changes in Department Position.** The inspector should briefly discuss any contact with the licensee management after the exit meeting to discuss new information relevant to an inspection finding. In addition, if the Department's position on an inspection finding changes after the exit meeting, that change should be discussed with the licensee before the report is issued.

- 6.2.7.3 **Characterization of Licensee Response.** Licensee responses should not be included in the summary except in cases where the licensee disagrees with the inspection findings. In that case, the summary should state that the licensee took exception to the findings.
- 6.2.7.4 Oral Statements and Regulatory Commitments. If at the exit meeting or at any other time during the inspection, the licensee makes an oral statement that it will take a specific action in response to a noncompliance, the statement may be documented in the body of the report. Details of statements made at the exit meeting should not be included in the exit meeting summary. Such statements should only be characterized in the report if the statements represent licensee commitments in response to a non-compliance in order to eliminate the need for a subsequent licensee response. However, the report cover letter must include a provision for the licensee to respond if the commitment documented in the report does not accurately reflect the licensee's corrective actions or position. Otherwise, licensee commitments are documented by licensee correspondence, after which the inspector may reference the correspondence in the inspection report. Because regulatory commitments are a sensitive area, the inspector should ensure that any reporting of licensee statements are paraphrased accurately and contain appropriate reference to any applicable licensee documents.
- 6.2.8 **Report Attachments.** The attachments discussed below are included at the end of the inspection report if applicable to the inspection. The attachments may be combined into a single attachment entitled "Supplementary Information".
- 6.2.9 Key Point of Contact. The inspector lists, by name and title, those individuals who furnished relevant information or were key points of contact during the inspection (except in cases where there is a need to protect the identity of an individual). The list need not be exhaustive; a list of 5-10 individuals is sufficient. The alphabetized list includes the most senior

licensee manager present at the exit meeting and Department technical personnel who were involved in the inspection if they are not listed as inspectors on the cover page.

- 6.2.10 List of Items Opened, Closed, and Discussed (Optional). The report should include a quick-reference list of items opened and close. Open items that were discussed (but not closed) should also be included in this list, along with a reference to the sections in the report in which the items are discussed.
- 6.2.11 List of Documents Reviewed. A list of the appropriate key documents and records reviewed during and inspection that are significant to any finding must be publicly available. Therefore, if a list is not otherwise made public, the report should include a listing of all the documents and records reviewed during the inspection that are not identified in the body of the report. (See IMC 0620, "Inspection Documents and Records") "Reviewed" in this context means to examine critically or deliberately. The list does not include records that were only superficially reviewed. Lists consisting of more than six condition reports, documents reviewed, procedures, etc., should normally be removed from the body of the report and included as an attachment to facilitate reading.
- 6.2.12 **List of Acronyms, as appropriate.** Reports whose details section exceeds 20 pages should include a list of acronyms. For reports in which a relatively small number of acronyms have been used, the list is optional. In all cases, however, acronyms should be spelled out when first used in inspection report text.

7.0 NOTICE OF VIOLATION

7.1 Licensees are officially notified that they have failed to meet regulatory requirements when Department issues a Notice of Violation (NOV). NOV's may be sent with an inspection report or in a separate letter which refers to an inspection report that was distributed previously. An NOV should not be sent to the licensee in advance of the inspection report. An example of a Notice of Violation Letter is Attachment 2.4-3 of RMCPP 2.4 Documentation of Inspection Reports.

- **7.2** Every NOV must be clear, so that there is little doubt that the licensee (or other reader) can understand the basis for the violation. The licensee may not agree with our basis, but they must understand our position.
- **7.3** Every NOV must clearly state what requirement was not met, including the date and revision number of any applicable documents related to the inspection. A clear statement of what happened (including when/if the timing is important) must be provided. The NOV should also provide the length of time the licensee was in non-compliance.

8.0 SIGNIFICANT OF OBSERVATION

- **8.1** This section discusses the significance of observations including violations, non-compliance, and enforcement actions. The guidance provided in this section is for informational purposes.
- **8.2** Thresholds of Significance. When conducting inspections, the Department inspector reviews a selection of procedures, events, and operation; he or she cannot hope to monitor all the activities in progress, nor to document every minor discrepancy that occurs. As part of maintaining a focus on safety, inspectors continually use Department requirements, inspection procedures, industry standards, and their own training and insight to make judgements about which issues are worth pursuing and which are not.
- **8.3** To communicate effectively, inspection reports must give evidence of that judgment and prioritization, discussing significant safety issues in appropriate detail, treating less significant issues succinctly, and avoiding excess verbiage. To maintain some consistency in how minor issues are treated, report writer must recognize certain "thresholds of significance." They must use similar criteria in deciding whether an issue is significant and will need documentation, and if the issue is important enough to track or follow up, etc.

9.0 MINOR VIOLATIONS AND DETERMINING WHETHER TO DOCUMENT

Minor violations are those that are less significant than a Severity Level IV violation. Minor violations do not warrant enforcement actions and are not normally documented in inspection reports. However, minor violations must be corrected. While in general minor violations should not be documented, certain exceptions apply. Documentation may be necessary as part of the resolution of an allegation. In other cases, while the violation itself is minor,

the associated technical information may relate directly to an issue of broader concern. If, for these reasons or any other reason, the report writers and reviewers wish to document a minor violation, then it should be documented as a minor violation.

10.0 VIOLATIONS IDENTIFIED AS PART OF LICENSEE SELF-ASSESSMENTS

Under certain circumstances, even a violation that could be classified as Severity Level IV ("more-than-minor") need not be documented. This is generally justified when the violation has been identified and corrected as part of a licensee self-assessment effort. As matter of policy, Department enforcement seeks to encourage licensee self-assessment efforts, and seeks to avoid the negative impact that can result from a redundant Department emphasis on problems which the licensee's responsible action has already identified and corrected.

- 10.1 For example, suppose that while evaluating the licensee's quality assurance efforts in the fire protection area, an inspector reviews relevant audits and surveillances conducted over the previous year. The review reveals that the audits have been probing and thorough; the findings are well-developed and technically sound, and include six noncompliance issues, four of which might be classified at Severity Level IV.
- **10.2** In such a case, the inspector should follow up on the non-compliances and other audit findings to ensure that root causes have been appropriately identified and assessed, that appropriate and comprehensive corrective actions have been taken, and that no new examples of the violations exist. Provided that no new problems are revealed by this follow-up, the inspector is normally not expected to cite the four violations individually, nor to report the details of those violations in the inspection report. Instead, the department report findings and conclusions should assess the adequacy of the licensee's quality assurance efforts, including a clear reference to the name, dates, and general subject matter of the audit or self-assessment.

NOTE: This expectation only applies to severity Level IV violations. Even when identified through a licensee self-assessment, violations that could be categorized at Severity Level III or above must be documented in the inspection report and given appropriate follow-up.

- **10.3** In some instances, reasons exist to document one or more of the violations found in a licensee audit or self-assessment. For example, if the report concludes that the licensee's self-assessment was especially negative, one or more examples should be given to support that conclusion.
- 10.4 In addition, the inspector may decide to document one or more of the violations found in a licensee self-assessment due to the technical significance or generic implications of the particular item. Technical details surrounding the violation may provide useful insight on equipment or system reliability, or on some aspect of human performance. In some cases, the inspector may decide to pursue additional follow-up of a particular licensee finding because of related licensee problems, previous Department observations or violations involving the same or a related topic, or emerging government or industry sensitivity in the given technical area.
- **10.5** If, for any of these reasons, the inspector decides to discuss in the inspection report a particular licensee self-assessment finding or audit finding, and that finding involves a violation, then the violation must be clearly dispositioned in the report. The violation may be dispositioned as a non-cited violation (NCV) unless any one of the following circumstances results in an NOV requiring a formal written response from the licensee:
 - 10.5.1 The licensee or non-licensee identified the violation.
 - 10.5.2 The licensee or non-licensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence.
 - 10.5.3 The violation is not repetitive as a result of inadequate corrective action.
 - 10.5.4 The violation is not willful.
- **10.6** If the issue represents a minor violation, it should be documented on the relevant inspection Checklist or other record outside the inspection report as follow: "This failure is considered a minor violation and should not be documented in a Department inspection report."

11.0 THRESHOLDS OF SIGNIFICANCE FOR NON-ENFORCEMENT-RELATED ISSUES

Inspectors must also make judgments about the relative significance of nonenforcement-related findings. As with enforcement issues, the judgment of individual inspectors will differ; questions on the relative significance of an issue should be discussed with other inspectors and with Department managers.

12.0 DETERMINING THE SIGNIFICANCE OF NEGATIVE FINDINGS

The following questions should be used to determine whether or not a finding should be documented in the inspection report. If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

- **12.1** Does the finding have any actual impact (or any significant potential for impact) on safety?
- **12.2** Is this finding illustrative of a programmatic licensee problem that could have a safety or regulatory impact?
- **12.3** Does this finding provide insights on an equipment, system, or human performance problem?
- **12.4** Could the finding be viewed as the possible precursor to a significant event?
- **12.5** If the licensee takes no action on this matter, will the condition worsen (i.e., will the safety significance increase)?
- **12.6** If this finding recurs, will its recurrence result in more significant or additional safety concerns?
- **12.7** Will this information be useful in assessing the long-term performance of this licensee program or functional area?
- **12.8** Does this finding have generic significance?

13.0 DETERMINING THE SIGNIFICANCE OF NEUTRAL OR POSITIVE FINDINGS

For neutral or positive findings or for licensee improvements, similar thresholds of significance should apply. The inspector should ask questions similar to those below. If the answer to any one of the questions is "yes," the Page 261 finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

- **13.1** Does the licensee improvement have an actual positive impact (or a significant potential for positive impact) on safety?
- **13.2** Will the licensee's efforts to impact change in this area be likely to result in programmatic improvements to safety or regulatory performance?
- **13.3** Will this upgrade be likely to result in improved equipment or system reliability or improved human performance? Does this information provide useful equipment, system, or human performance insights?
- **13.4** Does this licensee action significantly reduce the probability of a particular event?
- **13.5** Will this information be useful in assessing the long-term performance of this licensee program or functional area?
- **13.6** Does this finding have a generic significance?

14.0 FINDINGS PREVIOUSLY COVERED IN LICENSEE SELF-ASSESSMENTS

- 14.1 This decision should be treated similarly to the corresponding decision for enforcement issues. In general, little benefit exists in the Department's re-emphasis of issues already covered in licensee self-assessments, unless there is some problem with the licensee's actions.
- **14.2** In some instances, however, the technical significance or generic implications of an issue merit ensuring that it is discussed and preserved as a matter of public record.
- **14.3** If the licensee self-assessment that initially discussed the issue is already in the licensee files, the inspection report may simply refer to the discussion in the licensee self-assessment. If more detail is needed, or if the licensee self-assessment is not in the licensee files, the inspector may wish to discuss the issue in the inspection report narrative.

15.0 DOCUMENTING NONCOMPLIANCE

15.1 Types of Noncompliance. The manner of documenting a noncompliance in the inspection report depends on how that noncompliance will be dispositioned. A noncompliance may be

addressed as a non-escalated enforcement action (i.e., a Severity Level IV violation, a deviation, or a nonconformance); as an escalated enforcement action (i.e., an apparent Severity Level I, II, or III violation); or as a Non-Cited Violation (NCV).

- **15.2** Note that noncompliance may not be documented simply as a "weakness," "licensee failure," or a similar informal characterization. If the report narrative describes a condition or event in a manner that suggests to the reader that a violation may have occurred, then the finding must be clearly dispositioned as a violation, an apparent violation, or an NCV. If a violation does not exist (e.g., no requirement exists in this area), it may be appropriate to clarify the finding by stating that "this condition [or event] does not constitute a violation of Department requirements."
- **15.3** Non-Escalated Enforcement Actions. Most violations of moderate significance (i.e., more than a minor concern) fall into this category. If at the time of issuing the inspection report a violation has been identified, the inspection report will cite it as a "non-escalated" enforcement action.
- **15.4 Potential Escalated Enforcement Actions.** When an issue is being considered for escalated enforcement action, the inspection report narrative should refer to the potential noncompliance as an "apparent violation." The report details should not include any speculation on the severity level of such violations nor on expected Department enforcement sanctions. Potential escalated actions, by their nature, require further Department deliberation (and, usually, additional licensee input) to determine the appropriate severity level and Department action.
- **15.5** Similarly, report narratives that discuss apparent violations should be carefully constructed to avoid making explicit conclusions (i.e., final judgments) about the safety significance of the issue. The report should include any available details that demonstrate safety significance, or that would help in making such a decision and should also describe any corrective action automatically entails further evaluative steps, neither the inspection report details, nor the accompanying cover letter should present a final judgment on the issue.

- **15.6 Minor Violations.** Minor violations should not normally be documented in inspection reports. However, to the extent that documentation is necessary, the standard language should be used: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."
- **15.7 Supporting Details and Discussions of Safety Significance.** The discussion of noncompliance issues must be sufficiently detailed to substantiate any Department safety and regulatory concerns and to support any enforcement sanction the Department may choose to issue. At a minimum, for a violation, the report should state:
 - 15.7.1 What requirement was violated;
 - 15.7.2 How the violation occurred;
 - 15.7.3 When the violation occurred, and how long it existed;
 - 15.7.4 Who identified it, and when;
 - 15.7.5 Any actual or potential safety consequence;
 - 15.7.6 The root cause (if identified):
 - 15.7.7 Whether the violation appears isolated or programmatic;
 - 15.7.8 What corrective actions have been taken or planned; and
 - 15.7.9 Who was involved with the violation (i.e., management involvement or low-level individual).
- **15.8** The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance. Although supporting details clearly assist in determining the safety significance of the noncompliance, inspectors should be cautions in making direct statements regarding safety significance in the inspection report details.
- 15.9 Violation severity levels are based on the degree of safety significance involved. In assessing the significance of a noncompliance, the Department considers four specific issues: (1) actual safety consequences; (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the Department's ability to perform its regulatory function; and (4) any willful aspects of the violation.

- **15.10**As a result, if an inspection report refers to a noncompliance as being "of low safety significance" (meaning, in a general sense, that the noncompliance did not result in any actual adverse impact on equipment or personnel), the writer may have inadvertently made it difficult for the Department to subsequently decide that the potential for an adverse impact or the regulatory significance of the noncompliance warrants issuance of a Severity Level III violation. Therefore, before characterizing a violation as being of "low safety significance," the inspector should also address the pote4ntial consequences and regulatory consequences of the violation in addition to the absence of an actual adverse consequence.
- **15.11 Noncompliance Involving Willfulness.** Inspection reports should neither speculate nor reach conclusions about the intent behind a violation, such as whether it was deliberate, willful, or due to careless disregard. As with any observation, the report discussion should include relevant details on the circumstances of the violation without making a conclusion about the intent of the violator. EXAMPLE: "The radiographer failed to activate his alarming ratemeter, although he had informed the inspectors earlier that he had been properly trained on the use of the device:" not, "The radiographer deliberately failed to activate his alarming ratemeter."

16.0 SUPERVISORY ACCOMPANIMENTS

- **16.1** At least annually, the Radiation Control Program Director (RCPD) will accompany each Department materials license inspector on at least one inspection. This will allow the RCPD to determine whether the inspector is following Department guidelines and good practices as established in Inspection Manual Chapter 2800 "Materials Inspection Program."
- **16.2** In order to ensure the inspection meets Department criteria, the RCPD will use SA-102 Appendix B, "Inspector Accompaniment Summary Sheet" to document the inspection.
- **16.3** The review of the inspection will be discussed with the inspector. This will ensure that any deficiencies may be identified in a timely manner.
- **16.4** The inspection reports for the accompaniment inspection along with any associated correspondence will be placed in a file at the RCPD's office.

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16.5 Additionally, the RCPD will utilize SA-102 Attachment B-1 along with the relevant inspection checklist from the applicable NUREG-1556 Safety Audits when reviewing inspections and inspection reports to determine the adequacy of the inspection. The checklist provides for an objective evaluation of individual inspection tasks. Performance of each individual inspection task i.e., inspector instrumentation, inspection procedure used, effective licensee communication etc., are evaluated to determine the completeness of inspection preparation, performance and inspection report generation.

17.0 ATTACHMENTS

2.7-1 Inspection Report Quality Assurance (QA) Checklist

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.7-1 INSPECTION REPORT QUALITY ASSURANCE (QA) CHECKLIST

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ATTACHMENT 2.7-1 INSPECTION REPORT QUALITY ASSURANCE (QA) CHECKLIST

License Number:			
License Type:			
Inspector:			
Inspection Date(s):			
Inspection Type: Initial Reduced	Routine	Reactive	Special
Inspection Area	Evaluation	Com	ments
Inspection report issued within 30 days (RMCPP 2.4 section)	Satisfactory		
	Unsatisfactory		
Department Form 591M issued	Satisfactory		
	Unsatisfactory		
Report Details	Satisfactory		
	Unsatisfactory		
Observations and Findings	Satisfactory		
	Unsatisfactory		
Conclusions	Satisfactory		
	Unsatisfactory		

Documenting Noncompliance	Satisfactory
	Unsatisfactory
Report Review and Concurrence	Unsatisfactory List al items reviewed (note any non-concurrences)
Inspector:	Signature:
Secondary Reviewer	Signature:

4.4.3 Administrative Procedures for Inspections

There are five RMCPPs that guide the administration of the inspection program. RMCPP 2.1 is for the scheduling of inspections, RMCPP 2.2 helps inspectors prepare for inspections, RMCPP 2.3 provides specific guidance, so they are performance-based inspections, RMCPP 2.4 describes how inspection results are to be documented and RMCPP 4.2 describes how inspections are tracked.

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.1, Revision 0: Scheduling of Inspections

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

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Revision	Date	Description of Changes
0		

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1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to the scheduling of inspections based on the priorities assigned to the various licensed activities.
- 1.1.2 This procedure delineates core and non-core inspection priorities and establishes a program of special inspection activities for al licensees.
- 1.1.3 The Performance-Based Inspection program requires that poor performers be inspected more frequently.

1.2 References

- 1.2.1 NRC Inspection Manual, Chapter 1220 "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters', and Inspection of Agreement State Licensees Operating under 10 CFR 150.20"
- 1.2.2 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program"
- 1.2.3 290 IAC 3

1.3 Files

Records are primarily filed electronically and Web-Based Licensing (WBL) is the primary residence of these records.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Provides a list on a monthly basis, using Web-Based Licensing (WBL), for the Senior Health Physicist (S/HP) of inspections due for the next six months by priority code.
- 2.1.2 Maintains the files and the computer-based letters, forms and report files.
- 2.1.3 Conducts inspections and recommends reduction of internals in inspection frequency.
- 2.1.4 Reviews licenses and recommends inspection priorities.

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2.1.5 Shares appropriate information about inspections to other qualified members of the inspection and licensing staff.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Prepares inspection schedules and assigns inspectors, approves reduction of inspection frequency, and approves the assignment of license priorities.
- 2.2.2 Determines if a reduce, reactive or special inspection is warranted, should be performed promptly, or can be included in the next routine inspection; and initiates an inspection, if appropriate.
- 2.2.3 Reports inspection and licensing statistics to the Radiation Control Program Director on a quarterly basis.
- 2.2.4 Reviews and approves inspection plans and reports.
- 2.2.5 Debriefs all inspectors upon completion of the inspection and all of its documentation.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Approves inspection schedules and assignments.
- 2.3.2 Approves inspection plans and reports.

3.0 PROCEDURE

Scheduling of inspections should be in accordance with this procedure and Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes** in RMCPP 1.1 *Review of Initial Application for License or an Amendment Request*. All inspections, except initial inspections, certain special inspections and inspections determined by the S/HP, will be unannounced. To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled and performed within a window around their inspection due date as defined in IMC 2800. Inspections may be scheduled before their window if the inspector receives information that warrants an earlier inspection.

3.1 License Priorities

3.1.1 Each license Program Code is assigned a Priority Code, which is the inspection frequency expressed in years. Priority Code 1 is to be inspected annually, Priority Code 2 is inspected every two years, Priority Code 3 is inspected every three years and Priority Code 5 is inspected every five years.

- 3.1.2 Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes** is a listing of materials programs and their associated inspection priorities.
- 3.1.3 The S/HP, or designee, shall assign a primary program code which sets the inspection priority for each new license.
- 3.1.4 Some licenses authorize activities that can be classified under more than one program code.
 - 3.1.4.1 If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority.
 - 3.1.4.2 For example, a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate (HDR) remote afterloader unit (Program Code 02230, Priority Code 2).
 - 3.1.4.3 The licensee's primary program code would be Program Code 02230. However, both activities should be inspected simultaneously during the HDR inspection.

3.2 Inspection Priorities

- 3.2.1 An inspection priority code is assigned to each radioactive material license.
- 3.2.2 The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspections, expressed in years, i.e., priority code 1 is inspected annually, priority code 2 is inspected every two years.
- 3.2.3 The same priority code is assigned to all licenses that authorize that particular type of use.
- 3.2.4 Enclosure 1 of NRC Inspection Manual Chapter 2800 lists the program codes (types of use) along with the assigned priority codes. This is reproduced as Attachment 1.1-6 **Inspection**

Priority Codes Assigned to Program Codes in RMCPP 1.1 *Review of Initial License Application or an Amendment Request.*

- 3.2.5 The priority represents the relative risk of radiation hazard. Priority Code 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority Code 5 represents the lowest risk.
- 3.2.6 Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority code for the license is the code with the shortest routine inspection interval.
- 3.2.7 The performance of reactive inspections shall receive first priority in the inspection program followed by the performance of core, reduced, and special inspections.

3.3 Routine Inspections

- 3.3.1 **Core Inspection:** Routine inspections of licenses in priorities 1, 2, and 3 shall be conducted at intervals in years corresponding to the inspection priority. If approved, Priority 1 and 2 licensees may be extended to 50 percent of the routine inspection interval and Priority 3 licensees may be extended for up to one year in circumstances where the licensee has demonstrated high performance; however, the last inspection date must be used when scheduling the next inspection.
- 3.3.2 **Non-Core Inspections:** Priority 5 licenses shall be inspected at 5-year intervals. Priority 5 licensees are not eligible for this extension; however, the last inspection date must be used when scheduling the next inspection.
- 3.3.3 **Temporary Job Site Inspections:** For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to schedule an unannounced inspection of licensed activities at such a location(s). If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" data element in Web-Based Licensing may indicate a reduced inspection internal.

3.3.4 **Permanent Field Offices:** If the license authorized licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 filed offices) at least 2 locations must be inspected at the interval specified by the program code for the specific type of license. If the license authorized licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

3.4 Initial Inspections

- 3.4.1 All initial inspections, regardless of the license priority, are to be conducted within 6 months of the receipt of licensed material, within 6 months of beginning licensed activities, or within 1 year of license issuance, whichever comes first. Licensees are informed to notify the department of their first receipt of licensed material. Initial inspections of a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy – Other Emerging Technology) shall be announced.
- 3.4.2 To schedule the initial inspection, the date in the "next inspection date" data element in WBL shall be 12 months from the date the new license or amendment was issued. The "last inspection date" data element in the licensee folder in Web-Based Licensing shall be blank. If it is determined that the licensee has not possessed licensed material or performed any principal activities, the inspector should ensure that the date in the "next inspection date" data element in the licensee folder in Web-Based Licensing is 12 months from the date of the onsite visit. If the licensee does not yet possess licensed materials or has not yet performed any principal activities, the inspection date to within 18 months of license issuance. If it is determined that the licensee does not performed principal activities, the inspector should:
 - 3.4.2.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal

activities. Use this opportunity to discuss the license and applicable regulations with the licensee.

- 3.4.2.2 The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.
- 3.4.2.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.
- 3.4.2.4 Document the contact and enter the record into the licensee's file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.
- 3.4.2.5 Ensure that the due date is set for 18 months from license issuance.
- 3.4.3 Performing initial inspections. During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed. Methods for determining if principal activities have been performed include, but are not limited to the following:
 - 3.4.3.1 Performing a site tour,
 - 3.4.3.2 Performing independent measurements, and/or
 - 3.4.3.3 Contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.
 - NOTE: If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with this section and other applicable guidance.
- 3.4.4 If it is determined that the licensee has not possessed licensed material or has not performed principal activities, the inspector should:

- 3.4.4.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.
- NOTE: As defined in 10 CFR Part 30, principal activities, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- 3.4.4.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory question.
- 3.4.4.3 Remind the licensee to notify the Health Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.
- 3.4.4.4 Remind the licensee of the requirement in 10 CFR30.36(d) to provide written notification to the HealthDepartment within 60 days if no principal activitiesunder the license have been conducted for a period of24 months.
- 3.4.4.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.
- 3.4.4.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use for staff time and travel,

the date of the next initial inspection attempt may vary by \pm 6 months.

3.5 Reactive Inspections

- 3.5.1 Reactive inspections receive first priority in the inspection program.
- 3.5.2 Following the receipt of notification of an incident, allegation, or special information such as a medical event, the S/HP or designee shall determine if an immediate inspection is warranted or if the issue is best covered during the next scheduled inspection.
- 3.5.3 A reactive inspection counts as a scheduled inspection only if the total licensed program is evaluated.

3.6 Special Inspections

The following activities require special inspections:

- 3.6.1 **Expired and Terminated Licenses:** In accordance with the criteria outlined in RMCPP 1.3 *License Termination/Revocation*, notification that a license has expired or is being terminated may require that an inspection be conducted within 30 days of the date of notification. This is an announced inspection.
- 3.6.2 **Reciprocity Inspections:** Receipt of a request for reciprocity may require performance of an inspection. The priority of the license, the location of the activity, and the time to be spent in the state should be factors in determining the need for an inspection. Reciprocity inspections are required for Priority 1, 2, and 3 licenses and 20% of all reciprocity inspection must be performed in a given year.
- 3.6.3 **Team Inspection:** The S/HP shall schedule team inspections of major licenses within Indiana on an as-needed basis.

3.7 Significantly Expanded Programs

3.7.1 A license reviewer may request a special inspection, if during the licensing review process, it is determined that the licensee's program has significantly expanded.

- 3.7.2 The license reviewer should make the S/HP aware of the following examples of changes in a licensee's scope of use and shall ensure that the "next inspection date" data element in WBL is changed.
 - 3.7.2.1 A change in the Radiation Safety Officer
 - 3.7.2.2 A portable gauge user requesting to add a new storage facility and/or requesting additional gauges not approved on the initial application.
 - 3.7.2.3 A licensee has recently requested a significant increase in the types, quantities or forms, and uses of radioactive materials on the licenses and if these actions have resulted I the possession of risk significant radioactive material (RSRM).
 - 3.7.2.4 The licensee authorizes a physical move of a facility or a new use at a temporary jobsite.
 - 3.7.2.5 The license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;
 - 3.7.2.6 The licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;
 - 3.7.2.7 The number of authorized users has significantly increased or decreased; and
 - 3.7.2.8 The licensee has ceased activities at the entire site or in any building or area as defined in 10 CFR 30.36(d).
 - 3.7.2.9 Requests for new medical procedure involving the use of sealed or unsealed radioactive material Proposed revisions to licensees' facilities, etc.
 - 3.7.2.10 If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff, the license reviewer should complete the RSRM checklist to determine whether an on-site security review should be conducted.

3.7.3 During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. The S/HP may determine a special inspection is needed if there is a significant increase in activity discovered during the last inspection.

3.8 Abandonment of Licensed Activities

- 3.8.1 The S/HP will determine if an inspection will be scheduled based on the complexity of the licensed activities, and the types and quantities of licensed material if licensed activities are abandoned.
- 3.8.2 When a licensee does not respond to Department inquiries e.g., returned mail with no forwarding address and the licensee cannot be contacted by any other means, then a license will be considered abandoned.
- 3.8.3 If telephone contact is not established, then an inspector should be sent to the licensee's site.
- 3.8.4 The decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material. The S/HP and RCPD must take steps to terminate the license in these cases.

3.9 Reduced Inspection

- 3.9.1 At the discretion of the S/HP, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee.
 - 3.9.1.1 This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees.
 - 3.9.1.2 For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed

by individuals or smaller teams that specifically focus on higher risk licensee activities.

- 3.9.2 The inspection interval shall not be extended beyond that specified by the priority system indicated in section 3.1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation safety program. Poor compliance history is also a consideration.
 - 3.9.2.1 **Poor Licensee Performance:** Based on poor licensee performance the interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system. Poor performance is evidenced by moderate to severe problems in the radiation safety program, a poor compliance history, or a lack of management involvement or control over the radiation safety program. Reduction of inspection frequency shall be considered for licensees that meet one or more of the following conditions (this list is not all-inclusive):
 - 3.9.2.1.1 A severity Level I, II, or III violation on the most recent inspection;
 - 3.9.2.1.2 Issuance of an order or escalated enforcement on the most recent inspection;
 - 3.9.2.1.3 "Management Paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (management paragraph is a paragraph that requires the licensee to address adequate management control over the licensed program);
 - 3.9.2.1.4 An event requiring a reactive inspection;
 - 3.9.2.1.5 Repetitive violations;

- 3.9.2.1.6 Enforcement conference where the outcome did not include escalated enforcement action but did indicate the need for the licensee to improve some aspect(s) of its compliance program;
- 3.9.2.1.7 Industrial radiography licensee or a well logging licensee, who is authorized to use radioactive material at temporary job sites and the current inspection, was limited to an office inspection and no temporary job site inspection was completed during the current inspection.
- 3.9.2.2 **Follow-up Inspections:** Licensees that meet the above criteria may have their inspection interval reduced by any length. A follow-up inspection should be conducted within 6 months of receipt of a licensee's corrective action(s) following an escalated enforcement action (see **RMCPP** 2.5)
- 3.9.2.3 **Reduction Time Frame:** The reduction shall be valid only until the next inspection, but the S/HP shall consider the results of the inspection and determine if the reduced frequency should be continued, changed, or returned to normal. The recommendation to reduce the inspection frequency must be documented on the inspection report by the inspector and approved and signed by the S/HP.
- 3.9.2.4 **Recording and Identifying Change in Inspection Priority:** The designated inspection priority for these licensees should not be changed in the licensee folder in Web-Based Licensing. However, the "next inspection date" field in Web-Based Licensing should be changed to contain the reduced date for the next inspection.

3.10 Pre-Licensing Site Visit

3.10.1 Generally, pre-licensing site visits shall be conducted for new entities that do not have an existing Agreement State or NRC license, licenses changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope for their existing license.

- 3.10.2 Reviewers must use the Pre-Licensing Checklist and guidance in RMCPP 1.1 to determine if pre-licensing visits are needed.
- 3.10.3 The purpose of the pre-licensing site visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-Licensing Guidance Checklist. At a minimum, all storage and use locations must be visited.
- 3.10.5 The new license should not be provided to the licensee/applicant during the site visit.

3.11 Change of Control

- 3.11.1 **New License:** New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" data elements in WBL should remain the same as for the licensee's previous license.
- 3.11.2 **Change of Control:** New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
 - 3.11.2.1 The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);
 - 3.11.2.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
 - 3.11.2.3 The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);

- 3.11.2.4 The licensee significantly increases the different uses authorized; or
- 3.11.2.5 The new license authorized one or more new facilities.

If none of these conditions apply, then the "last inspection date" and "next inspection date" fields in WBL should remain the same as for the previous license.

4.0 RECORDS

Records are primarily filed electronically and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 ATTACHMENTS TO RMCPP 2.1

None

Indiana Department of Homeland Security Radioactive Materials Control Program:



Radioactive Materials Control Program Procedure 2.2, Revision 0 Inspection Preparation

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2.2-1 Radioactive Materials Control Program Guidelines for Completing an Inspection Plan

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to an inspector preparing for the performance of an inspection.
- 1.1.2 Preparation for conducting initial, routine, special, reactive, and reduced frequency is covered.

1.2 References

- 1.2.1 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program"
- 1.2.2 290 IAC 3

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Provides a list on a monthly basis, using Web-Based Licensing for the Senior Health Physicist (S/HP) of inspections due for the next 6 months. These are in accordance with their Priority Code and documented on the *Inspections Due for the Next 6 Months-By Priority Report*.
- 2.1.2 Maintains the files and WBL current with letters, forms, and reports.
- 2.1.3 Updates files
- 2.1.4 Properly prepares for each inspection by following the guidance in Section 3 below.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 May assign inspections to a qualified member of the inspection staff. This duty maybe delegated to the RCPD. Maintains the *Inspections Due for the Next 6 Months-By Priority Report*.
- 2.2.2 Discusses with inspection staff any items from previous inspection and their proposed inspection plan, if required.
- 2.2.3 Approves inspection plans if required, before the inspection begins.

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2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Assigns inspections to a qualified member of the inspection staff, in the absence of the S/HP.
- 2.3.2 Approves travel plans as necessary.

3.0 PROCEDURES

3.1 General Inspection Process

- 3.1.1 This procedure is designed to provide guidance that is applicable to all types of licensed programs.
 - 3.1.1.1 General inspection preparation should be completed in accordance with this procedure and other applicable RMCPPs.
 - 3.1.1.2 It is expected that inspectors understand and use the unique individual requirements for each type of inspection, such as use of an appropriate NRC Licensing Guide (NUREG-1556) Safety Audit or the appropriate Inspection Checklist and Inspection Procedure for the inspection type.
 - 3.1.1.3 Scheduling of inspections is in accordance with RMCPP 2.1 *Scheduling of Inspections*.
 - 3.1.1.4 Inspections of licensees shall be conducted per RMCPP 2.3 *Performance-Based Inspections*.
 - 3.1.1.5 Checklists for the different inspections by licensee type are in the applicable NUREG 1556 series checklist. Inspections should be conducted following these checklists and procedures.
 - 3.1.1.6 RMCPP 2.7 Assuring the Technical Quality of Inspections provides detailed guidance on inspections and their reports.
 - 3.1.1.7 Any new Regulatory Issue Summaries or Information Notices that may be applicable to the licensee since the last inspection.

- 3.1.2 It is not necessary for the inspector to review all the current licensing documents and procedures from the licensee file. However, to adequately prepare, an inspector shall review:
 - 3.1.2.1 The license to determine:
 - 3.1.2.1.1 If an unusual license conditions or tie-down commitments exist that would affect the approach to the inspection, i.e. authorization for non-routine maintenance, use of material at temporary job sites,
 - 3.1.2.1.2 If the licensee is authorized for activities at temporary job sites, prepare to make every reasonable attempt to include an unannounced inspection of licensed activities at any temporary jobsite(s).
 - 3.1.2.2 The licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items, and to determine whether any events have been reported by the licensee during the current inspection cycle. Older issues preceding the last inspection should be reviewed, if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.
 - 3.1.2.3 The Nuclear Material Events Database (NMED) to determine if any incidents have occurred since the last inspection.
 - 3.1.2.4 Any commitments made by the licensee or restrictions imposed by the Department as a result of an order or other enforcement action issued since the last inspection.
 - 3.1.2.5 Any information regarding special inspection emphasis, i.e., license reviewer's request for an inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of amendment.

- 3.1.2.6 Any allegation trends and a follow-up of the licensee's evaluations and response to the allegation.
- 3.1.2.7 Any changes to the Regulatory Requirements since the last inspection that affect the licensee's program.
- 3.1.2.8 A copy of the applicable Sealed Source and Device Registration Certificates.
- 3.1.3 For a reactive inspection, the inspector should review specific information as determined by the S/HP on a case-by-case basis.
- 3.1.4 Inspectors should anticipate whether or not they will encounter protected information during an inspection of a licensee and be prepared to provide the minimum handling requirements for confidential information.
- 3.1.5 Anticipate security requirements, guidance, questions, and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief and final Department determinations).
- 3.1.6 If the licensee is authorized to possess risk significant radioactive material (RSRM), request the National Source Tracking System (NSTS) inventory record at least two days in advance.
- 3.1.7 The inspector should identify the location of the licensee, make travel arrangements, and discuss special aspects of the inspection with the S/HP, as necessary.
- 3.1.8 The inspector should prepare questions for interviews and consider the focus areas or focus elements in the applicable NRC inspection procedure.
- 3.1.9 If necessary, methods for determining if licensed activities have been performed effectively may include contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee.
- 3.1.10 The inspector must be prepared to meet all entry requirements established by

The licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Staff must also wear their assigned dosimetry and appropriate personal protective equipment (safety shoes, glasses, hearing protection and hard hats).

- 3.1.11 The inspector should obtain the appropriate inspection reports, select appropriate and calibrated radiation detection instrumentation, and use the appropriate Inspection Procedure(s) and safety audits from the NUREG 1556 series for the inspection and obtain any other documentation that may be useful.
- 3.1.12 Radiation detection instruments are assigned to all RMCP staff to ensure appropriate instrumentation is available for potential surveys related to the licensed activities being inspected. Alpha, beta, gamma survey instruments, contamination and exposure rate instruments and radioisotope identification devices are available.

3.2 Initial Inspections

The licensee is informed to report the first receipt of licensed material to the Department. Initial inspections are conducted within six months following receipt of the notice from the licensee that licensed material has been received or one year following the issuance of the license whichever occurs first. All initial inspections of a new licensee, or any existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy – Other Emerging Technology) are to be announced. Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.

3.3 Routine Inspections

- 3.3.1 All routine inspections are unannounced unless specific instruction is received from the S/HP that an inspection is to be announce.
- 3.3.2 Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.

- 3.3.3 Routine inspection frequency is as determined by RMCPP 2.1
 Scheduling of Inspections and Attachment 1.1-6 Inspection
 Priority Codes Assigned to Program Codes in RMCPP 1.1
 Review of Initial License Application or an Amendment Request.
- 3.3.4 While encourage for use, an inspection plan is not required.

3.4 Reactive Inspections

- 3.4.1 Reactive Inspections focus on limited issues, often related to specific incidents, that are not within the scope of preparation for a routine inspection. If the reactive inspection does not cover the activities normally reviewed during a routine inspection, then the scheduling window still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.
- 3.4.2 The S/HP shall promptly assess the preliminary information received concerning the incident to determine if a reactive inspection is necessary.
- 3.4.3 The S/HP will notify a Health Physicist of the incident and if an inspection is required.
- 3.4.4 The inspector will review appropriate specific information to prepare for a reactive inspection.
- 3.4.5 The inspector should also prepare for issues of compliance, which will generally be addressed after all safety issues and program weaknesses are identified and clearly understood.
- 3.4.6 **Reactive Inspection for Incidents.** The emphasis while preparing for reactive inspection is response to incidents is the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.
- 3.4.7 **Reactive Inspection for Allegations.** Preparation for inspections of allegations shall be processed in accordance with RMCPP 3.1 *Management of Allegations*.

3.5 Special Inspections

Special inspections (i.e., reciprocity, security, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections may be under the supervision of the S/HP. Preparing for reciprocity inspections should be completed in accordance with this procedure and all applicable RMCPP. Narrative reports shall be prepared, if required by the S/HP, for special inspection. Inspection frequencies for special inspections are defined in RMCPP 2.1 *Scheduling of Inspections*.

- 3.5.1 **Reciprocity Inspections:** The inspector should prepare for an unannounced inspection of actual field work and review appropriate information to use during inspection.
- 3.5.2 **Temporary Job Site and Permanent Field Office Inspections:** The inspector should prepare to perform an unannounced inspection of licensed activities at these location(s). Preparation for temporary job site and permanent field office inspection should be conducted in accordance with Section 3.1 and other applicable guides.
- 3.5.3 Abandoned, Expired and Terminated License and Decommissioning Activities: Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.
 - 3.5.3.1 Emphasis should be placed on security and control of radioactive materials while preparing for an inspection at these types of facilities.
 - 3.5.3.2 Prepare to review the licensee's transfer, disposal, and closeout survey data; and/or prepare to perform confirmatory surveys.
 - 3.5.3.3 Prepare to review records of radioactive material disposals and public dose that may be required to be submitted to the Department.
 - 3.5.3.4 Prepare to verify that the licensee is complying with regulations for timely decontamination and

decommissioning and meeting the required schedules for licensee action.

- 3.5.3.5 Abandoned licensed activities indicated by returned mail, unreturned telephone calls or email, disconnected telephone messages or unoccupied or abandoned spaces found upon site visit need to be investigated to the degree determined by the S/HP and RCPD in consultation with Department leadership and legal counsel with particular attention to any potential for health and safety risk.
- 3.5.4 **Team Inspections:** Team inspections will be conducted on an as-needed basis.
 - 3.5.4.1 At the S/HP's discretion, inspection plans may be developed for all team inspections.
 - 3.5.4.2 Inspection plans should be considered for team inspections of major, broad scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the Department (other than NRC or other Agreement State radiation control agencies) are involved.
- 3.5.5 **Reduced Inspections:** Reduced inspections may be performed for a variety of reasons as determined by the Radioactive Material Program Manager.
 - 3.5.5.1 The most common reason is due to poor licensee performance. All other reasons will be addressed with the Health Physicist assigned to the inspection by the Radiation Control Program Director.
 - 3.5.5.2 Poor Performance History: The focus should be on the areas of poor performance and only other areas of the radiation safety program as time allows.
 - 3.5.5.3 The inspection should be unannounced unless specific individuals and/or activities need to be reviewed that are not available or performed on a routine basis by the licensee.

- 3.5.5.4 All other preparations should be conducted in accordance with RMCPP 3.1 and other applicable guides.
- 3.5.6 Inspections After Escalated Enforcement.

If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on the licensee's corrective actions in response to Severity Level III or above violation(s) shall be scheduled and conducted within 12 months of the issuance of the escalated enforcement action (Severity Level III or above).

3.6 Inspection Preparation Plan

See Attachment 2.2-1 **Inspection Plan** for completion of the inspection plan. The following items should be reviewed:

- 3.6.1 **License:** Differences between the license and the application, if any; and "tie-down" commitments and information submitted by the licensee that is not a "tie-down" condition in the license.
- 3.6.2 **License File:** Determine if the license has been amended since the last inspection. Note differences such as increased scope of operations, changes in principal staff, new/different facilities, new "tie-down" commitments or other special license conditions.
- 3.6.3 **Regulatory Requirements:** Determine changes in regulatory requirements since the last inspection that affect the licensee's program.
- 3.6.4 **Results of Last Inspection:** Review the results of the last inspection. If any enforcement action was taken, or if clear inspection form with minor noncompliance items was issued, note the items that the licensee committed to correct.
- 3.6.5 **Guidance:** Use appropriate Indiana guidance to determine specific requirements that should be reviewed during the inspection. [NOTE: This should include a review of the appropriate Inspection Procedures.]
- 3.6.6 **Notices:** Review the Department's and NRC's Information Notices and Regulatory Issue Summaries files and NRC's Office

of Nuclear Materials Safety and Safeguards Letters to determine if there have been any recent issues concerning this type of licensee that should be reviewed during this inspection.

- 3.6.7 **Nuclear Material Events Database (NMED):** Review NMED for licensee events.
- 3.6.8 Allegations, if appropriate. If there was an allegation, the next inspection should address the issue.
- 3.6.9 Sealed source and device registration should also be reviewed.
- 3.6.10 **NRC and State RMCP letters:** Review the variety of STC, NMSS, RCPD and other NRC or State RMCP letters for issues of relevance to the licensee.

4.0 RECORDS

4.1 Files

- 4.1.1 Records are primarily filed electronically and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.
- 4.1.2 The completed inspection reports and any necessary correspondence mailed to and/or received from the licensee are placed in the licensees electronic and paper files.

5.0 ATTACHMENTS TO RMCPP 2.2

Attachment 2.2-1 Inspection Plan

Attachment 2.2-1: Inspection Plan

DIRECTIONS:

The following guidelines are provided to help complete the inspection plan and prepare for the inspection.

DEFINITIONS:

- Area: The components of the licensee's program being inspected. Example areas include industrial radiography-field operations and Medical Licensee-Radiopharmaceutical Therapy or Radiation Therapy.
- Activity: Tasks performed by an individual within an area. Example activities are industrial radiography surveys, milking the generator, administration of I-131, or Gamma Knife patient treatment.
- **Element:** Observable aspects of an activity. Example elements are surveys of camera after source crank-in; use of shielded container, time, gloves, syringe shield, or survey meter.

LICENSEE ACTIVITY SELECTION GUIDELINES

- A. Identify high priority areas and activities.
- B. Activities in progress are preferred.
- C. Identify medium and low priority activities that can be inspected concurrently.
- D. Give preference to high priority elements

INSPECTION METHOD

The preferred method is direct observation. Acceptable alternatives include:

- A. Walk-through or demonstration
- B. Review of activity documents
- C. Interview selected licensee personnel

Radioactive Materials Control Program

Inspection Plan

Licensee Information

License Number

Licensee name and Address

Licensee Contact

(Name, Business email, and Telephone)

License and Inspection Information					
Amendment Number:	Priority:				
Last Inspection Date:	This Inspection Date:				
Type of Inspection:	Announced	Initial	Special		
	Unannounced	Routine	Re-inspection		

Performance-Based Inspection Plan

- 1. Identify the higher priority areas and activities to be reviewed. Note lower priority areas that may be reviewed concurrently.
- 2. Indicate the major element to be observed. List individuals/positions to be interviewed.
- 3. Check the documents that were reviewed during inspection preparation.

Previous Inspection Report

Reading File

NRC Inspection Procedure(s)

License Condition/Tie-downs

SSD Sheets

NUREG-1556

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Information Notices/Regulatory Issue Summaries NMED and allegation file, if appropriate

4. List survey meters that will be used on the inspection.

Acknowledgement

Inspector Signature Date
Approval Signature Date

(Senior Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.3, Revision 0: Performance-Based Inspections

Prepared By:	Date:
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- 3.10 Security
- 3.11 Pre-Licensing Visits

4.0 RECORDS

5.0 ATTACHMENTS TO RMCPP 2.3

None

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1.0 PURPOSE

1.1 Applicability

- 1.1.1 Inspections conducted by the Indiana Radioactive Materials Control Program (RMCP) are to be performance-based, meaning the inspector evaluates the licensee performing activities for which they are licensed.
- 1.1.2 This procedure describes how an RMCP inspector is to conduct performance-based inspections. The NRC Inspection Procedures and Inspection Manual 2800 are to be used along with the additional guidance found in:
 - 1.1.2.1 RMCPP 2.1 Scheduling of Inspections
 - 1.1.2.2 RMCPP 2.2 Inspection Preparations
 - 1.1.2.3 RMCPP 2.4 Documentation of Inspection Results
 - 1.1.2.4 RMCPP 2.6 *Materials Inspections Checklists and Definitions*
 - 1.1.2.5 RMCPP 2.7 Assuring the Technical Quality of Inspections
 - 1.1.2.6 RMCPP 4.2 Tracking Inspections
- 1.1.3 A review of a licensee's program documentation or a walk-down (tour) of a facility is not a performance-based inspection.
- 1.1.4 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.
- 1.1.5 This procedure helps the inspector identify and prioritize those activities that impact on a licensee's performance.

1.2 References

1.2.1 NUREG-1556 Volume 19, Revision 1, "Guidance for Agreement State Licensee About NRC Form 241 'Report of proposed Activities in Non-Agreement States, Area of exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement States Jurisdiction (Reciprocity)."

- 1.2.2 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."
- 1.2.3 NRC Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- 1.2.4 NRC Inspection Procedure 87103, "Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing."
- 1.2.5 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program."
- 1.2.6 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."
- 1.2.7 290 IAC 3

1.3 Files

- 1.3.1 Current Department and NRC Information Notices & Regulatory Issue Summaries.
- 1.3.2 Licensee File
- 1.3.3 Records are primarily filed electronically, and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

2.0 **RESPONSIBILITIES**

2.1 Health Physicists (HP)

- 2.1.1 For each initial, routine core and non-core inspection:
 - 2.1.1.1 Reviews, as appropriate, application, license and inspection reports, and Department and NRC Information Notices.
 - 2.1.1.2 Determines instruments needed to conduct independent measurements.
 - 2.1.1.3 Conduct performance-based inspections by observing licensed activities in progress.

- 2.1.1.4 Reviews the inspection findings with the Senior Health Physicist (S/HP) and/or Radiation Control Program Director (RCPD), as necessary.
- 2.1.2 For each reactive, reduced, or special inspection:
 - 2.1.2.1 Reviews relevant information based upon the required scope of the inspection.
 - 2.1.2.2 Conducts an inspection with a focus on the required scope by observing licensed activities in progress.
 - 2.1.2.3 Reviews the inspection finding with the S/HP and/or RCPD, as necessary.
 - 2.1.2.4 Informs the licensee of pending initial inspection and reactive inspections, if necessary.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Within one week of submission, reviews the inspection findings with the assigned inspector(s), as necessary.
- 2.2.2 Determines if a reactive or special inspection is warranted if it should be performed promptly or if it can be included in the next routine inspection. Assigns an inspector or team of inspectors to perform the inspection.
- 2.2.3 Provides inspection statistics to the RCPD quarterly. These may be generated using WBL.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 performs an annual accompaniment inspection with each Health Physicist and documents the results. [See Appendix B in SA-102 for template.]
- 2.3.2 May perform duties of the HP or S/HP in their absence.

3.0 PROCEDURE

3.1 General

3.1.1 An inspection will be considered to have been performed if:

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- 3.1.1.1 The inspection involves a licensee that possesses or has possessed licensed material since the last inspection, or that is performing or has performed licensed activities since the last inspection;
- 3.1.1.2 The inspection is an initial inspection that has been performed in accordance with this procedure;
- 3.1.1.3 Where inspection of temporary job site activities was not available to the inspector at the time of the inspection, this inspection should be recorded as an inspection of the main office and the inspection documentation should make note of this.
- 3.1.1.4 An inspection for licenses that have expired or are being processed for termination.
- 3.1.2 An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector should determine when another attempt will be made to inspect the licensee, document the attempted inspection in accordance with RMCPP 2.4 Documentation if Inspection Results.
- 3.1.3 Performing inspections should be completed in accordance with this procedure. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection that may be found in other Department or NRC guidance documents. All routine inspections are unannounced unless specific instructions are received from the S/HP or other factors (i.e., initial inspections and mobile unit at different locations) require that an inspection is to be announce.
- 3.1.4 Focus elements or focus areas in the NRC inspection procedures are selected as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material. The inspector should conduct the inspection in a manner that will

develop conclusions about licensee performance relative to the following focus elements or focus areas.

- 3.1.5 If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus element, the inspection effort expended in reviewing that particular focus element will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus element, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.
- 3.1.6 The inspector should use a performance-based approach to evaluate the focus elements. A determination regarding safety and compliance with Department requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by the Department, independent measurements of radiological condition at the licensee's facility, and, where appropriate, a review of selected records. Emphasis should be place on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program and integration of safety and security.
- 3.1.7 In reviewing the licensee performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.
- 3.1.8 The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments) prior to beginning the performance-based inspection.
- 3.1.9 Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be

conducted such that the inspector's presence does not interfere with licensed activities. The inspector shall not under any circumstances knowingly allow an unsafe work practice which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

- 3.1.10 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the information reviewed or gathered has been declared as proprietary information by the licensee.
- 3.1.11 Proprietary and/or patient information should not be taken from the licensee unless confidential, security-related, or personally identifiable information has been removed. In the case of a medical incident only the information relevant to the incident should be included. Personally identifiable patient information such as name, medical record and social security numbers are examples of Personally Identifiable Information (PII).
- 3.1.12 In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete. Inspectors shall ensure that the licensee understands that the retained record will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding the information.
- 3.1.13 The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

- 3.1.14 The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensee's understanding and agreement that an apparent violation occurred, preferably before leaving the site. The inspector shall also take the time to discuss any recommendations.
- 3.1.15 The inspector should keep the S/HP informed of significant findings (i.e., safety hazards, willfulness, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate Department guidance under such circumstances.
- 3.1.16 The inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns).

3.2 Inspection Preparation

Preparation for inspections is defined in RMCPP 2.2 *Inspection Preparation*. Attachment 2.2-1 is an example of an inspection plan.

3.3 Performance-based Inspections

- 3.3.1 **Entrance Meeting:** The inspection begins with a meeting with appropriate licensee personnel. The inspector shall assure that licensee management (signer of the application for license or appropriate senior management) will be made aware of the inspection. In certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observation of licensed activities currently in progress.
 - 3.3.1.1 The inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This is often an opportune time for the inspector to identify personnel to be interviewed.

- 3.3.1.2 The licensee representative should be asked to identify any recent problems related to the licensed program.
- 3.3.1.3 When an inspection is likely to involve proprietary information, Personally Identifiable Information (PII) and patient information, the inspector should discuss how the information will be handled during the inspection.
- 3.3.1.4 If appropriate, the exit meeting should be scheduled during the entrance meeting.
- 3.3.1.5 The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary, PII or patient related. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.
- 3.3.1.6 In all cases where licensee documents are retained beyond inspection, inspectors should follow the requirements of IMC 0620 "Inspection Documents and Records." Inspectors shall ensure that the licensee understands that the retained records will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding of the information.
- 3.3.2 **Follow-up on Previous Items:** Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took corrective actions as described in the licensee's response to the Notice of Violation (NOV) and followed up on safety concerns and unresolved issues identified during the previous inspection. Inspectors should ensure that corrective actions implemented from previous inspections are being followed to prevent recurrence of the violation by:
 - 3.3.2.1 Review of the original NOV in the original inspection report and verify the licensee instituted sufficient

corrective actions to prevent recurrence and are in accordance with the disposition of the NOV.

- 3.3.2.2 Determine whether the violation will be closed during the current inspection and obtain information necessary to close the unresolved item.
- 3.3.2.3 Document the results of the follow-up inspection activity in an inspection report.
- 3.3.3 **General Overview:** The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.
 - 3.3.3.1 Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection.
 - 3.3.3.2 Identify the reporting relationship and management structure between the licensee's executive management, the RSO, and, if applicable, the chairperson and other members of the Radiation Safety Committee (RSC).
 - 3.3.3.3 Interview cognizant personnel to determine the types, quantities, and use of radioactive material, frequency of use, staff size, etc., and anticipated changes in the radiation use program.
 - 3.3.3.4 Determine if the licensee possesses material in accordance with a general license.
- 3.3.4 **The Inspection:** The inspector should observe licensee operations, interview staff and conduct document review to complement and support observations. Perform radiation surveys to obtain independent and confirmatory measurements.
 - 3.3.4.1 Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety. In performance-based inspection, a problem with

licensee performance leads the inspector to identify programs or procedures for evaluation. If there is no opportunity to observe work in progress that involves Department regulated activities, the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites.

- 3.3.4.2 If an activity results in significant problems, licensee management should be informed as soon as possible. This will allow the licensee sufficient time to begin root cause analysis and possibly determine a corrective action prior to the exit meeting.
- 3.3.4.3 Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. The walkthrough may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.
- 3.3.4.4 Conduct inspections of principal activities that are a potentially significant contributor to dose, regardless of shift.
- 3.3.4.5 Perform routine inspections, when applicable, at times of high use of licensed material.
- 3.3.4.6 Make direct observations of radiation safety systems and practices used.
- 3.3.4.7 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of records should occur only if the current records are out of compliance and it is necessary to determine the presence of a prevalent or persistent problem.

3.3.5 **Independent and Confirmatory Measurements:** Independent measurements are those performed by the inspector without comparison to the licensee's measurements.

Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.

- 3.3.5.1 The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility.
- 3.3.5.2 Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e., inspector's detection equipment malfunctions during an inspection trip).
- 3.3.5.3 Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.
- 3.3.5.4 Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.
- 3.3.5.5 The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation. However, the inspector must use IDHS instrumentation for independent verification of the licensee's measurements.
- 3.3.6 **Special License Conditions:** If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that that licensee understands the additional requirements and maintains compliance with the special license conditions.
- 3.3.7 **Exit Meeting:** The inspection concludes with an exit meeting with licensee management. If a senior management representative is unavailable for the exit meeting, the inspector should hold an exit meeting with appropriate staff onsite.

Dependent on the results of the inspection, the inspector may hold another exit meeting directly with a senior management representative and the licensee's RSO. This meeting involving the licensee's management and RSO can be held by telephone.

- 3.3.7.1 When appropriate, the inspector should prepare **Department Form 591M Safety Inspection Report and Compliance Inspection** before the exit meeting so that the form can be properly executed during the exit meeting. IDHS RMCP form 591M may be issued while still in the field for:
 - 3.3.7.1.1 An inspection that results in no findings.
 - 3.3.7.1.2 To document a non-cited violation (NCV); or
 - 3.3.7.1.3 To document a Severity Level IV (health and safety only) that does not require an amendment to the license to correct and is not willful or repetitive in nature. The Severity Level IV violation being documented in this manner must be corrected while the inspector is present or can be easily corrected within 30 days of the date of the inspection. Any corrective actions must be listed on IDHS RMCP Form 591M Part 1.
- 3.3.7.2 When IDHS RMCP Form 591M is used to document the results of an inspection, IDHS RMCP Form 591M Part 3 must also be completed. The inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or non-cited violation and the facts necessary to demonstrate that a requirement was not met; reference to the regulation, license condition or other legally binding requirement that was violated; and a description of the licensee's corrective action.

- 3.3.7.3 The results of the inspection and any unresolved items will be discussed with the licensee. During the meeting, the inspector shall explain any violation of Department requirements and the inspector's understanding of the licensee's corrective action plan for each violation. The inspector should explain safetyrelated concerns or unresolved items identified during the inspection, and the status of any previously identified violations.
- 3.3.7.4 Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated, or the licensee has made a commitment to initiate corrective actions. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, the S/HP should be notified immediately.
- 3.3.7.5 Although deficiencies identified in some areas (e.g., a worker's knowledge of radiation protection regulations) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report of Notice of Violation (NOV).
- 3.3.7.6 At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature, including PII and patient information. If so, the inspector should assure proper handling of the information.
- 3.3.8 **Evaluating Inspection Results:** After returning from an inspection trip, the inspector shall discuss, either through verbal or written manner, the results of the inspection(s) with the S/HP. The inspector should make an accurate determination

of the actual condition of the activities inspected. The technical basis or root causes of identified problems must be emphasized, not just the symptoms or administrative indications. The reliability of both equipment and workers should be evaluated with respect to safety. Inspection findings should be evaluated for generic health and safety problems. Performance conditions should also be evaluated to predict their impact on future operations. Documentation for inspections is discussed in RMCPP 2.4 *Documentation of Inspection Results*.

3.4 Initial Inspection

- 3.4.1 Initial inspections of a new licensee shall be announced and completed within 12 months of the date the new license or amendment was issued by the Department; however, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months of license issuance. Scheduling initial inspections are determined in RMCPP 2.1 Scheduling of Inspections. If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:
 - 3.4.1.1 Determine the licensee's plans for future possession of license material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities, personnel, and equipment are in place to safely handle licensed material, as described in the license application.
 - 3.4.1.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions and give the licensee an opportunity to ask any regulatory questions.
 - 3.4.1.3 Remind the licensee to notify the Department within30 days after the receipt of licensed material orinitiation of licensed operations, as required by licensecondition. Document the contact and enter the record

into the file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.

- 3.4.1.4 Ensure that the due date is set for 18 months from license issuance.
- 3.4.2 Performing initial inspections. During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed.

Methods for determining if principal activities have been performed include but are not limited to the following: performing a site tour, performing independent measurements, and/or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.

If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with this procedure and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

- 3.4.2.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.
- 3.4.2.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.
- 3.4.2.3 Remind the licensee to notify the Department within30 days after the receipt of licensed material or

initiation of principal activities, as required by license condition.

- 3.4.2.4 Remind the licensee of the requirements in 10 CFR 30.36(d) to provide written notification to the Department within 60 days if no principal activities under the license have been conducted for a period of 24 months.
- 3.4.2.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.
- 3.4.2.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by \pm 6 months.
- 3.4.3 Document the onsite inspection by completing a **Department Form 591M Safety Inspection and Compliance Inspection** for the exit interview or complete other inspection reports as described in RMCPP 2.4 *Documentation of Inspection Results*. The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.
- 3.4.4 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by \pm 6 months.
- 3.4.5 New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

- 3.4.6 New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
 - 3.4.6.1 The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);
 - 3.4.6.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
 - 3.4.6.3 The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);
 - 3.4.6.4 The licensee significantly increases the number of authorized users; or
 - 3.4.6.5 The new license authorizes on or more new facilities.
- 3.4.7 If none of these conditions applies, the "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.
- 3.4.8 New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

3.5 Routine Inspections

- 3.5.1 Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority as defined in RMCPP 2.1 *Scheduling of Inspections*.
- 3.5.2 If the licensee has possessed material or performed principal activities since the last inspection, the inspector should perform

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a routine inspection of the facility as defined in the programspecific inspection procedure using a performance-based inspection as discussed in Section 3.3.

- 3.5.3 If the licensee has not possessed material or performed principal activities since the last inspection, the inspector should follow the instruction in Section 3.4.
- 3.5.4 Inspectors should plan to conduct routine inspections close to the due date. However, to achieve the goals of cost saving and efficient use of staff time and travel, routine inspections may be scheduled within a window around their inspection due dates. Inspection of licensees in Priority Codes 1 and 2 may vary around their due date by \pm 50 percent. Routine inspections of Priority Codes 3 and 5 licensees may vary around their due dates by \pm 1 year.
- 3.5.5 Inspections will not be considered "overdue" until they exceed the scheduling window. In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, inspections may be scheduled before their window if the Department receives information that warrants earlier inspection. The bases for scheduling the inspection before the window should be documented in the inspection records and signed by the inspector's immediate supervisor and place in the licensee file and in WBL.

3.6 Reactive Inspections

- 3.6.1 Reactive Inspections focus on limited issues that are not within the scope of a routine inspection. Inspections performed to follow up on incidents (i.e., medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. The S/HP shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary.
- 3.6.2 Preparation for these inspections shall be under the direction of the S/HP. Narrative reports shall be prepared, if required, by the S/HP. The inspection frequencies for reactive inspections

are defined in RMCPP 2.1 *Scheduling of Inspections*. Performing reactive inspections should be completed in accordance with RMCPP 3.1 *Management of Allegations* and/or RMCPP 3.2 *Incident Response*.

- 3.6.3 The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.
- 3.6.4 Issues of compliance will generally be addressed after all safety issues and program weaknesses are identified and understood.
- 3.6.5 It is particularly important that the inspector keep the S/HP informed of the inspection details and explain the exit meeting strategy before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's and inspector's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to the S/HP. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the S/HP. The licensee's next opportunity to discuss the finding will be after the S/HP has reviewed these matters.
- 3.6.6 If a narrative inspection report is required, the report will include a discussion of inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident.
 - 3.6.6.1 **Incidents:** Inspections of reportable incidents (e.g., medical events, overexposure, and loss or release of significant quantities of radioactive materials) take

precedence over the routine inspection program. All reactive inspections will be performed using the guidance in RMCPP 3.2 *Incident Response*. Reactive inspections of incidents will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy.

- 3.6.6.2 **Medical Events:** Inspection of medical events shall be conducted in accordance with the guidance in RMCPP 3.2 *Incident Response*. Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program."
- 3.6.6.3 **Allegations:** Allegations shall be processed in accordance with RMCPP 3.1 *Management of Allegations*.

3.7 Special inspections

- 3.7.1 Special inspections (i.e., reciprocity, temporary job site, team, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections shall be under the direction of the S/HP. Narrative reports shall be prepared, if required by the S/HP, for special inspections. Inspection frequencies for special inspections are defined in RMCPP 2.1 Scheduling of Inspections.
- 3.7.2 For a licensee authorized to work at a temporary job site, the inspector shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s)
 - 3.7.2.1 **Reciprocity Inspection:** Performing reciprocity inspections should be completed in accordance with RMCPP 2.2 *Inspection Preparations*, IMC 2800 "Materials Inspection Program" and IMC 1220 "Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore waters", and

Inspection of Agreement State Licenses under 10 CFR 150.20.

- 3.7.2.2 **Temporary Job Site Inspections:** For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).
 - 3.7.2.2.1 During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).
 - 3.7.2.2.2 The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.
 - 3.7.2.2.3 If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).
 - 3.7.2.2.4 If a temporary job site inspection not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" data element in Web-Based Licensing may indicate a reduced inspection interval.
- 3.7.2.3 **Permanent Field Offices:** If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was

implemented to determine the performance of its field office activities. If an inspection identifies significant program weaknesses (indicative of poor program management/oversight), the S/HP should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

- 3.7.2.3.1 If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or two field offices), only one location must be inspected at the interval specified in this procedure for the type of license.
- 3.7.2.3.2 If the license authorized licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this procedure for the type of license.
- 3.7.2.3.3 It the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected.
- 3.7.2.3.4 Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.
- 3.7.2.3.5 If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.
- 3.7.2.3.6 If an inspection identifies significant program weaknesses (i.e., Severity Level

III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the license reviewer should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

- 3.7.2.4 Expired and Terminated Licenses and Decommissioning Activities: Notification that a license has expired or is being terminated (and an inspection is required in accordance with RMCPP 1.3, License Termination/Revocation), requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.
 - 3.7.2.4.1 Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys.
 - 3.7.2.4.2 The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the Department of termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.
 - 3.7.2.4.3 If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the

required schedules for licensee action, as specified in the decommissioning timeliness rule.

- 3.7.2.5 **Abandonment of Licensed Activities:** Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.
- 3.7.2.6 **Inspection After Escalate Enforcement:** If escalated enforcement action has taken place for a particular licensee, a special inspection follow-up shall be scheduled and conducted within 6 months of the last inspection or sooner after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous Severity Level III or above violations. The Department may perform this follow-up inspection as a part of a routine inspection. In determining when to conduct the followup inspection, the Department should consider the risk-significance, number, and severity level of the violations.
- 3.7.2.7 **Significantly Expanded Programs:** During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license review may request a near-term onsite inspection for a significant licensing actin that was recently completed. Both the inspector and the reviewer should make their supervisors aware of the following changes in a licensee's scope of work. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

- 3.7.2.7.1 The licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of risk significant radioactive material (RSRM);
- 3.7.2.7.2 The licensee authorized a physical move of a facility or a new use at a temporary jobsite;
- 3.7.2.7.3 The licensee authorizes new (i.e., since the previous inspection) satellite facilities where licensed materials will be used or stored;
- 3.7.2.7.4 The licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;
- 3.7.2.7.5 The number of authorized users has significantly increased or decreased; and
- 3.7.2.7.6 The licensee has ceased activities at the entire site or in any building area as defined in 10 CFR 30.36(d).

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded, or activities have ceased. See the six points in the preceding paragraph. An onsite inspection must be performed to verify that the applicant has implemented the security requirements before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.

3.8 Reduced Inspections

- 3.8.1 The inspection interval shall not be extended beyond that specified by the priority system indicated in RMCPP 2.1 *Scheduling of Inspections*. The interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. If there was a reduction in inspection frequency, ensure that frequencies are reduced as discussed in RMCPP 2.1 *Scheduling of Inspections*. The inspection should be performed in accordance with this procedure; However, special attention should be focused on the areas of poor performance. Other aspects of the program should only be focused on as time and opportunity allows.
- 3.8.2 At the discretion of the **S/HP**, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent a timely inspection from being complete. The bases for altering the scheduling of inspections should be documented in the inspection records and signed by S/HP and placed in the license file and WBL.

3.9 Team Inspections

- 3.9.1 The Department shall schedule and conduct team inspections of major licensees within Indiana on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside IDHS shall be made by the S/HP and RCPD.
- 3.9.2 Examples of situations where team inspections may be appropriate are:

- 3.9.2.1 Routine inspections of major licensees (i.e., broadscope academic, broad-scope medical licensees, and large processor/manufacturers). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.
- 3.9.2.2 Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).
- 3.9.2.3 Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess a licensee's strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, prelicensing visits are not considered inspections, and team inspections should not take the place of prelicensing visits.
- 3.9.2.4 Inspections of any type (routine or reactive) that include team members from outside the Department, including other state agency or federal agency representatives.

3.10 Coordination with Other Agencies

- 3.10.1 The Department does not conduct inspections of licensee compliance with the requirements of other local, state, or federal agencies, except the U.S. Department of Transportation (DOT). However, a Health Physicist (HP) may identify concerns that are within another agency's regulatory authority.
 - 3.10.1.1 If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the S/HP

should inform the appropriate liaisons within the other agency about the concerns.

- 3.10.1.2 Except for DOT regulations, it is important that all HP's recognize and understand that they are not to make decisions regarding activities under the purview of other agencies.
- 3.10.1.3 Thus, in discussing the concerns with the licensee, HP are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations but are to point out concerns to heighten licensee awareness. For example, if an HP identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation.
- 3.10.1.4 The HP should also advise the licensee of the obligation to inform the S/HP who may coordinate the information with the other lead agency.

3.11 Security Inspections

- 3.11.1 The requirements of 10 CFR Part 37 apply only to licensees in possession of aggregated category 1 and 2 quantities of radioactive materials, including sealed and unsealed sources.
- 3.11.2 Affected licensees may include manufacturers and distributors, self-shielded irradiators, open-air beam calibrators, pool-type irradiators, medical facilities with blood irradiators and/or gamma-ray stereotactic radiosurgery (gamma knife), radiopharmacies, industrial radiographers, and licensees transporting category 1 and 2 quantities of radioactive material.
- 3.11.3 The focus of this inspection is the security inspections of those licensed under 10 CFR Part 30, subject to Part 37 requirements when possessing certain aggregated category 1 and 2 quantities of radioactive material. (See Inspection Procedure 87137 for additional details.)

3.12 Pre-Licensing Site Visits

- 3.12.1 The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-licensing Checklist.
- 3.12.2 At a minimum, all storage and use locations must be visited.
- 3.12.3 By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application.
- 3.12.4 Pre-licensing visits must be completed before the issuance of a license.

4.0 RECORDS

- 4.1 Letter with Notice of Violation or Department Letter or clear inspection form.
- 4.2 Inspection Report maintained in file and WBL.
- 4.3 Records are primarily filed electronically, and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 ATTACHMENTS TO RMCPP 2.3

None

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.4, Revision 0: Documentation of Inspection Results

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	
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1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure is designed to ensure that reports of inspections clearly communicate significant inspection results to licensees, licensing staff, and the public. It is the Department's goal that all Radioactive Materials Control Program staff should be qualified in both licensing and inspections of all uses of radioactive materials in the State of Indiana. Significant findings in the inspection reports will be reviewed during the program staff meetings conducted by the Radiation Control Program Director (RCPD) and attended by all program staff.
- 1.1.2 This procedure will ensure that reports of inspections provide conclusions about the effectiveness of the program(s) and/or principal activities inspected. The depth and scope of the documented conclusions should be commensurate with the depth and scope of the inspection.
- 1.1.3 The documentation described in this procedure will provide a basis for enforcement action.

1.2 References

- 1.2.1 NRC Inspection Manual, Chapter 0610, "Nuclear Material Safety and Safeguards Inspection Reports."
- 1.2.2 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."
- 1.2.3 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program."
- 1.2.4 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."
- 1.2.5 290 IAC 3
- 1.2.6 NRC Enforcement Manual

1.3 Files

1.3.1 Letter with Notice of Violation Letter, Clean Inspection Report, and Department Form 591M.

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- 1.3.2 Other elements of inspection reports maintained in the licensee file.
- 1.3.3 Records are primarily filed electronically, and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Maintains files, records, letters, forms, and other records related to inspections.
- 2.1.2 Prepares the inspection documentation issued within 30 days of completing the inspection.
- 2.1.3 Prepares a Department letter transmitting the inspection findings to the licensee.
- 2.1.4 Tracks the inspection documentation until completed.
- 2.1.5 Updates the inspection history record and enters next inspection date in Web-Based Licensing (WBL).

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Updates the data in WBL. Once the inspection is completed, record the inspection date, licensee name, license number, lead inspector, and accompanying inspector(s) in WBL.
- 2.2.2 Reviews a report of inspection findings and recommended enforcement action. If warranted due to the severity of the inspection findings, notifies the Radiation Control Program Director, as soon as possible.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Concurs with the inspector's and/or S/HP's findings and recommendations or prescribes alternative actions.
- 2.3.2 Reviews and approves the narrative report of the inspection findings and transmittal letter, as necessary.
- 2.3.3 Signs all correspondence to the licensee related to the inspection report.

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3.0 PROCEDURE

Review RMCPP 2.3 *Performance-Based Inspection*, to determine if an inspection was performed. If an attempt was made, but the inspection was not performed, this needs to be documented to note the attempt in the license file. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection documentation. Documentation of inspections should be completed in accordance with this procedure and other applicable IDHS RMCP and NRC Guidance.

3.1 Methods of Documenting Inspection Results

- 3.1.1 Results of inspections are reported to the licensee with a Department Form 591M Safety Inspection and Compliance Inspection (Attachment 2.4-1) and may be followed up with additional documentation.
- 3.1.2 They may also be documented with a department letter as described in RMCPP 2.7 *Assuring the Technical Quality of Inspections*.
- 3.1.3 The content of an inspection report should include that found in Attachment 2.4-2 **Inspection Report Content**.
- 3.1.4 Inspection Reports should also include either an Attachment
 2.4-3 Notice of Violation Letter or Attachment 2.4-4 Clean
 Inspection Report.
- 3.1.5 Notes taken during the course of the inspection shall not be official documentation of the inspection performance. The S/HP may make an exception to this if the notes are determined by the S/HP to be sufficient documentation. If so, the notes will be place in the licensee file and WBL.

3.2 Inspection Reports

3.2.1 Upon completion of an inspection for a licensee, a narrative report or an inspection memo shall be generated on
 Department Form 591M Safety Inspection and Compliance Inspection.

- 3.2.2 Inspection reports should be completed within 15 working days following the completion of the on-site portion of the inspection.
- 3.2.3 Narrative reports shall contain:
 - 3.2.3.1 Sufficient detail to describe the inspection that was conducted including operations observed to document the performance-based part of the inspection;
 - 3.2.3.2 Compliance status of topics;
 - 3.2.3.3 The status of follow-up items involving prior enforcement or reported licensee events;
 - 3.2.3.4 Sufficient information to support cited violations, noncited violations, and closed violations identified during a previous inspection;
 - 3.2.3.5 Description of completed or anticipated corrective actions to any identified minor violations cited in Department Form 591M;
 - 3.2.3.6 Sufficient description of the scope of the licensee's program for the S/HP, license reviewers, and other inspectors to evaluate the licensee's overall safety program; and
 - 3.2.3.7 For inspections that include a review of Part 37 requirements with no violations, the inspector should include in a non-publicly available inspection record (e.g., Form 591M Part 3) describing the licensee's implementation of security requirements. This form is Attachment 2.4-5 **IDHS RMCP Form 591M Security-Related**.
- 3.2.4 An inspection report shall contain sufficient information to provide a general overview of the current status of the licensee's radioactive material program, including but not limited to, use of licensed material, staff size and hours, any changes from information previously noted in a narrative report, and any other information deemed relevant by the inspector.

3.3 Reports to licensees

- 3.3.1 Inspection findings shall be reported to the licensee upon acceptance of the inspection report by the S/HP or RCPD. Inspection findings should be sent to the licensee through a department letter unless a Department Form 591M was provided to the licensee at the conclusion of the inspection and that is deemed sufficient by the S/HP or RCPD. Any Form 591M completed in the field must be signed by a supervisor when the inspector returns to the office. The form does not need to be reissued unless the characterization of any findings changes during supervisory review.
- 3.3.2 **Department Form 591M Safety Inspection and Compliance Inspection** shall be used to document clear inspections and inspections resulting in non-cited violations (Severity Level IV violations that are neither willful nor repetitive and that can be corrected while the inspector is present, or that the licensee agrees to correct).
- 3.3.3 The inspector will present Form 591M Part 1 to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with Department management is necessary, the inspector may transmit Form 591M Part 1 from the Department office.
 - 3.3.3.1 The Form 591M, "Safety Inspection Report and Compliance Inspection," shall include the name of the responsible inspector.
 - 3.3.2 The inspector shall sign the completed Form 591M Part1. Supervisory review is required but is not necessaryprior to issuance of Form 591M Part 1, tot eh licensee.
 - 3.3.3.3 If no changes are needed after supervisory review, the supervisor will sign the final signature block and the completed form will be put in WBL (only one form is maintained since it provides record of both the finding communicated to the licensee, and the final approved action).
 - 3.3.3.4 If changes are needed after supervisory review, Form 591M Part 1 will be reissued to the licensee, and both

the original Part 1 and the revised completed form will be put in WBL (both versions are maintained in order to provide record of both the initial finding communicated to the licensee and the final approved action).

- 3.3.4 Form 591M Part 1 may not be used to transmit non-cited or cited security-related violations.
- 3.3.5 The inspector must document findings with enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement (use titles only, names should be avoided, if possible), and when it was violated (including dates, or period of time of non-compliance, if known). If the licensee provides immediate or long-term corrective action for the violation, this information should also be included as part of the inspection record.
- 3.3.6 When Department Form 591M is used to document the results of an inspection, the inspector must ensure that for each cited violation, the form includes:
 - 3.3.6.1 A brief statement of the circumstances, including the date(s) of the violation or the period of time of the non-compliance.
 - 3.3.6.2 The facts necessary to demonstrate that a requirement was not met; and
 - 3.3.6.3 The reference to the regulation, license condition or legally binding requirement that was violated.
- 3.3.7 The Severity Level IV violation being documented in this manner must be corrected while the inspector is present or can be easily corrected within 30 days of the date of the inspection. Any corrective actions must be listed on the Form 591M Part 1.
- 3.3.8 Following are examples of cited violations on Department Form 591M:
 - 3.3.8.1 10 CFR 20.1101 requires the licensee to annually review the content and implementation of the radiation protection program. During years 2010 and 2011, the licensee did not complete the review. The

licensee will complete the review in October 2012 for the period of January 2010 through September 2012. The licensee intends to complete future reviews in October of each year by completing NUREG-1556 Volume 9, Revision 2 Appendix L, Suggested Medical License Audit.

3.3.8.2 As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2010, to October 24, 2010 to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system to notify the Radiation Safety Officer to perform the inventories.

Note: Attachment 2.5-1 of RMCPP 2.5 contains examples of violations that may be cited on Department Form 591M

- 3.3.8.3 IDHS RMCP Form 591M shall include the name of the responsible inspector. The inspector shall sign the completed Department Form 591M. The inspector will present the Department Form 591M to the licensee at the conclusion of the exit interview or, as necessary, by facsimile, mail, or electronic mail in accordance with State requirements.
- 3.3.9 **Department Letters:** A letter, signed by the inspector and/or the S/HP, shall be used if a Department Form 591M was not issued to documents a clear inspection. A Department letter shall be sent within 30 days of completion of the inspection if a Department Form 591M has not been issued. Department letters shall be sent along with a Notice of Violation(s) if any of the following situation are found:
 - 3.3.9.1 Repetitive violations;
 - 3.3.9.2 Violations involving willfulness:
 - 3.3.9.3 Where an apparent Severity Level III or higher violation or problem is detected;

- 3.3.9.4 When an enforcement conference or a management meeting is to be held;
- 3.3.9.5 Where the licensee needs to take extensive corrective action(s) or make programmatic changes to address the violation(s);
- 3.3.9.6 Where the licensee needs to perform further evaluations before taking corrective action
- 3.3.9.7 Where the corrective action includes a request for an amendment to the license;
- 3.3.9.8 When a specific message should be provided to the licensee;
- 3.3.9.9 If the inspector questions the effectiveness of the licensee's planned action or the ability of the licensee to carry out the corrective action;
- 3.3.9.10 Where it is appropriate to request a written response to the violation.

3.4 Marking of Inspection Documentation

- 3.4.1 Information relative to the licensee's physical protection measures (security-related information) is confidential information and needs to be protected.
- 3.4.2 The inspector should ensure that the NOV, documentation of findings (i.e., Form 591M Part 3 or narrative inspection report), and any other separate enclosure are appropriately protected, handled, and marked in accordance with the following security-related information guidance:
 - 3.4.2.1 Paper copies must be filed in the padlocked secure files cabinet and electronic files saved in the secure access only server folder.
 - 3.4.2.2 Files must be Marked: "THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC AND/OR PAPER FILES ONCE FILLED OUT."

- 3.4.2.3 Files must be maintained under the visual and physical possession of the user when outside of the electronic or padlocked file storage area.
- 3.4.3 All cover letters to licensees will be publicly available and should not contain confidential information. Security-related information should not be made available to the public.

3.5 Reports for Special Inspections

A narrative report should be completed documenting all special inspections. Reports should be completed and issued within 30 working days of the completion of the on-site portion of the inspection.

- 3.5.1 **Escalated Cases:** For escalated cases, the report should address all areas covered in the inspection.
- 3.5.2 **Medical Events:** for medical events the report should follow the guidance in NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility".
- 3.5.3 **Allegations:** For allegations the report should follow the guidance in RMCPP 3.1 *Management of Allegations*.
- 3.5.4 **Reactive and Reduced Inspection:** A reactive and reduced inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

4.0 RECORDS

- 4.1 Inspection reports and inspection transmittal letters in licensee's file.
- 4.2 Records are primarily filed electronically, and Web-Based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 ATTACHMENTS TO RMCPP 2.4

- 2.4-1 Department Form 591M Safety Inspection Report and Compliance
- 2.4-2 Inspection Report Content
- 2.4-3 Notice of Violation Letter
- 2.4-4 Clean Inspection Report

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2.4-5 Security Related 591M Part 3

Attachment 2.4-1

Department Form 591M Safety Inspection Report and Compliance Inspection

INDS RMCP		
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION		
1. LICENSEE/LOCATION INSPECTED:		
2. LICENSEE NUMBER:	DATE(S) OF INSPECTION	
LICENSEE:		
The inspection was an examination of the activities conducted under you license as they relate to radiation safety and to compliance with the Indiana Department of Homeland Security Radioactive Materials Control Program (IDHS RMCP) rules and regulations and condition of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:		
1. Based on the finding, no violations we	ere identified.	
2. Previous violation(s) closed.		
3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the IDHS RMCP enforcement procedure to exercise discretion, were satisfied		
Non-cited violation(s) were discurrequirements:	ussed involving the following	
4. During the inspection, certain of your attached, were in violation of IDHS RMCP	•	

NOTICE OF VIOATION, which may be posted in accordance with 10 CFR 19.11 (Violation and corrective Actions)

Statement of Corrective Action

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of I.C § # (corrective steps already taken, corrective steps which will be taken date when full compliance will be achieved). I understand that no further written response to the IDHS RMCP will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE REPRESENTATIVE			
IDHS RMCP INSPECTOR			
IDHS RMCP Radiation Control Program Director			

IDHS RMCP 591M PART 2		
DEPARTMENT OF HOMELAND SECURITY		

INDIANA

RADIOACTIVE

MATERIALS CONTROL PROGRAM

SAFETY INSPECTION AND COMPLIANCE INSPECTION

LICENSEE/LOCATION INSEPCTED:

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LICENSE NUMBER:	DATE(S) OF INSPECTION
(OBSERVATIONS)	
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FORM 591 Part 3		
Indiana Department of Homeland Security		
Radioactive Materials Control Program		
File Information		
SAFETY INSEPCTION AND COMPLIANCE INSPECTION		
1. LICENSEE/LOCATIONS INSPECTED	2. LICENSE NUMBER(S)	
3. DATES OF INSPECTION	4. TYPE OF INSPECTION	
5. INSPECTION PROCEDURES USED	6. INSPECTION FOCUS AREAS	
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODES	2. PRIORITY
3. LICENSEE CONTACT	4. TELEPHONE NUMBER

Inspector Information

Name:	Signature:
Phone No.:	Email address:

Main Office Inspection

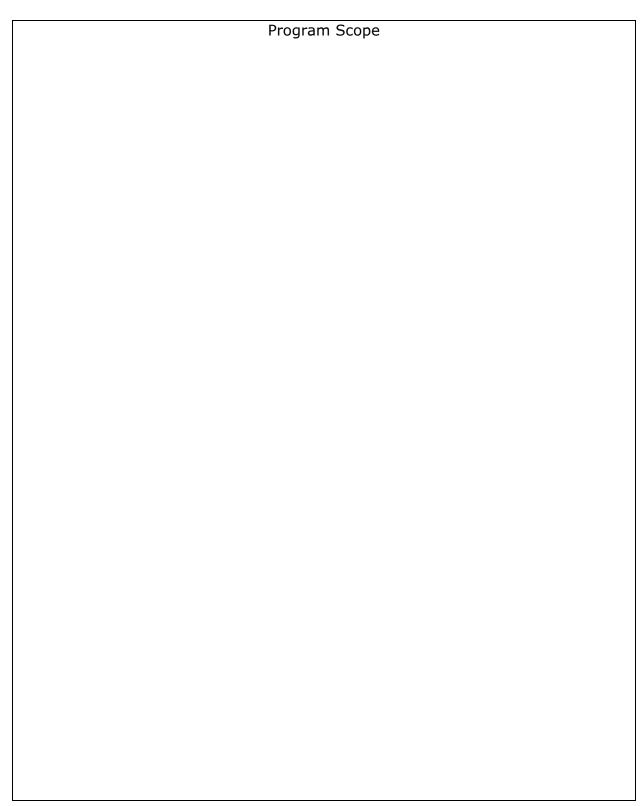
Next Inspection Date

Field Office Inspection

Temporary Job Site Inspection

Approve:

Radiation Control Program Director Signature/Date



Conclusions

Attachment 2.4-2 Inspection Report Content

Indiana Department of Homeland Security

Radioactive Materials Control Program

The content for Radioactive Materials Control Program Inspection Reports should consist of the applicable elements on this list. Details about these elements are in RMCPP 2.4 Documentation of Inspection Results.

- Cover Letter on Department letterhead
 - □ Address, Date, Salutation
 - □ Subject
 - Introductory Paragraphs
 - □ Body
 - □ Closing
- Department Form 591M, Notice of Violation Letter or Clean Inspection Report (Attachments 2.4-1, 2.4-3, and 2.4-4)
- Report
 - □ Scope
 - Observations and Findings
 - Generic issues, if any
 - Violations, if any
 - Conclusions
 - Exit Meeting Summary
 - Absence of Proprietary Information
 - Characterization of Licensee Response
 - Oral statements and Regulatory Commitments
 - Report Attachments
 - □ Key Points of Contact
 - □ List of Items Opened, Closed and Discussed (optional)
 - List of Documents Reviewed
 - □ List of Acronyms

Attachment 2.4-3 Notice of Violation Letter Indiana Department of Homeland Security Radioactive Materials Control Program

Date:

Name of Licensee Attn: Licensee Contact Address Street Address City, State, Zip Code

Dear [Insert salutation]:

This letter refers to the inspection conducted on [Insert Date] at your [Facility name] by [Inspector's name].

This inspection was an examination of the principal activities conducted under you Indiana Radioactive Materials [License number], a selective examination of procedures and representative records, observations, and interviews with personnel as they relate to radiation safety and to compliance with the Department's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities and interviews with personnel.

Based on the results of this inspection, the Department has determined that [Insert number of violations] of Department requirements occurred. The violation(s) is/are cited in the enclosed Notice of Violation (Notice).

You are required to respond to this letter within 30 days and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the Department should consider, you may provide it in your response to the Notice. The Department review of your response to the Notice will determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal, privacy, or proprietary information so that it can be made public without redaction.

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If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earlier convenience.

[Insert Health Physicist Inspector name, phone number, and email]

NOTICE OF VIOLATION

[Licensee Name]

[License Number]

During an inspection conducted on XX/XX/XXXX, [INSERT DATE(S)] # [INSERT NUMBER] violations of Department requirements were identified. The violations are listed below:

[INSERT VIOLATIONS WITH REGULATION AS APPROPRIATE]

This is a Severity Level # [INSERT SEVERITY LEVEL] violation.

######## [INSERT LICENSEE] is hereby required to submit a written statement of explanation to the Indiana Department of Homeland Security Radioactive Materials Control Program ATTN: Radioactive Materials Control Program, [ADD VALID IDHS ADDRESS WE DECIDE ON], within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received with the time frame specified in this Notice, an order may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken.

If you contest this enforcement action, you should reply to Indiana Department of Homeland Security Radioactive Materials Control Program ATTN: [ADD VALID IDHS ADDRESS WE DECIDE ON].

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To the extent possible your response should not include any personal privacy, proprietary information so that it can be made public without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire to not be placed in the public document and provide the legal basis to support your request for withholding the information from the public.

Dated:

Approved:

Radiation Control Program Director

Attachment 2.4-4 Clean Inspection Report Indiana Department of Homeland Security Radioactive Materials Control Program

Date:

<Name of licensee> Attn: <Licensee Contact> <Address> <Street Address> <City, State, Zip Code>

Dear [Insert salutation]

This letter refers to the inspection conducted on [INSERT DATE] at your facility.

This inspection was an examination of the activities conducted under your Indiana Department of Homeland Security Radioactive Materials Control Program [License Number], as they relate to public health and safety, and to confirm compliance with the Department's rules and regulations and the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the findings, no violations of Department rules or regulations were identified.

You are not required to respond to this letter; however, you should retain a copy for your records.

If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earliest convenience.

Sincerely,

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Radiation Control Program Director

Attachment 2.4-5 IDHS RMCP 591M Security-Related

Indiana Department of Homeland Security

Radioactive Materials Control Program

Official Use Only – Security-Related information

Initial	Announced	Unannounced	Routine	Special	Security		
IDHS RMCPP FORM 591M PART 3 Indiana Department of Homeland Security							
10 CFR 2.201 Radiation Materials Control Program							
		-					
1. LICENSEE/LOCATION INSPECTED: 2. INSPECTED BY:							
REPORT NUMBER(S)			Indiana Department of Homeland Security				
			Radioactive Materials Control Program				
			[ADD ADDRESS]				
3. DOCKET NUMBER(S):			5. DATE(S)) OF INSPECTI	ON		
6. INSPECTION 7. INSPECTION PROCEDURES:		AREAS:					

SUPPLEMENTAL INSPECTION INFORMATION						
1. PROGRAM CODE(S):	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER			
Main Office Inspection Date:						
Field Office Inspection						
Temporary Job Site Inspection						
PROGRAM SCOPE						
IDHS RMCPP FORM 5	91M PART 3 (Securit	v-Related)				

Official Use Only – Security Related Information

THIS DOCUMENT MUST BE KEPT IN SECURED Non-Public

ELECTRONIC OR PAPER FILES ONCE FILLED OUT

Confidential-Security-Related

Supervisory Review By

Non-Public

Radiation Control Program

Director (RCPD):

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.6, Revision 0: Materials Inspection Checklists and Definitions

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	
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1.0 Purpose

2.0 Definitions

3.0 Attachments

2.6-1 10 CFR 37 Inspection Checklist

1.0 Purpose

- 1.1 To provide checklists that better assure quality inspections of radioactive materials licensees where the NRC NUREG-1556 Series does not provide an Audit. With this revision of the procedure, the only checklist in this procedure is **Attachment 2.6-110 CFR Part 37 Inspection Checklist**. There are audits and checklists in the NRC NUREG 1556 Series for all the license types in Indiana.
- 1.2 Inspections are to be performed using the applicable NRC inspection procedures found at [ADD HYPERLINK], in conjunction with the guidance of NRC IMC 2800, found at [ADD HYPERLINK].
- 1.3 Inspections are documented on Department Form 591M, as well as inspections reports. Form 591M and other inspection forms are Found in RMCPP 2.4 *Documentation of Inspection Results*.
- 1.4 Inspection Checklists attached to this procedure and in the NUREG-1556 Series are used during the inspection and may be helpful when writing inspection reports.
- 1.5 This procedure also serves to capture key terms and define them as they relate to the Indiana Department of Homeland Security Radioactive Materials Control Program.

2.0 Definitions

- 2.1 **Acute Performance Conditions:** Conditions that have an obvious adverse impact on safety and/or reliability.
- 2.2 **Department:** Means Department of Homeland Security as established by I.C. 10-19-2-1.
- 2.3 **Core Inspection:** All initial inspections of priority 1, 2, 3, and 5 licensees and all routine inspections of priority 1, 2, or 3 licensees.
- 2.4 Incident: An event that may have caused, or threatens to cause, conditions described in Title 10 Code of Federal Regulations (CFR) 20.1906, 20.2201 through 20.2203, 10 CFR 30.50, 10 CFR 31.5, 10 CFR 34.27, 10 CFR 34.101, 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 35.3067, 10 CFR 36.83, 10 CFR 39.35, 10 CFR 39.77, 10 CFR 40.60, 10 CFR 71.95, or other regulatory reporting requirements imposed by order or license condition.

2.5 **Initial Inspection:** The first inspection after a new license is issued. Page|367

- 2.6 **Initial Security Inspection:** An inspection to verify that an applicant has implemented security requirements identified in the On-Site Security Review of the Risk Significant Radioactive Materials (RSRM) Checklist after the licensing action is issued allowing the applicant to take possession of RSRM.
- 2.7 **Inspection:** The act of assessing licensee performance to ensure the health and safety of worker and the public and to protect the environment. It is also used to determine if radioactive materials are used safely and whether the licensee is in compliance with rules, regulations, statutes, license conditions, and the license commitments incorporated in the licensee by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing site visits or telephone communications are not inspections.
- 2.8 **Inspection Document:** A written record documenting the results of the inspection. Any material obtained or developed during an inspection that is considered to be a Department record.
- 2.9 **Inspection Follow-up Item:** A matter that requires further inspection because of a potential problem, because specific licensee or Department action is pending, or because additional information is needed that was not available at the time of the inspection.
- 2.10 **Inspection Plan:** An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.
- 2.11 **Inspection Priorities:** An inspection priority code is assigned to each radioactive materials license. The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspection, expressed in years. The same priority code is assigned to all licenses that authorize that particular type of code. The priority represents the relative risk of radiation hazard. Priority Code 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority Code 5 represents the lowest risk. Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority code for the license is the code with the shortest routine inspection interval.

- 2.12 **Inspection Report:** A computer-generated inspection report used to document the inspection.
- 2.13 **Inspection/Scheduling Window:** A window in which scheduling and performing of inspections should be performed in accordance with NRC Inspection Manual Chapter 2800.
- 2.14 **Inspector:** A Health Physicist qualified to plan, perform, and document an inspection of a specific category of license and, where appropriate, to prepare enforcement documents and review the response to such a document for adequacy.
- 2.15 **Latent Performance Conditions:** Conditions that are underlying and usually obscure. If unchanged, these may result in acute conditions at some future time if circumstances change.
- 2.16 **Lead Inspector:** A Health Physicist qualified to plan, supervise, and document an inspection by a team of inspectors. An inspector shall not act as a lead inspector in any category of license they are not qualified for, unless being evaluated or supervised by a qualified inspector. A lead inspector is responsible for review of a licensee's reply to a Notice of Violation (NOV).
- 2.17 **Minor Violation:** Minor violations are those that are less significant than a Severity Level IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations must be corrected.
- 2.18 **Noncompliance:** A violation (see below).
- 2.19 **Non-Core Inspection:** Routine inspections of Priority 5 licensees, other than initial inspections.
- 2.20 Notice of Violation (NOV): A formal written notice that sets forth one or more apparent violations of a legally binding regulatory requirement and normally requires the recipient to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken by the licensee or other person and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. The Department may waive all or portions of a written response to the extent that relevant information has already been provided to the Department in writing or documented in

an inspection report or inspection record. The Department may require responses to NOVs to be under oath; however, normally, responses under oath will be considered necessary only for SL I, II, or III violations; or violations of Department Orders. A civil penalty may be issued in conjunction with an NOV.

- 2.21 **Performance-Based Inspection (PBI):** Observation of a licensee's program activities to determine if regulatory and radiation safety objectives are being achieved. This type of inspection can be applied to any functional area of any license. The only variable is the technical nature of the activities of different licensees. The principal measures of successful performance are safety and reliability. A performance-based inspection focuses on the safety and reliability of program activities.
- 2.22 **Potentially Generic Issue:** An inspection finding that may have implications for other licensees, certificate holders, or vendors whose facilities or activities are of the same or similar manufacture or style.
- 2.23 **Precursor Performance Conditions:** Conditions that are changing with time and will likely result in acute conditions at some future time. Precursors are similar to latent condition but are more definite in their eventual outcome.
- 2.24 **Pre-Licensing Checklist:** The purpose of this checklist is to provide a basis for confidence that a new applicant (i.e., an entity that has never had a license or is unknown) requesting a specific license, or a licensee requesting transfer or control to a new applicant or unknown entity, will store and use radioactive materials at locations as specified and under the authorization of the license.
- 2.25 **Pre-licensing Site Visit:** A site visit and face-to-face meeting with an entity to provide a basis for confidence that radioactive material will be used as specified. Staff should use the Pre-Licensing Checklist to determine which applicants require visits. The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-Licensing Checklist. At a minimum, all storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis for confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be

completed before the issuance of a license. The new license will NOT be provided to the applicant during a Pre-Licensing Site Visit.

- 2.26 **Reactive Inspection:** A special inspection in response to an incident, allegation, or special information obtained by the Department (e.g., allegation, lost or stolen radioactive material, overexposure, medical events). These inspections may focus on one or several issues and need not examine the rest of a licensee's program. A reactive inspection counts as a routine inspection only if the total licensed program is evaluated.
- 2.27 **Reduced Inspection:** Changes in the inspection interval of a licensee made at the discretion of the Radioactive Material Program Manager, for several purposes, including but not limited to, poor licensee performance or due to a significant licensing action.
- 2.28 **Regulatory Commitment:** An explicit statement to take a specific action, agreed to or volunteered by a licensee, where the statement has been submitted in writing to the IDHS RMCP and is "tied down" to the license.
- 2.29 **Reliability:** The capability to perform as designed or intended when needed and for the duration required. A lack of reliability is generally only of concern when safety is adversely affected as a result. It is important for inspectors to recognize that reliability applies to both equipment and workers.
- 2.30 **Requirement:** A legally binding obligation such as a statute, regulation, license condition, or order.
- 2.31 **Risk:** The relationship between consequence and probability. The highest probability coupled with the most severe consequence represents the highest risk.
- 2.32 **Risk-informed:** An approach to regulation taken by the Department, which incorporates an assessment of safety significance or relative risk. This approach ensures that the regulatory burden imposed by an individual regulation or process is appropriate to its importance in protecting the health and safety of the public and the environment.
- 2.33 **Risk Significant Radioactive Material (RSRM)** refers to the values in 10 CFR 37 Appendix A.

- 2.34 **Routine Inspection:** A periodic, comprehensive inspection performed at a specified frequency based on the activities authorized under the license.
- 2.35 **Safety:** Relative freedom from harm or hazard to the public, workers, or the environment. Safety is a relative measure of the hazard associated with a given activity. Inspectors need not be able to quantify levels of safety during an inspection. It is sufficient to identify whether or not an activity, condition, or trend is adverse to safety. Safety must not be dependent on any administrative classification system.
- 2.36 **Security Requirements:** Requirements mandated by regulation, order, license condition, or other legally binding requirement for certain licensees possessing or shipping RSRM.
- 2.37 Special Inspection: Those inspection activities where special guidance is needed. These activities include but are not limited to: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning; (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary job- site or field site inspections; (5) team inspections; (6) inspections of abandoned licenses; (7) general licensee's program inspections; (8) reactive inspections; and (9) follow-up to escalated enforcement.
- 2.38 **Team Inspections:** Inspections conducted by two or more inspectors or any inspection which includes an inspector from outside of Indiana (other than NRC or agreement state program representatives). A team inspection can be a routine inspection of a major licensee or a reactive inspection in response to a particular incident or event. Team inspections do not include those where a supervisor accompanies an inspector in order to evaluate the inspector's performance.
- 2.39 **Tie-down condition:** A written commitment made by the applicant in an application for a license or amendment to a license that is made a condition of the license (i.e., the commitment is "tied-down" as a legal requirement). Signed letters or signed fax transmissions can be used.
- 2.40 **Unresolved Item:** A matter about which more information is required to determine whether the issue in question is an acceptable item or a violation.

- 2.41 **Department Record:** Any written, electronic, or photographic record under legal IDHS RMCP control that documents the policy or activities of the Department or a Department licensee. The official records are maintained in WBL.
- 2.42 **Vendor:** A supplier of products or services to be used in a Department licensed facility or activity. The vendor may be an NRC, another Agreement State, or Department licensee or the vendor's product may be required to have an NRC Certificate of Compliance (e.g., certain transport packages such as waste casks or radiography devices). See NUREG-1556 Volume 18.
- 2.43 **Violation:** The failure to comply with a legally binding regulatory requirement such as a statute, regulation, order, or license condition.
- 2.44 **Willfulness:** There are two types of willfulness:
 - a. Deliberate misconduct, an intentional act or omission that the person knows (1) Would cause a violation of any rule, regulation or order, or any term condition, or limitation, of any license issued by the Department or (2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a license, applicant, contractor, or subcontractor;
 - b. Careless disregard refers to situations in which an individual acts with reckless indifference to at least one of three things:
 - (1) the existence of a requirement,
 - (2) the meaning of a requirement, or
 - (3) the applicability of a requirement.

Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless proceeds to engage in conduct that the individual knows may cause a violation. Although aware that the action might cause a violation, the individual proceeds without ascertaining whether a violation would occur.

3.0 Attachment:

Attachment 2.6-1 10 CFR Part 37 Inspection Checklist

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.6-1 CFR Part 37 Inspection Checklist

THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC AND/OR PAPER FILES ONCE FILLED OUT

Security Inspections of materials licensees who possess Category 1 and Category 2 quantities of radioactive material, are required to be performed and documented in accordance with the guidance in NRC Manual Chapter 2800 and NRC Inspection Procedure 87137, "10 CFR Part 37 Materials Security Programs."

Also, please note, if you record notes on the exact location of Category 1 or 2 quantity, a device model number, possession limits or actual inventory, or any physical security measures, the notes should be controlled in accordance with NRC Regulatory Information Summary 2005-031 Revision 1.

Licensee Name:

Date(s) of Inspection:	
License No.	
Inspection No.	
Licensee Mailing Address:	
Licensee Address:	
Location(s) Inspected:	
Licensee Contact:	Telephone No.
RSO:	RSO Phone No.
RSO Email:	
Reviewing Official:	RO Phone No.
LLEA:	
LLEA Contact:	
LLEA Address:	
LLEA Phone No.:	
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10 CFR Part 37 Subpart B

Background Investigations and Access Authorization

(AA) Program

- §37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material
- §37.23 Access authorization program requirements.
- §37.25 Background investigations
- §37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material
- §37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials or other property.
- §37.31 Protection of information.
- §37.33 Access authorization program review.

§37.21 Personnel Access Authorization (AA) requirements.

- (a) 1-3: Licensee established, implemented, and maintains an access authorization program (before taking possession and currently).
- (b) AA program ensures appropriate individuals are trustworthy and reliable (T&R).
- (c) Licensee subjects the following to the AA program: Individuals who have unescorted access (UA) to Cat. 2 or greater. Reviewing Official (RO).
 - (c)(2) Licensee <u>does/does not</u> exclude from the AA program
 categories of individuals identified in §37.29(a)(1) (13)
 - (c)(3) Licensee approves for UA to radioactive material (RAM) only those individuals who require access.
 - (c)(4) Licensee <u>does/does not</u> include individuals needing access to SGI-M under Part 73 in the AA program.

§37.43 General Security Program Requirements

(d)(3) Individuals who only have access to confidential information such as the security plan or implementing procedures, and who do not have full UA to Cat. 1 or Cat 2 quantities, have been certified as T&R 10 CFR §37.25(a)(2) through (a)(7). (i.e., Background screening without fingerprints).

§37.23 Access Authorization (AA) Program Requirements

- (a) Granting Unescorted Access (UA)
 - (2) T&R individuals have received training 10 CFR §37.43(c) prior to access to Cat. 1 or Cat. 2 quantities.
- (b) Reviewing Official(s) (RO)
 - Reviewing Official(s) is/are the only one(s) who makes T&R determination allowing access to Cat. 1 or Cat. 2 quantities.
 - (2) Prior to naming an RO, the licensee:
 - Completed a background investigation
 - Had fingerprints performed by an appropriate provider; and
 - Approved by licensee and Submitted Certification, under Oath or Affirmation, that RO is T&R.
 - Licensee requires RO to be recertified as T&R 10 CFR §35.25(b) every 10 years.
 - (3) RO **<u>permitted/ qualified to be permitted</u>** UA to Cat. 1 or Cat. 2 quantities and Confidential Information.
 - (4) RO cannot approve other ROs (unless the RO is senior management).
 - (5) An RO applicant does not need to undergo a new background investigation if they are already certified as T&R including fingerprinting or relieved from the requirement by §37.29(a).
- (c) Informed Consent
 - Licensee obtains signed informed consent by subject prior to initiating a background investigation. (*Licensees Can Use Sample Consent Form NUREG 2155, Annex BJ*)
 - Consent includes authorization to share personal information in order to complete the background investigation.
 - Prior to taking an adverse action, the licensee provided subject an opportunity to correct any inaccurate or incomplete information.
 - N/A if T&R per§ 37.25(b) (i.e., grandfathered).

- For recertification or re-investigation.
- (2) Subject can withdraw consent at any time. Licensee requires individual to be informed that:
 - The licensee cannot proceed with remaining elements of background investigation that were not in progress.
 - Withdrawal of consent is sufficient cause for denial or termination of UA.
- (d) Personal History Disclosure
 - Individuals are aware that when applying for UA, they must disclose the required personal information to enable the RO to make a T&R determination.
 - Individuals are aware that refusal to provide or falsification of personal history information is sufficient cause for denial or termination of UA.
- (e) Determination Process
 - (1) The RO is empowered to:
 - Permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's UA based on an evaluation of the required personal history information.
 - Deny UA to any individual based on information obtained at any time during the investigation.
 - (2) Deny UA until the RO has evaluated all the information collected to meet the requirements until the individual is determined to be T&R.
 - (3) The licensee has documented the basis for concluding whether or not there is reasonable assurance that an individual is T&R.
 - (4) The RO can terminate or administratively withdraw UA based on information obtained after the T&R determination.
 - (5) Licensee maintains a list of individuals who have UA:
 - Licensee removes individuals from T&R list ASAP and within 7 working days if they no longer require or meet UA requirements, and takes prompt actions to deny UA to material
- (f) Procedures

Licensee has developed, implemented, and is maintaining written procedures for implementing the access authorization program. Procedures include:

- Notification to individuals who are denied UA;

- Provisions for the review, at the request of the affected individual, of a denial or termination of UA;
- Provisions to ensure individual informed of grounds for denial or termination of UA and allow the individual an opportunity to provide additional relevant information.
- (g) Right to correct and complete information
 - (1) Prior to a final adverse determination, the licensee provides the subject the right to correct and explain information obtained as a result of the licensee's background investigation.
 - Licensee maintains confirmation of receipt by the individual of this notification for a period of one year.
 - Individuals are made aware of challenge procedures 10 CFR § 37.23 (g)(2)
- (h) Records.
 - (1) T&R records are maintained for 3 years from the date they are no longer required for UA.
 - (2) Licensee maintains AA procedures for 3 years after they are no longer needed or portions superseded.
 - (3) Licensee retains a list of persons approved for UA for 3 years after the list is superseded or replaced.

§37.25 Background Investigations

(a) Initial Investigations

Licensee has completed a background investigation prior to granting UA

Background investigations encompass at least 7 years preceding the date of investigation.

Background investigations include:

- Fingerprinting and an FBI identification and criminal history records check 10 CFR §37.27;
- Verification of true identify using official documentation and compares that information to personal information that was provided.
- Licensee has documented the type, expiration, and identification number of the identification document, or maintains a photocopy.

- Licensee certifies in writing that documentation was properly reviewed and maintains records for review during inspection.
- Employment history verification, including military service, includes the most recent 7 years
- Verification of participation in education process during the claimed period.
- Character and reputation reference checks (plural) have been performed and are limited to whether the individual has been and continues to be T&R. Unless other references are not available, reference checks do not include close family members or anyone who resides in the individual's household.
- Licensee, to the extent possible, obtains information to corroborate that provided by the individual (e.g., seek references not supplied by the individual);
- If T&R applicant's previous employer, educational institution, etc., cannot be contacted, or cannot or will not provide information in a timely manner (e.g., >10 business days), then the licensee documents the refusal, unwillingness, or inability in the record of investigation and attempts to obtain information from an alternate source.

(b) Grandfathering.

Licensee grandfathers individuals T&R'd for UA under Fingerprint Security Orders but subjects them to a reinvestigation every 10 years.

If licensee grandfathered individual T&R'd under Part 73 or Security Order requiring fingerprints, then they document that, and subject the individual to the reinvestigation requirement.

(c) Reinvestigation

Licensee conducts reinvestigations on a 10-year frequency that consists of fingerprinting and an FBI criminal history records check.

§37.27 Requirements for Criminal History Records Checks

- (a) General Performance Objectives
 - (1) Licensee fingerprints, submits records to NRC for transmission to the FBI, and uses information received from FBI to determine T&R,

unless individual excepted under§ 37.29, or grandfathered under§ 37.25(b).

- (2) Licensee notifies individuals that fingerprints will be used to secure their criminal history record and informs the individual of procedures to revise the record or add explanations to the record.
- (3) FP not required if reinstating an individual within 365 days of termination of UA, and termination was under favorable conditions.
- (4) If granted T&R based on T&R from different program (i.e., another licensee or M&D), then the licensee obtained criminal history records check file from other program to grant UEA 10 CFR § 37.31(c).
- (5) Licensee uses information obtained as part of a criminal history records check solely for determining suitability for UA, or access to confidential information to grant UEA 10 CFR §37.31(c).
- (b) Prohibitions
 - (1) Licensee does not base final T&R determination based on information received from FBI regarding an arrest more than 1 year old with no disposition, or an arrest that resulted in dismissal of the charge.
 - (2) Licensee does use information received from FBI to infringe upon First Amendment rights, or discriminate based on race, religion, national origin, gender, or age.
- (c) Procedures for Processing fingerprint checks.

(1, 2, and 3) Licensee follows procedures outlined in 37.27 for processing fingerprint checks.

§37.29 Relief from Elements of Background Screening

- (a)(1-12) Licensee exempts individuals from fingerprinting, ID, and background screening requirements if they are individuals designated in§ 37.29 (e.g., NRC, Congress, Governor or designee, State Rad Pro, IAEA, Emergency Response personnel, commercial vehicle drivers, package handlers and transportation facilities, and individuals with active security clearance, etc.)
- (a)(13) Licensee exempts Service Provider from fingerprinting, ID, and background screening requirements if Licensee obtains written verification of T&R from Service Provider prior to granting UA and retains documentation for 3 years after no longer needing it.

(b) Licensee exempts individuals from fingerprinting and ID and criminal history records check requirements if they have been favorably adjudicated by U.S. Gov. criminal history records check with in the last 5 years, under comparable Gov't program involving fingerprinting and criminal history records checks, provided the individual makes available appropriate documentation.

Licensee has received written confirmation from the agency employer that reviewed the criminal history records check and maintains it for 3 years from the date it is no longer needed. Examples include:

NACI; TWIC; ATF; H&HS Security Risk Ass; Hazardous Material Security Threat for hazardous material endorsement for commercial drivers; CBP Free & Secure Trade (FAST) program.

§37.31 Protection of Information

- (a) Licensee maintains a system of files and written procedures for protection of collected background and personal information from unauthorized disclosure.
- (b) Licensee does not disclose the record or personal information to persons other than:
 - Subject individual, or Subject's representative; or
 - Individuals who have a need to know in the course of granting or denying UA; or
- (c) Licensee provides personal information obtained during background screening to another licensee, ONLY if
 - (1) Subject individual provides a written request;
 - (2) Recipient licensee verifies information such as name, date of birth, SSN, gender, and other physical characteristics.
- (d) Licensee makes background investigation records available to NRC to determine compliance with the regulations.
- (e) Licensee retains fingerprint and criminal history records (including data indicating no record) received from FBI, or a copy of those records, if the record has been transferred, for 3 years from the date no longer needed.

§37.33 Access Authorization (AA) Program Review

- (a) Licensee has conducted an annual review of all elements of the AA program content and implementation.
- (b) Licensee has documented the annual AA program review including recommendations for program improvement. The review includes:
 - (1) Conditions adverse to proper performance (if identified);
 - (2) Cause of the adverse condition;
 - (3) Preventative actions.
- (c) Annual AA review records are maintained for three years.
 - (1) T&R records licensee should have for each individual granted unescorted access (unless grandfathered) includes;*
 - a. Verification of Applicant's True Identify
 - b. Photocopy of ID, or record of Type, Expiration, ID No. of ID
 - c. Written certification that applicant's ID was properly reviewed
 - (2) Signed Consent Form
 - (3) Verification that applicant Meets All Background Screening Elements including
 - a. Verification of 7 years work experience
 - b. Verification of Education for the claimed period
 - c. Developed references
- (d) Fingerprint & Criminal History Records Received, Reviewed, and Approved Documented Basis Documented
- (e) Security Training
- (f) Included on List Authorized for Unescorted Access

Note: T&R records for individuals granted access to confidential information must include all the above, except for fingerprinting and a criminal history records check.

* Due to Grandfathering authorized by 10 CFR 37.25(b), T&R Records for long term (i.e., >3 years) employees who were originally T&R'd 10 CFR the ICs may simply consist of a review of the individual's work history with the licensee, a fingerprint and criminal history records check, and a documented basis

Note: The licensee can accept T&R reviews conducted by a Security Service Provider (e.g., contract security guard company) provided the Security Service

Provider provides written verification that background screening has been performed that meet the elements of $\S37.25(a)(2)$ through (a)(?) (i.e., background screening without fingerprinting)

37 Subpart C

PHYSICAL PROTECTION DURING USE

- §37.41 Establishment of a security program.
- §37.43 General security program requirements (Development and maintenance of a plan, implementing procedures, training, protection of information
- §37.45 LLEA coordination and notification
- §37.47 Establishment of security zones (Permanent and temporary, access control, Category 1 quantities)
- §37.49 Monitoring, detection, assessment, and response.
- §37.51 Maintenance, testing, and calibration. (Intrusion alarms, communication equipment, other components)
- §37.53 Requirements for mobile devices.
- §37.55 Security program review.
- §37.57 Reporting of events (LLEA, IDHS RMCP, NRC Operations Center)

§37.41 Security program

Licensee established a security program.

Applicant/licensee established security program before taking possession of Cat. 1 or Cat. 2 materials.

Licensee has established, implemented, and maintains a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Cat. 1/2 quantities.

Licensee's security program includes program features described in §§37.43, 37.45, 37.47, 37.49, 37.51, 37.53, and 37.55.

§37.43 General security program requirements

(a) Security Plan

Written Security Plan has been developed which is specific to facilities and operations and provides licensee's overall security strategy to ensure the integrated and effective functioning of the security program.

The security plan:

(1) Describes the measures and strategies used to implement requirements; and

- (2) Identifies security resources, equipment, and technology used to satisfy requirements
- (3) Security plan, and revisions, are reviewed and approved by the individual with overall responsibility for the security program.
- (4) Affected individuals instructed on revised plan before the changes are implemented
- (5) Licensees retain copies of the security plan and revisions for 3 years after the plan or portion is no longer needed
- (b) Implementing Procedures
 - (1) Licensee has developed and is maintaining written procedures that document how the requirements of this subpart and the security plan will be met.
 - (2) Written procedures and revisions have been approved in writing by the individual with overall responsibility for the security program.
 - (3) Licensee retains copies if the security procedures and revisions for 3 years after the procedure is no longer needed or superseded
- (c) *Training*
 - (1) Licensee conducts training to ensure that individuals implementing the security program possess and maintains the knowledge, skills, and abilities to carry out their assigned duties
 - (2) The training includes instruction in:
 - Security program and procedures including the purposes and functions of the security measures employed;
 - Individual's responsibility to promptly report to the licensee and LLEA any actual or attempted theft, sabotage, or diversion of Cat, 1 or Cat. 2 quantities of RAM; and
 - The appropriate response to security alarms
 - (3) Training is commensurate with individuals' potential involvement in the security of Cat. 1 and Cat. 2 quantities of RAM
 - (4) Refresher training provided within 12 months, and after significant changes, and includes:
 - Review of general training requirements;
 - Relevant security issues, problems, and lessons learned;
 - Relevant results of NRC/IDHS RMCP inspections; and
 - Results of the annual security program review.
 - (5) Licensee maintains records of the initial and refresher training for 3 years from the date of the training. Training records include dates of the training, topics covered, a list of attendees, and related information.

(d) Protection of Information

- (1) Licensee limits access to and unauthorized disclosure of their security plans, implementing procedures, and unescorted access list.
- (2) Licensee has developed and maintains written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures
- (3) Before granting access to the security plan or implementing procedures, licensee has:
 - evaluated an individual's need to know;
 - Determined that the individual is T&R 10 CFR §37.25(a)(2) –
 (a)(7)/ (i.e., Background screening without fingerprints)
- (4) Relief from T&R requirements
 - Licensee does/does not subject individuals to a background investigation who have been relieved from the requirements per§ 37.29 (a)(1) (a)(7)
- (5) Security service providers have been T&R'd by licensee based on:
 - Licensee's standard procedures, OR
 - Background investigation provided by service provider 10 CFR § 37.29 (a)(2) - (a)(7)
- (6) Licensee has documented the basis for granting individuals access to confidential information (e.g. security plan or implementing procedures).
- (7) Licensee maintains a list of individuals who have access to the security plan or implementing procedures.
 - Individuals who no longer need access to confidential information are removed from the list ASAP and within 7 days, and prompt measures taken to restrict access to confidential information.
- (8) Licensee stores its security plan and implementing procedures in a manner to prevent unauthorized disclosure. Non-removable electronic media is password protected.
- (9) Licensee retains a record for three years after no longer needed:
 - Copy of information protection procedures
 - List of individuals approved for access to the security plan and procedures.
- (10) Licensees who possess Safeguards information do so 10 CFR § 73.21 and protect the information.

§37.45 LLEA coordination

- Licensee coordinates with LLEA
- Information provided to LLEA includes:
 - (1) Description of facility and security measures
 - (2) Cat. 1 or Cat. 2 quantities of Radioactive Material
 - Notification that the licensee will request a timely armed response in the event of actual or attempted theft, sabotage, or diversion.
- Licensee notifies IDHS RMCP within 3 business days if:
- LLEA has not responded within 60 days of coordination request.
- LLEA notified licensee that they do not plan to participate in coordination activities.
- Licensee coordinates with LLEA every 12 months, or when changes adversely affect potential vulnerability to theft, sabotage, or diversion
- Licensee has documented LLEA coordination activities and maintains a record for 3 years.

§37.47 Security Zones (NEW TERM)

- Licensee uses or stores material in a permanent or temporary security zone (SZ)
- Security zones limit unescorted access only to approved individuals by:

Isolating material with a continuous physical barrier that allows access only through the established access control points; or Direct control by approved individuals at all times; or Combination of direct control and physical barriers.

- Licensee maintains continuous surveillance of Cat. 1 sources in temporary SZ, or any SZ in which barriers or intrusion detection have been disabled.
- Licensee uses approved individuals in a security zone to escort individuals who have not been approved for unescorted access.

§37.49 Monitoring, detection, assessment

(a) Monitoring and detection

- Licensee maintains the capability to continuously monitor and detect without delay all unauthorized entries into the SZ

- Licensee's detection scheme is sufficient to detect the most reasonably foreseeable means to gain unauthorized access.

Licensee can continuously monitor in the event of a loss of the primary power source or provide for an alarm and response if a loss of primary power occurs.

- Monitoring and detection performed by:

Monitored intrusion detection system linked to onsite/offsite central monitoring facility; or

Intrusion detection which annunciates locally to alert nearby personnel. or Continuously monitored video surveillance system, or

Direct visual surveillance by approved individuals located within the security zone; or

Direct visual surveillance by a licensee designated individual located outside the security zone.

- Licensee can detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

Cat. 1: Immediate detection of any attempted unauthorized removal of the radioactive material from the SZ, by electronic sensors linked to an alarm; or continuous monitored video surveillance; or direct visual surveillance.

Cat. 2: Weekly verification through physical checks, tamper indicating devices, or other means.

(b) Assessment.

- Licensee immediately assesses each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(c) Personnel communications and data transmission

- Electronics or personnel for monitoring, detection, and assessment are able to:

Maintain continuous capability among site security systems; and

Provide alternative communication and data transmission in the event of loss of primary communications or data transmission. Backup methods are not subject to the same failure mode as primary systems

(d)Response

by

- Licensee immediately responds to actual or attempted unauthorized access or theft, sabotage, or diversion of RAM, and without delay requests an armed response from LLEA.

§37.51 Maintenance, testing, and calibration

- Licensee implements maintenance and testing program for intrusion alarms and communication components, the systems are maintained in an operable condition, and are inspected and tested at the manufacturer's suggested frequency.

- Testing is performed on a 12-month frequency if not suggested manufacturer.

- Maintenance and testing records are maintained for 3 years.

§37.53 Requirements for mobile devices

- For mobile devices, licensee has two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

- For devices in or on a vehicle or trailer, licensee disables the vehicle when not under direct surveillance by licensee (unless site requirements prohibit the disabling of the vehicle).

- Licensee uses method other than removal of ignition key to disable vehicle.

§37.55 Security program review

- Licensee performs an annual review of the content and implementation of the RAM security program and takes comprehensive actions to correct non-compliances.

- Annual security review is documented and maintained for 3 years.

- Annual review conditions adverse to proper performance, the cause of the condition(s), and, when appropriate, recommend and taken corrective actions.

Note: Licensee must review both the AA and Security Program on an annual basis. Therefore, the licensee may simply combine these reviews into one annual review.

§37.57 Reporting of events

- Licensee immediately notifies LLEA after determining that an actual or attempted theft/sabotage/diversion occurred.

NRC

day

- Following LLEA notification, notifies, IDHS RMCP at [TELEPHONE #], at (301) 415-5100 ASAP, and no later than 4 hours. 10 CFR 37.57.
- Following the telephonic notification, Licensee submits a written 30-report to IDHS RMCP.

- Licensee assesses any suspicious activity related to possible theft/sabotage/diversion and makes similar notifications to LLEA and IDHS RMCP/ NRC.

10 CFR Part 37 Subpart D Physical Protection in Transit

§37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.

§37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.

§37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

§37.77 Advance notification of shipment of category 1 quantities of radioactive material.

§37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

§37.81 Reporting of events.

§37.71Transfer of Cat. 1 & Cat. 2 Quantities

- Prior to transferring a Cat. 1 or Cat. 2 quantity, the licensee verifies with the NRC license verification system or the license issuing authority, that the transferee's license authorizes receipt of the type, form, and quantity of RAM, <u>AND</u>, IE Cat. 1 quantity, the receipt address is authorized.

- Licensee documents verification (verification not required for inter- organizational transfers).

- <u>IF</u> emergency, and could not reach issuing authority/verification system inoperable, <u>THEN</u> can accept written certification by transferee that they are authorized to receive the type, form, and quantity of RAM. Must include license number, revision, issuing agency, expiration date, and for a Cat. 1 facility, authorized address. Must perform follow-up confirmation by the end of the next business day.

Verification documentation maintained for 3 years Note: The inspector uses the LVS to verify that the shipping licensee verified that the receiving licensee is authorized to receive the type, form, and quantity of material prior to shipping the material. The inspector does this by entering the LVS; Clicking on "Query Verification Activity"; Then entering licensee information and date range; the Verification Information will then be displayed. This enables the inspector to verify that the license conducted a proper verification before shipping the Cat. 1 or Cat. 2 material.

§37.73 Applicability of Physical Protection During Transit

- 73(a) Cat 1 shipments shall comply with physical protection requirements in §§ 37.75(a) and (e); 37.77; 37.79(a)(1) and (b)(1)&(c); and 37.81(a), (c), (e), (g) and (h)

- 73(b) Cat 2 shipments shall comply with physical protection requirements in §§37.75(b) through (e); 37.79(a)(2), (a)(3), (b)(2), and (c); and 37.81(b), (d), (f), (g), and (h). Also, if shipment meets 71.97(b), then also comply with 71.97.

- 73(c) Shipper responsible for security unless transferee assumes responsibility in writing.

- 73(d) Licensee import/export shipments of Cat. 1, complies with§§ 37.75(a)(2) and (e);

37.77; 37.79(a)(1) and (b)(1); and 37.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

- 73(d) Licensee import/export shipments of Cat. 1, complies with§§ 37.75(a)(2) and (e);

37.77; 37.79(a)(1) and (b)(1); and 37.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

§37.75 Shipment Preplanning & Coordination

§37.75 Definitions

- **Safe haven** means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.
- **Mobile device** means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.
- Movement control center means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.
- No-later-than arrival time means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

75(a) Cat 1 shipments

Preplan & Coordinate shipment departure & arrival times with receiving Page | 393

licensee

Preplan & Coordinate shipment departure & arrival times with governors of all transit states.

Discuss States' intention to provide law enforcement escorts

ID safe havens, and

Document preplanning and coordination activities.

75(b) Cat 2 shipments

Coordinate shipment arrival with receiving licensee.

Document preplanning and coordination activities.

75(c) Cat 2 shipments

Receiver confirms receipt with originator.

Receiver must notify originator if shipment not received by intended arrival time.

75(d) Cat 2 late shipments

Originator notifies Receiver of new "no-later-than" arrival time

75(e) Coordination and Planning Shipment records

Retain copy of record and revisions for 3 years.

Difference: The rule does not require training of the individuals instead requiring the individuals to have access to procedures.

Difference: The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

§37.77 Advance Notification of Cat. 1 Shipments

Advance notification to NRC, IDHS RMCP and governor of affected states

77(a) Notification in writing

To governor: by mail, postmarked 7 days before transport, or other means, at least 4 days prior to transport.

To NRC, by mail, secure email to RAMQCSHIPMENTS@nrc.gov,

To IDHS RMCP by mail or secure email [ADD EMAIL]

77(b) Advanced Notification Required Information

Name, address, and telephone number of the shipper, carrier, and receiver;

License numbers of the shipper and receiver;

Description of RAM contained in the shipment, including radionuclides and quantity;

Point of origin of the shipment and the estimated time and date that shipment will commence;

Estimated time and date that the shipment is expected to enter each State along the route;

Estimated time and date of arrival of the shipment at the destination; and

Point of contact, with a telephone number, for current shipment information.

77(c) Shipment Notification revisions

Licensee notifies IDHS RMCP /NRC and governors regarding shipment revisions as soon as possible.

77(d) Shipment Cancellation Notification

Licensee notifies IDHS RMCP /NRC and governors regarding shipment cancellation as soon as possible.

77(e) Cat. 1 Shipment Record Retention

Licensee retains copies of advance notifications and revisions for 3 years.

77(f) Cat. 1 Shipment Protection of Information

State Officials, State employees, and others (licensee or not), who receive schedule information (37.77(b)) protect information against unauthorized disclosure as specified in 73.21.

§37.79 Physical Protection of Cat. 1 & 2 Shipments

79(a)(1) Cat. 1 Shipments by road

Licensee establishes a movement control center.

Maintains position information from a remote location.

Monitors shipments 24 hours a day, 7 days a week;

Has ability to communicate immediately with the appropriate law enforcement agencies.

Establishes redundant communications to enable transport to contact escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

Utilizes continuous monitoring by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center.

Movement control center provides positive confirmation of the location, status, and control over the shipment.

Movement control prepared to promptly implement preplanned procedures in response to deviations from authorized route or upon notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. Procedures include identification of and contact information for the appropriate LLEA along the shipment route.

Individual accompanies driver when driving period greater than maximum in 24 hours as established by DOT Federal Motor Carrier Safety Administration (may be another driver)

Licensee who made arrangements for Cat. 1 Shipment has developed written normal and contingency procedures to address:

Notifications to the communication center and law enforcement agencies;

Communication protocols that include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost; Loss of communications; and Responses to an actual or attempted theft or diversion of a shipment.

Difference: The rule does not require training of the individuals instead requiring the individuals to have access to procedures.

Difference: The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

79(a)(2) Licensee Cat. 2 Shipments by road

Licensee maintains constant control and/or surveillance during transit and has capability for immediate communication to summon assistance.

79(a)(3) Carrier Cat. 2 Shipments by road

Carrier has established package tracking systems that allows the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

Carrier maintains constant control and/or surveillance during transit and has the capability for immediate communication to summon appropriate response or assistance; and Carrier has established tracking systems that requires an authorized signature prior to releasing the package for delivery or return.

79(b) Cat. 1 Shipment by rail

Rail shipment monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center.

Rail communications center provides positive confirmation of the location of the shipment and its status.

Rail communications center implement preplanned procedures in response to deviations from the authorized route or to a notification of

actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures include contact information for the appropriate LLEA along the shipment route

Include periodic reports to the communications center at preset intervals.

79(b) Cat. 2 Shipment by rail

Carrier has established package tracking system which allows the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

Carriers maintains constant control and/or surveillance during transit and has capability for immediate communication to summon appropriate response or assistance; and

Carrier has established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

Difference: The rule does not require procedures or training as the railroad will have its own training and procedures that must be followed.

Difference: The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

79(c) Cat. 2 Rail Shipment Investigations

Immediately conducts investigation, in coordination with the receiving licensee, of shipment that has not arrived by the designated no-later-than arrival time.

§37.81 Reporting of Events

81(a) Event Reporting Cat 1 Shipments

Notifies LLEA (last confirmed location), IDHS Watch Desk, and NRC Ops Center within 1 hour of lost or missing Cat. 1 shipment

Licensee provides IDHS Watch Desk and NRC on status of investigation.

81(b) Event Reporting Cat 2 Shipments

Notifies IDHS Watch Desk and NRC Ops Center within 4 hours of lost or missing Cat. 2 shipment.

Licensee provides IDHS Watch Desk and NRC updates on status of investigation.

Licensee immediately notifies IDHS Watch Desk and NRC Ops Center, if after 24 hours, a lost or missing shipment has not been located and secured.

81(c) Event Reporting Cat 1 Shipments.

Notifies designated LLEA upon discovery of actual theft/sabotage/diversion of Cat. 1 quantity. Notifies IDHS Watch Desk and NRC Ops center ASAP after LLEA notification.

81(d) Event Reporting Cat 2 Shipments

Notifies IDHS Watch Desk NRC Ops center ASAP upon discovery of actual theft/sabotage/diversion of Cat. 2 quantities.

81(e) Event Reporting Recovery of Cat 1 Quantity

Notifies IDHS Watch Desk and NRC Ops center & LLEA ASAP upon recovery of any lost or missing Cat. 1 quantity of RAM.

81(f) Event Reporting Recovery of Cat 2 Quantity

Notifies IDHS Watch Desk and NRC Ops center & ASAP upon recovery of any lost or missing Cat. 2 quantities of RAM.

81(g) Event Reporting 30 Day Report Following Telephonic Notification

Telephonic notifications required by paragraphs (a) through (d) followed within 30 days by a written report.

81(h) Event Reporting Additional Substantive Information

After filing a 30-day report, if licensee learns of additional substantive information, on the loss or theft, then licensee shall file that information within 30 days.

Subpart F – Records §37.101 Form of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy authenticated by authorized personnel and is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§37.103 Record retention

Difference: The rule does not require records to be maintained after the license is terminated.

Appendix A to Part 37-Category 1 and Category 2 Radioactive Materials

Table 1 - Category 1 and Category 2 Threshold¹

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Difference: The radioactive material and thresholds are the same; however, the rule provides the Ci value to 3 figures

Attachment 1: Reminders

New Procedures & Documents the Licensee Must Maintain

Access Authorization Procedures & Documents

Photocopy of ID, or record of Type, Expiration, ID No. of ID

Written certification that applicant's ID was properly reviewed

Signed Consent Form

Documented basis for concluding an individual is T&R and can be granted access to the security plan and implementing procedures

Documented basis for concluding an individual is T&R and can be granted unescorted access to the security zone.

List of individuals authorized to access confidential information

List of individuals authorized for unescorted access to the security zone(s)

Security Plan

Implementing Security Procedures

Procedures for the Protection of Confidential Information

LLEA Information (coordination documents)

Procedures for Shipping (e.g., Notifications and Coordination)

Attachment 2

Part 37 Time Requirements

Time Requirements: Immediate

- Must maintain capability to continuously monitor and detect without delay all unauthorized entries into security zones."
- ▶ Immediately Detect Attempts to remove Cat. 1 Material
- Prompt measures must be taken to ensure an individual who no longer needs unescorted access is prevented from gaining access.

Individuals who no longer require access must be removed ASAP from access authorization list.

Time Requirements: 4 Hours

► Following LLEA notification, notifies IDHS RMCP ASAP at [TELEPHONE #], and no later than 4 hours.

Time Requirements: 3 Days

- ► Notify IDHS RMCP within 3 days, if
 - LLEA has not responded to a coordination request in 60 days, OR
 - LLEA notifies licensee that the LLEA does not plan to participate in coordination activities.

Time Requirements: 4 & 7 Days

- Advanced Notification to IDHS RMCP /NRC & Governors of Cat. 1 Shipment:
 - 4 Days Phone or Email
 - ▶ 7 Days if Mailed.
- When no longer required, Remove individual from access authorization list ASAP, but no later than 7 working days.

Time Requirements: Weekly

• Perform Weekly Verifications to ensure Cat. 2 Material is Present

Verification through physical checks, tamper indicating devices, etc.

Time Requirements: 10 Days

Time licensee allows individual to challenge FBI & Criminal History Records Check: 10 days.

If a previous employer, educational institution, etc. fails to provide information within 10 business days (or unwilling or unable), licensee can document that and attempt to obtain the information from an alternate source.

Time Requirements: 90 Days

Licensee notified IDHS RMCP in writing at least 90 days before aggregating a Cat. 2 quantity.

Time Requirements: 12 Months

- Security Refresher training (or when significant changes occur)
- ► LLEA Coordination (or when significant changes occur)
- ► Alarm Testing (If there is no manufacturer's suggested frequency)

Time Requirements: Annually

- Each licensee shall periodically (at least annually) review:
 - ► The access control program content and implementation, <u>AND</u>
 - The security program content and implementation.

Time Requirement 365 Days

- Fingerprinting not required if individual returns to same facility within 365 days, and termination was under favorable conditions.
- 1 Year- Prior to Background Screening Adverse Action, Must Notify Individual and Provide Opportunity to Correct Record. Record of Confirmation of receipt Must be Maintained by Licensee for 1 Year
- Licensee does not base final T&R determination based on information received from FBI regarding an arrest more than 1 year old with no disposition, or an arrest that resulted in dismissal of the charge.

Time Requirement 3 Years

- ► Maintain for 3 Years:
 - Implementing Security Procedures after no longer needed, and superseded portions.
 - ► Training, Initial and Refresher
 - ► Information protection procedures
 - List of individuals approved for access to the security plan or implanting procedures.
 - Alarm System maintenance and testing activities
 - ▶ Results of annual review of the security program
 - Efforts to verify that a receiving licensee is authorized to receive material.
 - ► Transportation: documentation for preplanning and coordination
 - Copy of the advance notifications and revisions.

Time Requirement 5 Years

Fingerprinting, and the identification and criminal history records checks not required for individual favorably adjudicated under comparable U.S. Government criminal history records check within the last 5 years.

Time Requirement 7 Years

 Background Investigations - 7 Years, or time since 18th Birthday, whichever is shorter

Time Requirement 10 Years

- Reviewing Official Recertification
- ► T&R Recertification

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 4.2, Revision 0: Tracking Inspection Reports & Correspondence

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
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None

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to tracking inspections that are performed, completion of the inspection report, and transmittal of correspondence, if any.
- 1.1.2 Tracking shall begin upon notification from the Health Physicist that an inspection has become due and ends with completion of an inspection report and:
 - 1.1.2.1 The issuance of a clear inspection form Attachment 2.4-4 **Clean Inspection Report**, or
 - 1.1.2.2 Transmittal of a Department letter or other form designating a clear inspection such as an RMCPP 2.4 Attachment 2.4-1 Department Form 591M Safety Inspection Report and Compliance Inspection, Attachment 2.4-4 Clean Inspection Report (or other documentation of "no response required" by the licensee due to action already taken), or
 - 1.1.2.3 The final letter documenting acceptance of the proposed corrective actions.

1.2 References

1.2.1 290 IAC 3

1.3 Files

Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records.

2.0 **RESPONSIBILITY**

2.1 Health Physicist (HP)

- 2.1.1 Prepares a list from Web-Based Licensing (WBL) on a monthly basis for the Senior Health Physicist (S/HP) of inspections due for the next 6 months in accordance with the Priority Codes in RMCPP 1.1 Attachment 1.1-6 Inspection Priority Codes Assigned to Program Codes.
- 2.1.2 Maintains files in WBL related to the inspections conducted.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Responsible for tracking dates of performance for:
 - 2.2.1.1 The Inspection
 - 2.2.1.2 Correspondence Sent to the Licensee
 - 2.2.1.3 Issuance of Clear Inspection Form
 - 2.2.1.4 Reply due Dates for Licensee Requests for Information
 - 2.2.1.5 Reply from Licensee, and
 - 2.2.1.6 Final Acceptance and Inspection Closure
- 2.2.2 Ensuring the overall tracking activities of inspection staff.
- 2.2.3 Maintaining the *Inspections Due for the Next 6 Months-By priority Report* and ensuring inspections are completed when due.

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Provides guidance to the Radioactive Materials Program staff relative to inspection tracking.
- 2.3.2 May assume the duties of the S/HP or assign to others as necessary.

3.0 PROCEDURE

3.1 Assignment of Inspection

Inspections will be performed by Health Physicists based on workloads, experience levels, and the priority assigned to the inspection. Health Physicists should review the *Inspections Due for the Next 6 Months-By Priority Report* and RMCPP 2.1 *Scheduling of Inspections* to determine inspection options.

3.2 Performance of Inspection and Initiation of Tracking

Once the inspection has been performed, the Health Physicist informs the Senior Health Physicist of the licensee's name, license number, the date of the inspection, and the name(s) of all inspectors. The exit meeting date may be used for inspections longer than one day. The Health Physicist enters this information into Web-Based Licensing

3.3 Tracking Inspection Report Completion and Transmittal of

Correspondence.

- 3.3.1 For routine inspections, the time period for completion of the inspection checklist/report and transmittal of correspondence to the licensee, if any, is 30 days (see note below).
- 3.3.2 If a clear inspection form was issued, then no other correspondence will normally be sent to the licensee (a Form 591M may have also been left at the time of the exit interview provided there are no findings, an NCV, or Severity Level IV).
- 3.3.3 The Health Physicist will enter the date the inspection report was completed and the date the inspection letter was sent.
- 3.3.4 The date the inspection reply is due should be obtained from the letter and entered into the Radioactive Materials Program WBL database for those licensees who must respond to a Notice of Violation.

Note: Escalated enforcement actions may require a faster tum-around time (i.e.; within 10 days)

3.4 Receipt of Corrective Action(s) and Negative Evaluation or Missed Deadline

- 3.4.1 **Receipt of Corrective Action(s):** Once the corrective actions are received, the receipt date should be logged into the Radioactive Materials Program WBL database. Each Health Physicist shall be responsible for checking the pending inspection completions report to determine the current status of received correspondence. An evaluation should be performed as soon as possible by the Health Physicist, but no longer than 30 days, from receipt of the information.
- 3.4.2 **Negative Evaluation:** If the corrective action(s) are not satisfactory or the information is incomplete, then a telephone conference call should be conducted. Subsequently, a follow-up letter or email should be sent to the licensee requesting additional information by a specified date and documenting the results of the conference call. The

Health Physicist should enter the specified due date into the Radioactive Materials Program WBL database.

3.4.3 **Missed Deadline:** If a deadline is missed, the Health Physicist shall, as soon as possible, follow up with the licensee to request submittal of the corrective action information. A new due date for the requested information should be established. The Health Physicist should modify the 'Inspection Reply Due' date upon request of the Senior Health Physicist. If deadlines are missed more than twice, the S/HP and RCPD may consider responses including enforcement actions, reduced inspection frequency or increasing the severity level or civil penalty of a violation.

3.5 Receipt of Acceptable Information and Close-out of Inspection Tracking

- 3.5.1 **Receipt of Acceptable Information:** Once the licensee provides the corrective actions, the receipt date should be logged into the Radioactive Materials Program WBL database. Each Health Physicist shall be responsible for checking the pending inspection completions report to determine the current status of received correspondence.
- 3.5.2 **Close-out of Inspection Tracking:** If the corrective action(s) are satisfactory, then a 'Close Out' letter should be sent to the licensee, normally within 30 days, stating that the action(s) will be evaluated on the next inspection. Once this final reply acknowledgement letter is sent and the date logged in the Radioactive Materials Program WBL database by the Health Physicist, the tracking is closed out for the licensee. The Health Physicist should file the inspection report and related correspondence in the Department license file and WBL.

4.0 RECORDS

- 4.1 Clear inspection form or Notice of Violation-filed in Department inspection file
- 4.2 Licensee Corrective Actions/Reply, if applicable filed in Department license file
- 4.3 RMCP letter accepting Corrective Actions/Reply-filed in Department

license file

- 4.4 Inspection Report(s) filed in Department license file.
- 4.5 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

5.0 ATTACHMENTS TO RMCPP 4.2

None

4.5 Enforcement Program Elements

Section 4.5.1 of the Handbook for Processing an Agreement addresses routine enforcement procedures and Section 4.5.2 addresses escalated enforcement procedures. The primary documentation for both for the Indiana Radioactive Materials Program is identical and found in this application in one document in Section 4.5.2: RMCPP 2.5 *Enforcement, Escalated Enforcement and Administrative Actions*. RMCPP 2.5 is modeled after the NRC Enforcement Manual NUREG-1600 and the NRC Enforcement Policy to help assure compatibility between Indiana's Agreement Program and the NRC.

4.5.1 Routine Enforcement Procedures

RMCPP 2.5 *Enforcement, Escalated Enforcement and Administrative Actions* describes how the Indiana Department of Homeland Security Radioactive Materials Control Program will enforce its regulations. This procedure is designed to be a fair and impartial administration of regulatory law. Indiana scales the enforcement actions to the seriousness of the violation and establishes standard methods of communicating sanctions to the licensee. In particular, the State gives written notice using standardized wording and formats. The Department's legal counsel shall review the wording and format of these notices.

Because RMCPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions describes both routine and escalated enforcement procedures, it is attached to this application once, in Section 4.5.2.

4.5.2 Escalated Enforcement Procedures

Escalated enforcement procedures are described in the same document where routine enforcement procedures are described, RMCPP 2.5 *Enforcement and Administrative Actions*. Escalated enforcement procedures are designed for serious or repeated violations of regulatory requirements. The Indiana Radioactive Materials Control Program will use the escalated enforcement actions to supplement routine enforcement actions. Escalated enforcement actions include:

- Administrative or civil monetary penalties.
- Modification, suspension, or revocation of the license; and
- Referral for criminal prosecution.

As with routine enforcement actions, escalated enforcement actions are scaled to the seriousness and the licensee is notified of the escalated enforcement actions in writing using standard wording and format and coordinated with legal counsel. Escalated enforcement sanctions are more severe than those used in routine enforcement. Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 2.5, Revision 0 Enforcement, Escalated Enforcement, and Administrative Actions

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- 4.2 Assessment for Escalated Enforcement Action
- 4.3 Escalated Enforcement

5.0 Attachments to RMCPP 2.5

 $2.5\mathchar`-1$ Examples of Violations That May Be Cited on a Clear Inspection

2.5-2 Examples of Severity Level I – IV Violations

1.0 General Information

1.1 Purpose

The purpose of the Indiana Department of Homeland Security Radioactive Materials Control Program (RMCP) is to support the overall safety mission of protecting the public health, safety, and environment through appropriate enforcement actions. Enforcement actions should be used to:

- 1.1.1 Deter noncompliance by emphasizing the importance of regulatory compliance.
- 1.1.2 Encourage prompt identification and comprehensive action following the occurrence of violations.

1.2 Applicability

Enforcement actions are dependent upon the circumstances of each individual case of violation. The implementation of specific enforcement actions requires the exercise of discretion after consideration of all available alternatives. However, under no circumstances will licensees unable or unwilling to achieve and maintain adequate levels of safety be permitted to conduct licensed activities.

1.3 Statutory Authority

Statutory authority for promulgation and implantation of enforcement procedures is contained in Indiana law at I.C. § 10-19-12-6.

1.4 References

- 1.4.1 NUREG-1600, General Statement of Policy and Procedures for NRC Enforcement Action
- 1.4.2 NRC Enforcement Manual.
- 1.4.3 NRC Enforcement Policy (ADAMS Accession No. ML 23333A447).

1.4.4 Indiana Radioactive Materials Rule

1.5 Definitions

- 1.5.1 Administrative Action: Action implemented in addition to formal enforcement actions to supplement the enforcement program.
- 1.5.2 Aggregation of Violations: Group of violations that may be evaluated in the aggregate, providing the violations have the same underlying cause, resulting in a violation of a higher severity level. For example, a group of Severity Level IV violations may be evaluated in the aggregate and result in a Severity Level III violation, or a group of Minor Violations, if evaluated in the aggregate, may result in a Severity Level IV violation. Severity Level II and III violations are normally not aggregated except in the most egregious cases.
- 1.5.3 Civil penalty: Any monetary penalty levied on a licensee or registrant because of violations of statues, regulations, license, or registration certificates, but does not include criminal penalties.
- 1.5.4 Civil Enforcement: An action brought by the Indiana Department of Homeland Security, pursuant to IC 10-19-18, due to a violation of IC 10-19-12 or any rules, permits, or order issued by the Indiana Department of Homeland Security, or due to a public health hazard or public health risk.
- 1.5.5 Discretion: The Department's authority to either escalate or mitigate enforcement sanctions to ensure that the resultant enforcement action appropriately reflects the level of the Department's concern regarding the violation at issue and conveys the appropriate message to the licensee

- 1.5.6 Enforcement Action: Actions taken by the Department to enforce the provisions of statute, rules, permits or orders, including issuing a Notice of Violation.
- 1.5.7 Escalated Enforcement Action: An enforcement action for any Severity Level I, II, or III violations. Violations with willful aspects (i.e., careless disregard or deliberate misconduct) will typically be considered for escalated enforcement action may include...
- 1.5.8 Inspector: A Senior Health Physicist, Health Physicist, or Radiation Control Program Director qualified to plan, perform, and document an inspection of a specific category of license and where appropriate, to prepare enforcement documents and review the response to such a document for adequacy.
- 1.5.9 Lead Inspector: A Senior Health Physicist or a Radiation Control Program Director qualified to plan, supervise, and document an inspection by a team of inspectors. An inspector shall not act as a lead inspector in any category of license that they are not qualified, unless evaluated or supervised by a qualified inspector. A lead inspector is responsible for review of licensee's reply to a Notice of Violation (NOV)
- 1.5.10 Licensee Official: A first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on the license.
- 1.5.11 Notice of Violation (NOV): A formal written notice setting forth one or more apparent violations of a requirement following an inspection. An NOV formally documents violations and is typically the only enforcement action taken unless the criteria for escalated enforcement are met.
- 1.5.12 Pre-decisional Enforcement Conference: A meeting between the IDHS RMCP and the licensee that may be

called whenever the Department becomes aware of potential violation(s) which may warrant escalated enforcement action. The purpose of the conference is to allow the Department to obtain additional information necessary to determine the level of enforcement action needed. A pre-decisional enforcement conference takes place prior to the issuance of a NOV.

- 1.5.13 Repetitive Violation: A violation that could have been prevented by a licensee's action to correct a previous violation occurring either (1) within the past two years of the inspection at issue, or (2) during the period between the last two inspections, whichever is longer.
- 1.5.14 Requirement: A legally binding obligation such as a statute, regulation, license condition, or order.
- 1.5.15 Routine Inspection: A periodic, comprehensive inspection performed at a specified frequency, based on the activities authorized under the license.
- 1.5.16 Severity Level: Categorization of violations of license requirements based on the seriousness of the violation. One of four levels of severity is assigned to a violation, ranging from Severity Level I, signifying the most significant, to Severity Level IV, the least.
- 1.5.17 Special Inspection: Those inspection activities where special guidance is needed. These activities include but are not limited to: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning; (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary jobsite or filed inspections; (5) team inspections; (6) inspections of abandoned licenses; and (7) general licensee's program inspections.
- 1.5.18 Willfulness: There are two types of willfulness:
 - 1.5.18.1 <u>Deliberate Misconduct</u>: occurs when an individual voluntarily and intentionally (1) engages in

conduct that the individual knows to be contrary to a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license; or (2) provides materially inaccurate or incomplete information to a license.

1.5.18.2 <u>Careless Disregard</u>: refers to situations in which an individual acts with reckless indifference to at least on of three things: (1) the existence of a requirement, (2) the meaning of a requirement, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless, proceeds to engage in conduct that the individual knows may cause a violation. Although aware that the action might cause a violation, the individual proceeds without ascertaining whether a violation would occur.

2.0 **RESPONSIBILITIES**

2.1 Health Physicist (HP)

- 2.1.1 Conducts routine inspections and special inspections as defined in Section 1.5, in with applicable procedures, rules, and instructions.
- 2.1.2 Categorizes and documents any apparent violations of license conditions observed during the inspections.
- 2.1.3 Reports the violations to the Radiation Control Program Director (RCPD).
- 2.1.4 Generally, Health Physicists perform both licensing and inspection functions.

2.2 Senior Health Physicist (S/HP)

- 2.2.1 Reviews all inspection reports or delegates this review to an appropriate designee.
- 2.2.2 Approves the issuance of any proposed NOVs.
- 2.2.3 Determines if the threat to health and safety described in any NOVs warrants the prompt issuance of an order.
- 2.2.4 Determines whether a pre-decisional enforcement conference is conducted prior to issuing an NOV to allow the licensee an opportunity to demonstrate that corrective actions have been made or will be made in order to maintain compliance with Indiana's Radioactive Materials Control Program regulations.
- 2.2.5 Makes recommendations pertaining to the exercise of discretion in any proposed enforcement action.
- 2.2.6 Forwards, as appropriate, any escalated enforcement recommendations to the Radiation Control Program Director (RCPD)

2.3 Radiation Control Program Director (RCPD)

- 2.3.1 Reviews recommendations forwarded from the S/HP and, as appropriate, approves, modifies, or denies the recommendation for assessment and issuance of forfeiture, issuance of an order, or both.
- 2.3.2 For the actual issuance of an escalated enforcement action, responds as necessary to a request for hearing by a licensee made in accordance with *ADD IC#*
- 2.3.3 In the event of licensee's failure to pay an imposed penalty, requests enforcement assistance from legal counsel.

3.0 Enforcement Actions

This section describes the various ways the Department can disposition violations. The manner in which a violation is disposed is intended to reflect the seriousness of the violation and the circumstances involved. All available escalated enforcement actions should be reviewed by legal counsel for wording and format, provided a means of tracking the completion of enforcement actions, and assured to be a fair and impartial administration of regulatory law.

Enforcement Process

Minor Violations: No Enforcement Action

Minor violations that are below the significance of Severity Level VI violations are typically not the subject of enforcement action and are not described in inspection reports. Nevertheless, minor violations must be corrected. Violations as indicated in Attachment 2.5-1 **Examples of Violations That May Be Cited on a Clear Inspection** if they are non-repetitive and non-willful and the licensee has self-implemented corrective actions. Minor violations are not the subject of formal enforcement action.

Non-Escalated Enforcement Process: Licensees and Non-Licensees Severity Level IV Violations

Violations as exemplified in Attachment 2.5-1 may be cited on a clear inspection. If the licensee failed to self-identify and/or correct the nonconformance, and/or the violation was willful, and/or if the licensee failed to restore compliance in a reasonable amount of time after a violation was identified, then a Notice of Violation (NOV) is issued. Restoring compliance includes those actions taken to stop an ongoing violation from continuing and does not include those actions necessary to address root causes and prevent recurrence.

Escalated Enforcement Process: Severity Level I, II and III violations with and without civil penalty.

An NOV including Severity Level I, II, or III violations is considered escalated enforcement action. Escalated NOVs are normally issued subsequent to pre-decisional enforcement conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report. Examples of Severity Level I, II and III violations are included in Attachment 2.5-2 **Examples of Severity Level I – Level IV Violations.**

The Department assesses significance by assigning a severity level to all violations, for example:

- Severity Level I violations are those that resulted in or could have resulted in serious safety or security consequences (e.g., violations that created the substantial potential for serious safety or security consequences or violations that created the substantial potential for serious safety or violations that involved systems failing when actually called on to mitigate a serious safety or security event).
- Severity Level II violations are those that resulted in or could have resulted in significant safety or security consequences (e.g., violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serious or security event.)
- Severity Level III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).
- Severity Level IV violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences).
- Minor (non-cited) violations that are listed in Attachment 2.5-1
 Examples of Violations That May Be Cited on a Clear
 Inspection, e.g., failure of the Radiation Safety Committee to
 meet as scheduled, or licensee observed eating, drinking, etc. in
 laboratories where un-sealed radioactive materials are stored but
 not being used.

3.1 Notice of Violation (NOV)

- 3.1.1 A NOV is issued to a licensee and non-licensee (e.g., contractors) when items of noncompliance with regulations have been determined or suspected. A NOV is a formal written notice setting forth one or more apparent violations of a requirement, following an inspection. The NOV formally documents violations and is typically the only enforcement action taken unless the criteria for escalated enforcement are met.
- 3.1.2 The recipient of an NOV is normally required to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken by the licensee or other persons and the results achieved; (2) the corrective steps that have been taken by the licensee or other persons and the results achieved; (3) the corrective steps planned to prevent reoccurrence; and (4) the date when full compliance will be achieved.
- 3.1.3 All or portions of the written response may be waived to the extent that relevant information has already been provided in writing or documented in the inspection report or inspection record.
- 3.1.4 A civil penalty may be issued in conjunction with a NOV.
- 3.1.5 An NOV shall be revised if the determination is later made that the violations were Severity Level I, II, or III, rather than the originally assigned severity level, necessitating an escalated enforcement action.
- 3.1.6 A follow-up inspection must be conducted within six months of receipt of a licensee's corrective action following an escalated enforcement action.

3.2 Pre-decisional Enforcement Conference

- 3.2.1 A pre-decisional enforcement conference is a conference held between the Radioactive Materials Control Program with a licensee for violation of Department regulations as determined by inspection and is convened prior to implementation of an escalated enforcement action if considered warranted by the Department. The purpose of this conference is to gather further information from the licensee and will assist the Department in determining the appropriate enforcement actions. In this situation, the licensee is informed that a potential violation of Department regulations has occurred, and the licensee is being granted an opportunity to discuss the findings and resolutions with the Department. This conference shall accomplish, at the least, a mutual understanding between the licensee and the Department, of:
 - Facts, root causes, and missed opportunities associated with the apparent violations;
 - Any prior corrective actions taken or planned; and
 - The significance of the issues and the need for lasting comprehensive corrective action.
- 3.2.2 The Department will normally provide an opportunity for an individual to address apparent violations before they take escalated enforcement action. Whether an individual will be provided an opportunity for a pre-decisional enforcement conference or an opportunity to address an apparent violation in writing will depend on the circumstances of the case; including the severity of the issue, the significance of the action the Department is contemplating, and whether the individual has already had an opportunity to address the issue.
- 3.2.3 If the Department concludes that it has sufficient information to make an informed enforcement decision involving a licensee, contractor, or vendor, a pre-decisional enforcement conference will not be held. If a predecisional enforcement conference is not held, the licensee may be given an opportunity to respond to a documented

apparent violation (including its root causes and a description of planned or implemented corrective actions) before the Department takes enforcement action.

3.2.4 If a violation requires immediate action to protect public health and safety, an emergency order will be issued before the conference. In these cases, a conference may be held after the emergency order is taken.

3.3 Civil Penalty

- 3.3.1 A monetary penalty is intended to deter future violations by both the involved licensee and other licensees conducting similar activities. It emphasizes the need for licensees to identify and report violations and to take prompt comprehensive corrective action.
- 3.3.2 Civil penalties may be levied pursuant to IC 10-19-12-18 for any violation of Title 10, or rules, permits, or orders issued pursuant to the title. In determining whether to levy a civil penalty, the Director may consider the following:
 - The imposition on the licensee of any escalated enforcement action within the last two years or last two inspections, whichever is longer;
 - Any credit merited to the licensee for identification of violations or non-compliances;
 - Any licensee corrective action taken or planned related to the identification; and,
 - Whether, in view of all circumstances surrounding the violation, the exercise of discretion is warranted.

3.4 License Suspension and Revocation

3.4.1 The Director may, after notice and opportunity for a hearing, suspend, revoke, or modify a license pursuant to IC 10-19-12-6.

- 3.4.2 Types of Actions:
 - 3.4.2.1 <u>Suspension</u>: A suspension (temporary) requires time-limited suspension of all licensed activity. Normally, a licensed activity is only suspended, or a suspension is prolonged, for failure to comply with requirements where such failure is willful, or the corrective action taken or planned is inadequate. The Director may suspend a license when:
 - The license holder submitted materially false or inaccurate information;
 - The license holder has violated any material requirement, restriction, or condition of any license, rule, statute, or order; or
 - There is a change in any condition that requires either a temporary restriction, limitation, or elimination of the licensed use. IC 10-19-12-6
 - 3.4.2.2 <u>Revocation</u>: The Director may revoke (permanent) the license authorizing use of radioactive materials when:
 - A licensee is unable or unwilling to comply with license requirements;
 - A licensee refuses to correct a violation;
 - A licensee does not respond when required by an issued NOV;
 - A licensee refuses to pay an applicable fee under Department rules; or
 - Any condition exists which would warrant refusal of a license on an original application. IC 10-19-12-6

3.5 Orders

- 3.5.1 Health Orders: The Department shall, for the protection of the occupational health and safety, public health and safety, and environment . . . issue such orders . . . as may be necessary. Ind. Code § 10-19-12-5(c)(4).
- 3.5.2 Emergency Health Orders: Whenever the department finds that an emergency exists requiring immediate action to protect public health and safety, the department may . . . issue emergency orders under IC 4-21.5-5-4 to address the emergency. Ind. Code § 10-19-12-14(f).

3.6 Assurance of Discontinuance - Reserved

3.7 Administrative Actions

3.7.1 Confirmatory Action Letter (CAL)

- 3.7.1.1 A CAL, issued immediately following an inspection, is a letter confirming a licensee's verbal agreement to take the necessary actions to correct significant concerns regarding health and safety, security, or the environment.
- 3.7.1.2 Issuance of a CAL requires the concurrence of the S/HP and RCPD.
- 3.7.1.3 Issuance of a CAL does not preclude the implementation of an escalated enforcement action, if deemed warranted by the Department.

3.8 Enforcement Actions Against Non-Licensees

3.8.1 Any individual may be subject to enforcement action if the individual (1) deliberately causes or would have caused, if not detected, a licensee to be in violation of any regulation

or order, any term, condition, or limitation of any license issued by the Director related to licensed activities or (2) deliberately submits materially inaccurate or incomplete information to the Department, a licensee, an applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license. The Director has authority pursuant to IC 10-19-12-16 to take enforcement action against non-licensees. This includes contractors and subcontractors, holders of Department approvals (e.g., emergency and operating procedures and quality assurance program approvals) or applicants for any of them, and to employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to Department regulation. The prohibitions and sanctions for any of these people who engage in deliberate misconduct or knowing submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct.

- 3.8.2 When inspections determine that violations or Department requirements have occurred, enforcement action will be taken. Notices of Violation and orders will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements.
- 3.8.3 Notices of Violation will be issued for any violations of Indiana Radioactive Materials Control Program Rules. Nonlicensees in violation of the statute or rule shall be subject to civil penalties, impounding of materials, or injunctive relief a proved in IC 10-19-12-18.

3.9 Exercise of Discretion

3.9.1 Notwithstanding the normal guidance contained in this policy, the Department may choose to exercise discretion and either escalate or mitigate enforcement actions within the Department's statuary authority to ensure that the

resulting enforcement action takes into consideration all of the relevant circumstances of the particular case.

3.9.2 If licensee management is directly or indirectly involved in the violation, an increase in the amount of the penalty may be imposed. However, if licensee management is not involved in the violation, that information alone shall not be used to mitigate the penalty sought by the Director.

4.0 Enforcement Procedures

4.1 Disposition of Inspection Findings

- 4.1.1 Determination of Severity Level: Determination of the severity level of a violation requires consideration to be given to the seriousness of the regulatory requirement violated and whether it results in or has the potential to result in safety or security consequences, as described in section 3.0.
- 4.1.2 In addition, the severity level may be escalated depending on the willful and/or repetitive nature of the violation.
- 4.1.3 In determining the severity level of a violation involving willfulness, consideration should be given to the position and responsibilities of the person(s) involved, the significance of the underlying violation, the intent of the violator(s), and any economic advantage gained.
- 4.1.4 If the licensee refuses to correct a minor violation in a reasonable time such that it continues, then the resulting vio9lation should be assigned to at least Severity Level IV. Upon conclusion of an inspection, staff inspection personnel shall review the preliminary findings and determine the severity level of the violation.

4.2 Assessment for Escalated Enforcement Action

- 4.2.1 <u>No Violations or Severity Level IV Violations</u>: If inspection findings result in no violations, no Severity Level IV violations or violations that have been addressed by the licensee, then inspection personnel shall issue to the licensee, a Department Inspection Form 591M or a Department letter documenting the clean inspection. If inspection findings result in any Severity Level IV violations that are not addressed by the licensee and/or that have not been corrected, inspection personnel should issue to the licensee a Department letter and/or a Notice of Violation.
- 4.2.2 <u>Severity Level IV Violations with willfulness or repetition</u>: If inspection findings result in any Severity Level IV violations with willfulness or where violations are repetitive, then inspection personnel shall upgrade the violations to Severity level III and issue a Notice of Violation to the licensee.
- 4.2.3 <u>Severity Level III, II or I Violations</u>: If inspection findings result in any Severity Level III, Severity Level II, or Severity Level I violations, then inspection personnel shall, as soon as possible, refer the findings to the S/HP. The S/HP shall confer with the RCPD for determining the extent of escalated enforcement action, and whether a predecisional enforcement conference is warranted.

4.3 Escalated Enforcement

- 4.3.1 The Department considers violations categorized at Severity Level I, II, or III to be significant regulatory concern.
- 4.3.2 If the application of the enforcement procedure of this RMCPP does not result in an appropriate sanction, with the approval of the S/HP and in consultation with the RCPD, and the Department Legal Division has warranted, the Department may apply its full enforcement authority; this may include escalating civil penalties and/or issuing appropriate orders.

4.3.3 A follow-up inspection must be conducted within 6 months of receipt of a licensee's corrective action(s) following an escalated enforcement action.

5.0 Attachments to RMCPP 2.5

- 2.5-1 Examples of Violations That May Be Cited on a Clear Inspection
- 2.5-2 Examples of Severity Level I IV Violations

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.5-1 Examples of Violations That May Be Cited on a Clear Inspection

Examples of Violations That May Be Cited on a Clear Inspection

- 1. Inventories not performed at the required frequency on one or two occasions that did not result in any consequences (e.g. lost material).
- 2. Licensee observed eating, drinking, etc. in laboratories where less than or equal to megabecquerel (microcurie) quantities of unsealed radioactive materials are stored, but not being used (a survey should be performed to confirm the absence of contamination).
- 3. Failure to calibrate survey instruments, alarm rate meters, or pocket dosimeters at the required frequency on one or two occasions.
- 4. Failure to use a dedicated check source before each use of a survey instrument, on one or two occasions.
- 5. Failure to perform routine surveys (e.g., radiation, contamination, airflow checks, or fume hood monitoring) at the required frequency on a few occasions.
- 6. Failure of the radiation safety committee to meet at the required frequency on one or two occasions.
- 7. Failure to have required attendees at all radiation safety committee meetings.
- 8. Rare failures to exchange personnel dosimetry at the required frequency, but with no loss of dosimetry data.
- 9. Failure to have properly prepared shipping papers.
- 10. Failure to include the emergency phone number, reportable quantity (RQ) designation, or SI units on shipping papers.
- 11. Occasional failure to meet all transportation requirements of 49CFR.
- 12. Users of radioactive materials are adequately trained, but not as stated in the license tie-down conditions.
- 13. On rare occasions, dose calibrator tests are not performed as required.
- 14. Isolated cases of missed or late leak tests
- 15. Failure to appropriately post areas where radioactive materials are stored or used.

Note: This list is not all-inclusive. Most Severity Level IV violations may be cited on Department Form 591M if they are not repetitive and are corrected within 30 days.

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT 2.5-2 Examples of Severity Level 1 – IV Violations

SL I violations (examples)

- 1. The loss of control over licensed activities, including chemical processes that are integral to the licensed or certified activity, resulting in serious injury or loss of life.
- 2. A system designed to prevent or mitigate a serious safety event is inoperable when required to perform its design function, and this results in serious injury or loss of life.
- 3. Failure to use a properly prepared written directive as required by 10 CFR 35.40, "Written Directives," or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," results in serious injury or loss of life.
- Failure to have or to follow written operating procedures as required by 10 CFR 36.53, "Operating and Emergency Procedures," results in a serious injury or loss of life.

SL II violation (examples)

- 1. The loss of control over licensed activities, including chemical processes that are integral to the licensed or certified activity, results in the substantial potential for a significant injury or loss of life, whether or not radioactive material is released.
- 2. A system designed to prevent or mitigate a serious safety event is inoperable when required to perform its design function.
- 3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41, or a failure to train personnel in those procedures, results in a medical event.
- Failure to have or to follow written operating procedures as required by 10 CFR 36.53 results in a substantial potential (e.g., an event did not occur, but no barriers, neither procedural nor system, including

interlocks, would have prevented it, and the event was not highly unlikely to occur) for a serious injury or death.

SL III violations (examples)

- 1. A system designed to prevent or mitigate a serious safety event has one of the following characteristics:
 - It is unable to perform its intended function under certain conditions (e.g., a safety system is not operable unless the required backup power is available), or
 - It is outside design specifications to the extent that a detailed evaluation would be required to determine its operability.
- 2. A programmatic failure occurs to implement written directives or procedures for administration requiring a written directive, such as the following:
 - A licensee's procedures fail to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41,
 - A licensee fails to train personnel in procedures for administrations requiring a written directive,
 - A non-isolated failure occurs to use and follow written directives or procedures for administrations requiring a written directive; or
 - A licensee fails to have procedures or requirements for written directive or fails to have procedures for administrations that require written directives.
- 3. Except as provided for in "**SLV IV violations (examples)**" below, item number 10, a licensee fails to secure a portable gauge as required by 10 CFR 30.34(i).
- 4. A significant failure to implement the requirements of 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety

Requirements for Industrial Radiographic Operations," during radiographic operations includes, but is not limited to, the following:

- During radiographic operations at a location other than a permanent radiographic installation, a licensee fails to have present a radiographer and at lest one additional radiographer or qualified individual,
- A licensee fails, during radiographic operations, to use radiographic equipment, radiation survey instruments, or personnel monitoring devices as required by 10 CFR Part 34, or
- During radiographic operations, a failure to stop work occurs, after a pocket dosimeter is found to have gone off-scale or after an electronic dosimeter reads greater than 2—millirem (mrem), and before a determination is made of the individual's actual radiation exposure.
- 5. An unqualified person conducts licensed activities. The unqualified person is characterized by either of the following:
 - Lacking adequate qualifications, experience, or training to safely conduct activities, or
 - Lacking the required certification or training for positions such as radiographer; authorized user under 10 CFR Part 35, "Medical Use of Byproduct Material"; or irradiator operator under 10 CFR 36.51, "Training."
- 6. Licensed material is used on humans where such use is not authorized.
- 7. A licensee authorizes the release from its control of an individual who does not meet the release criteria in 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material."
- 8. An individual without supervision operates an irradiator when the individual has not been trained as required by 10 CFR 36.51.

- 9. A programmatic failure occurs and the licensee fails to follow written operating procedures as required by 10 CFR 36.53.
- A programmatic failure occurs and the licensee fails to perform inspection and maintenance checks as required by 10 CFR 36.61, "Inspection and Maintenance."
- 11. A licensee fails to seek required Department approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance, such as the following:
 - A significant failure to meet decommissioning as required by regulation or license condition, or
 - Failure to meet required schedules without adequate justification.
- 12. Failures occur involving decommissioning requirements, such as the following:
 - A significant failure to meet decommissioning as required by regulation or license condition, or
 - Failure to meet required schedules without adequate justification.

SL IV violations (examples)

- 1. A licensee fails to use a properly prepared written directive as required by 10 CFR 35.40, or fails to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures are characterized by al of the following:
 - Are isolated,

- Do not demonstrate programmatic weaknesses in implementation,
- Have limited consequences if a medical event is involved.
- 2. A licensee fails to keep the records required by 10 CFR 35.2040, "Records of Written Directives," and 10 CFR 35.2041, "Records for Procedures for Administrations Requiring a Written Directive."
- 3. A licensee fails to implement procedures including, but not limited to, recordkeeping, surveys, and inventories.
- 4. A licensee fails to comply with the U.S. Department of Transportation requirement to provide hazardous material (HAZMAT) employee training as required by 10 CFR 71.5(a).
- 5. There is an isolated failure to have and to follow written operating procedures as required by 10 CFR 36.53.
- 6. A licensee fails to document the required certification or training for positions such as radiographer, authorized user under 10 CFR Part 35, or irradiator operator under 10 CFR 36.51.
- 7. A licensee fails to seek required Department approval before the implementation of a change in ownership that results in little or no adverse impact on radiological or programmatic activities or on the Department's ability to inspect licensed activities, such that the locations and types of activities are unaffected by the unauthorized license transfer.
- 8. A licensee fails to seek required Department approval prior to replacement of the RSO, where the RASO was evaluated as qualified.
- 9. A licensee fails to seek Department approval, when required, before changing the location where licensed activities are being conducted or where licensed material is being stored that has little or no radiological or programmatic significance, and all other safety and security requirements have been met.
- 10. A licensee fails to secure a portable gauge as required by 10 CFR 30.34(i), whenever the gauge is not under the control and constant

surveillance of the licensee, where one level of physical control existed and there was no actual loss of material, and that failure is not repetitive.

4.6 Technical Staffing and Training

The State of Indiana is using the NRC Inspection Manual Chapter 1248 Formal Qualification Program for Federal and State Materials and Environmental Management Programs as a model for technical staffing and for training program elements. This is described in this section of the Application. In Section 4.6.1 below we describe the organization of the program and provide a staffing analysis to indicate the organization will be sufficient to maintain the Agreement State Program. In Section 4.6.2, we describe the staff qualification plan, and in Section 4.6.3, we describe the qualifications of the current staff.

4.6.1 Organization

As described in Section 4.1.2, the Radioactive Materials Control Program will reside within the Indiana Department of Homeland Security. The staff responsible for the Agreement State Program work in the Radiation Program which is shown in the organization chart below. The staff is comprised of two Senior Health Physicists and three Health Physicists. The program will also have the support of the Radiation Programs Director, Hazmat Section Chief, General Counsel for the Indiana Department of Homeland Security, and additional legal support from the Office of General Council. For emergency preparedness, the Radiological Emergency Preparedness Coordinator, the Radiological Transportation and Radiological Nuclear Prevention Program Manager, and the Indiana Department of Health Radiochemistry Lab support prevention, response, and recovery efforts.

The primary document describing the qualifications and training of Radioactive Material Control Program staff is RMCPP 5.1 *Qualifications and Training*. In this procedures, various roles are described. RMCP staff will become qualified as Materials Inspectors and License Reviewers following the guidance of RMCPP 5.1 *Qualification and Training* and are tracked in RMCPP 5.1 Attachment 5.1-1 *Health Physicist Qualification Journal*. The RMCPP and Qualification Journal are in Section 4.6.2 below.

Staff Needs Analysis

An analysis was performed using the forms from the Handbook for Processing an Agreement. The first form is the Staff Needs Analysis, Table 4.6-1. The values in the table are based on the types and numbers of licensees at the time of this application. The second form is the Staff Resource Analysis, Table 4.6-2. This indicates the time in days available for each of the individuals who may conduct inspections and license review activities. The final form, Table 4.6-3, shows the difference between the amount of staff time needed and available. It indicates that for the radioactive material licensees in Indiana, there is more than a sufficient amount of staff time available. Each of the categories of inspections in the table includes security inspections.

License Category	Numbe r of License s	Licensing actions/y r	Staff days per actio n	Licensin g staff days	Inspection s per year	Staff days per inspectio n	Inspectio n staff days
Broad Scope Academic	5	1	2	2	2	5	10
Nuclear Med - Written Directive Not Req	23	6	2	12	5	5	25
Nuclear Med- Therapy	41	10	2	20	14	5	70
Brachytherap y	23	5	2	10	12	5	60
Medical - Broad Scope	1	1	2	2	1	5	5
Nuclear Pharmacy	16	4	2	8	8	5	40
Fixed Gauge	38	6	1	6	8	3	24
Portable Gauge	24	4	2	8	5	5	25
Industrial - other Includes Irradiators	15	2	2	4	3	5	15

Table 4.6-1 Staff Needs Analysis

Industrial Radiography	11	2	1	2	10	5	50
Well Logging	0	0	0	0	0	0	0
Veterinary	3	1	1	1	1	3	3
Services	6	1	1	1	1	3	3
Research/ Development Broadscope	4	1	2	2	1	5	5
Manufacturin g/ Distribution Broadscope	0	1	0	1	0	0	0
Manufacturin g/ Distribution	9	1	2	2	2	5	10
LLRW broker	N/A						
LLRW site	N/A						
U recovery	N/A						
SS&D	N/A						

Table 4.6-2 Staff Resource Analysis

		9	STAFF	RES	OURC	E AN	ALYSI	S								
Staff					Coff	ma									Diffe	ren
Member	Stuc	ler	Tub	bs	n		Sta	hl	Turr	ıer	Tot	al	Need	ded	Ce	9
License	Ins	Li	Ins	Li	Ins	Li	Ins	Li	Ins	Li	Ins	Li	Ins	Li	Ins	Li
Category	р	С	р	С	р	С	р	С	р	С	р	С	р	С	р	С
Broad												1				
Scope	14	8	8	3	6	2	0	0	6	6	34	9				
Academic												9	10	1	24	18
Nuclear																
Med -												2				
Written	8	2	12	5	8	6	6	3	10	6	44	2				
Directive												2				
Not Req													25	6	19	16

Nuclear Med- Therapy	14	4	18	8	26	1 5	26	8	16	7	100	4 2	70	1 0	30	12
Brachythera py	14	4	10	4	24	6	6	3	14	6	68	2 3	60	5	8	18
Medical - Broad Scope	0	0	0	0	0	0	8	4	0	0	8	4	5	1	3	3
Nuclear Pharmacy	0	0	6	3	22	1 2	16	1 6	12	1 0	56	4 1	40	4	16	37
Fixed Gauge	12	2	16	4	6	2	6	2	17	5	57	1 5	24	6	33	9
Portable Gauge	0	0	9	2	10	3	17	4	4	2	40	1 1	25	4	15	7
Industrial - other Includes Irradiators	6	3	9	2	6	2	12	5	4	2	37	1 4	15	2	22	12
Industrial Radiograph y	12	4	12	2	0	0	6	1	30	4	60	1 1	50	2	10	8
Well Logging	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Veterinary	0	0	0	0	6	2	2	1	0	0	8	3	3	1	5	2
Services	3	2	0	0	0	0	6	2	2	1	11	5	3	1	8	4
Research/ Developme nt Broadscope	10	2	0	0	0	0	5	2	0	0	15	4	5	1	10	3
Manufacturi ng/ Distribution Broadscope	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Manufacturi ng/ Distribution	14	5	4	2	3	1	6	3	4	2	31	1 3	10	1	21	12
LLRW broker	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LLRW site	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
U recovery	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SS&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Reciprocity	2	1	5	2	10	5	5	2	8	5	30	1 5	11	1 1	19	4

Total 109	3 7	109	3 7	127	5 6	127	5 6	127	5 6							
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Table 1.6-3 Staff Balance Analysis

		Staff Days		Staff Days
License Category	Needed	Available	Needed	Available
Broad Scope Academic	10	35	1	19
Nuclear Med - Written Directive Not Req	25	44	6	22
Nuclear Med- Therapy	70	100	10	42
Brachytherapy	60	68	5	23
Medical - Broad Scope	5	8	1	4
Nuclear Pharmacy	40	56	4	41
Fixed Gauge	24	57	6	15
Portable Gauge	25	40	4	11
Industrial - other Includes Irradiators	15	37	2	14
Industrial Radiography	50	60	2	11
Well Logging	0	0	0	0
Veterinary	3	8	1	3
Services	3	11	1	5
Research/ Development Broadscope	5	15	1	4
Manufacturing/ Distribution Broadscope	0	0	1	0
Manufacturing/ Distribution	10	31	1	13
LLRW broker	N/A	N/A	N/A	N/A
LLRW site	N/A	N/A	N/A	N/A
U recovery	N/A	N/A	N/A	N/A
SS&D	N/A	N/A	N/A	N/A

STAFF BALANCE ANALYSIS

4.6.2 Qualification Program

The qualification program is described in RMCPP 5.1 Qualification and Training. This is attached below. Individual accomplishment of the qualification process is documented in that person's Qualification Journal. In general, individuals are trained to conduct inspections and to do license review activities through training classes and on-the-job training. Individuals maintain proficiency through on-going training classes and on-the-job training. Individuals maintain proficiency through training classes and on-thejob training. Individuals maintain proficiency through on-going training that enhances licensing and inspection professional abilities. These are described in the RMCPP in Section 4.6.1 of this application. Individual completion of the qualification components is documented in that person's Qualification Journal. This, too, is in Section 4.6.3 of this application.

The processes described in RMCPP 5.1 are for future staff. The qualifications of current technical staff are described in Section 4.6.3 of this application. The Radiation Control Program Director will take all steps available to replace staff that either leaves or retires from the Agreement State Program. One element of this is technical training and qualification of other Radiation Program Staff. This will be undertaken after the five current staff members assigned to the Radioactive Materials Program are fully qualified.

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 5.1, Revision 0 Qualifications and Training

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

Revision	Date	Description of Changes
0		

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5.1-1 Health Physicist Qualification Journal

Qualifications and Training

1.0 PURPOSE

- **1.1** Applicability
 - 1.1.1 This procedure defines the minimum essential elements of training required for each Health Physicist position and additional training required for the performance of specialized activities. The procedure also details the training required to maintain qualified technical staff.
 - 1.1.2 The procedure describes the Qualifications Journal maintained by/for the Health Physicist.

1.2 References

- 1.2.1 NRC Inspection Manual Chapter 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs."
- 1.2.2 NRC Inspection Manual Chapter 1248, Appendix A, "Materials Health Physics License Review Qualification Journal.
- 1.2.3 NRC Inspection Manual Chapter 1248, Appendix B, "Materials Health Physics Inspector Qualification Journal."
- 1.2.4 NRC Inspection Manual Chapter 1248, Appendix F "Training Requirements and Qualification Journal for Decommissioning Inspector."
- 1.2.5 Indiana Radioactive Materials Control Program Rules

1.3 Files

1.3.1 Health Physics Qualifications Journal(s)

1.4 Definitions

1.4.1 <u>Advanced training</u>: Training beyond the core training that is used to enhance inspector or license reviewer expertise. Not required for all Health Physicists, however it is encouraged to increase the capabilities of the individual and the program.

- 1.4.2 <u>Agency</u>: The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security (IDHS or Department).
- 1.4.3 <u>Core Training</u>: Minimum classroom and on-the-job training required for an inspector or license reviewer.
- 1.4.4 <u>Continued education:</u> Education designed to update and maintain level of proficiency. Methods used may include training courses, professional meetings, review of policy and guidance documents, reading professional journals or new letters, etc.
- 1.4.5 <u>Inspector</u>: A Health Physicist qualified to plan, perform, and document an inspection of a specific category of license and where appropriate, to prepare enforcement documents and review the response to such a document for adequacy.
- 1.4.6 Lead Inspector: A Health Physicist qualified to plan, supervise, and document an inspection by a team of inspectors. An inspector shall not act as a lead inspector in any category of license that they are not qualified, unless being evaluated or supervised by a qualified inspector. A lead inspector is responsible for review of a licensee's reply to a Notice of Violation (NOV) when a Team Inspection is conducted.
- 1.4.7 <u>License Reviewer:</u> A Health Physicist qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a second review for any category of license for which they are not qualified.
- 1.4.8 <u>On-the-job Training (OJT)</u>: A training method using structured hands-on activities to develop the required job-related knowledge and skills.
- 1.4.9 <u>Program Orientation</u>: Instructions provided to a new employee regarding state, Department, and RMCP policies, statutes, rules, and procedures.
- 1.4.10 <u>Refresher Training:</u> Additional training required after qualification that allows a staff member to maintain a "qualified" status.
- 1.4.11 <u>Specialized Training:</u> Additional training necessary for each category of radioactive material use, such as medical, industrial radiography, well logging, large irradiators, etc. Specialized training in processing allegations, medical events, over exposures, and incidents may also be necessary.
- 1.4.12 <u>Trainee</u>: A Health Physicist assigned to the Radioactive Materials Control Program, working on qualification in an inspection or license action program.

2.0 **RESPONSIBILITIES**

- **2.1** Health Physicist (HP)
 - 2.1.1 Assists in the orientation of new employees in the RMCP and ensures he/she has access to copies of the Indiana Radioactive Material Control Program rules, RMCP procedures, NRC guidance and other required or relevant documents for training.
 - 2.1.2 Maintains his/her personal training records and Qualifications Journals.
- 2.2 Senior Health Physicist (S/HP)
 - 2.2.1 When qualified in each program type, is responsible for assisting trainees in becoming qualified, as assigned.
 - 2.2.2 Participates in a continuing education program, refresher training, specialized training, and qualification programs, as assigned.
- **2.3** Radiation Control Program Director (RCPD)
 - 2.3.1 Manages the training and qualification program.
 - 2.3.2 Assures that a qualified staff is available to adequately perform the RMCP licensing, inspection, and enforcement activities.
 - 2.3.3 Periodically audits the RMCP training and qualification program.

3.0 PROCEDURE

IDHS and RMCP orientation shall be provide by the RMCP staff and Indiana State Personnel Department staff. Attachment #. #-# Health Physicist Qualification Journal is used to document self-study, formal, on-the-job, core, specialized, enhancement, refresher training, and continuing education to satisfy the requirements of NRC Inspection Manual Chapter 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs" and its appendices to qualify and maintain qualification as an Inspector and License Reviewer.

The qualification journal contains a detailed series of activities and study areas. The Health Physicist will complete the activities in the qualification journal usually within two years after hire. If more than two years is needed to complete their qualification journal, the RCPD may grant an extension. The RCPD may designate qualified staff members to sign and verify qualification for the training activities completed.

3.1 Required Initial Training

The self-study, core training, and on-the-job training described below is required for all Health Physicists assigned to the RMCP to perform inspections of material licensee's facilities and to process radioactive material licensing actions. Credit for training may be granted by the RCPD for applicable education, training, and/or experience received prior to joining the RMCP.

- 3.1.1 <u>Self-Study</u>: The trainee is responsible for completing the following activities and for having completion signed off in their Qualification Journal by the RCPD or assignee, as soon as possible. The new employee should be encouraged to ask questions of and assistance from other Health Physicists with more experience in the RMCP.
 - Review of Indiana Radioactive Materials Control Rules.
 - Review of RMCPPs.
 - Review of appropriate NRC Regulatory Guides.
 - Review of NUREG-1556, "Consolidated Guidance About Materials Licenses."
 - Review of current and historical (as needed) RMCP reading file.
 - Review of appropriate NRC Information Notices.
 - Review of appropriate RMCP Information Notices.
- 3.1.2 Core Training: The following courses are minimum formal classroom training requirements. Attendance at these courses will be scheduled, as openings become available, through the NRC or equivalent training courses. The RCPD may grant an exemption to courses based on previous education and/or training.
 - Medical Uses of Radiation (H-317S)
 - Fundamental Health Physics Self-Study (H-122S)
 - Transportation of Radioactive Materials Self-Study (H-308S)
 - Inspection Procedures (G-108)
 - Licensing Practices & Procedures (G-109)
 - Industrial Radiography (H-305)
 - Materials Control & Security Systems & Principles (S-201)
 - Advanced Health Physics (H-201)
- 3.1.3 On-the-Job Training (OJT): The following activities, Inspection (I) and Licensing (L), shall be conducted in concert with a qualified inspector or license reviewer at a specific category licensee facility or on a specific category license action. Items (I) and (L) shall be completed for each of the principal categories of licensees and licensing actions. These are identified in the table in Section 3.2 below. The individual actions shall be conducted at different licensee facilities or on different license actions. The trainee shall inspect, or process license actions as follows:

- 3.1.3.1 Type (I) Inspection of Specific Categories of Licensees
 - 3.1.3.1.1 Trainee observes the qualified inspector preparing for and conducting an inspection. During the inspection, the trainee may be assigned minor duties that don't interfere with the observation of the inspection.
 - 3.1.3.1.2 Under the supervision of the qualified inspector, the trainee prepares for, conducts, and records findings for assigned parts of the inspection. This step should be conducted with a least two different types of licenses.
 - 3.1.3.1.3 Under the observation of the RCPD, or other RMCP staff as assigned, the trainee prepares for and conducts an inspection, including recording inspection findings and preparing enforcement correspondence. If problems are observed, this activity should be repeated.
- 3.1.3.2 Type (L) Processing of Specific Categories of License Licensing Actions
 - 3.1.3.2.1 The trainee is provided examples of standard licenses, access to the NUREG-1556 Series, Indiana Radioactive Materials Control Rule, standard form letters, standard deficiency paragraphs, reviewer checklists, and standard license formats and assigned directed review of selected licensing case work. Directed review consists of:
 - 3.1.3.2.1.1 Trainee observes the review processing an application for a license or a license renewal in entirety.
 - 3.1.3.2.1.2 Trainee will be assigned sample licensing actions for evaluation.
 - 3.1.3.2.1.3 Trainee shall be assigned processing of selected license actions under the supervision of a reviewer.
 - 3.1.3.2.2 Under the supervision of a reviewer, the trainee processes a license application or a license renewal in entirety, including preparing the license, tying-down all license conditions, and recommending the license for signature to the license reviewer. This step should be conducted twice with different reviewers and licensing actions.

- 3.1.3.2.3 Under the observation of the RCPD or assignee, the trainee processes an application for license or an application for license renewal in entirety, including preparing the license, tying down all license conditions, and recommending the license to the RCPD or assignee for signature. If problems are identified this step may be repeated.
- **3.2** Qualified Inspector and/or License Reviewer
 - 3.2.1 The trainee becomes qualified as an inspector or license reviewer in one or more of the various core program categories as described in the following table by completing the classroom, on-the-job training, and supervised inspections as described in subsection 3.1 items have been completed and signed-off in the trainee's Qualification Journal, a trainee becomes qualified as an inspector or license reviewer as follows:

Training Completed	OJT Completed	Qualified Program
Advanced Health Physics (H-201) Inspection Procedures (G-108) Transportation of Radioactive Materials (H-308)	All Broad Scopes – except Medical Fixed & Portable Gauges In-Vitro	Inspection - 1100-1120, 3610-3630, 3211-3213 Inspection - 3120/3121 Inspection - 2410
Advanced Health Physics (H-201) Inspection Procedures (G-108) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308)	Medical Institution – (Broad – A, B, & C) WD required WD not required Mobile HDR/Teletherapy Other Medical Uses Veterinary	Inspection - 2110-2113 Inspection - 2120/2200 Inspection - 2121/2201 Inspection - 2220/2301 Inspection - 2230/2300 Inspection - 2240 Inspection - 2400
Advanced Health Physics (H-201) Inspection Procedures (G-108) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308)	Nuclear Pharmacies	Inspection – 2500

Advanced Health Physics (H-201) Inspection Procedures (G-108) Safety Aspects of Industrial Radiography (H-304) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308) Materials Control & Security Systems & Principles (S-201)	Industrial Radiography Gamma Knife	Inspection – 3310/3320 Inspection – 2310
Advanced Health Physics (H-201) Licensing Practices & Procedures (G- 109) Transportation of Radioactive Materials (H-308)	All Broad Scopes – except Medical Fixed & Portable Gauges In-Vitro	Licensing - 1100-1120, 3610-3630, 3211-3213 Licensing - 3120/3121 Licensing - 2410
Advanced Health Physics (H-201) Licensing Practices & Procedures (G- 109) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308)	Medical Institution – (Broad – A, B, & C) WD required WD not required Mobile HDR/Teletherapy Other Medical Uses Veterinary	Licensing - 2110-2113 Licensing - 2120/2200 Licensing - 2121/2201 Licensing - 2220/2301 Licensing - 2230/2300 Licensing - 2240 Licensing - 2400
Advanced Health Physics (H-201) Licensing Practices & Procedures (G- 109) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308)	Nuclear Pharmacies	Licensing – 2500
Advanced Health Physics (H-201) Licensing Practices & Procedures (G- 109) Safety Aspects of Industrial Radiography (H-304) Medical Uses of Radiation (H-312S) Transportation of Radioactive Materials (H-308) Materials Control & Security Systems & Principles (S-201)	Industrial Radiography Gamma Knife	Licensing - 3310/3320 Licensing - 2310

3.3 Specialized Training

3.3.1 In addition to the above Type I and/or Type L training and OJT requirements, the inspector and/or reviewer may become qualified in the following programs on completion of additional training, as follows:

Training Completed	Qualified Program
Inspection Procedures (G-108) Licensing Practices and Procedures (G-109) Irradiator Technology (H-315)	Inspection & Licensing - 3521
Inspection Procedures (G-108) Licensing Practices and Procedures (G-109) Safety Aspects of Well Logging (H-314)	Inspection & Licensing – 3110
Advanced Health Physics (H-201) Inspection Procedures (G-108) Licensing Practices and Procedures (G-109)	Decommissioning Services Inspection & Licensing – 3219
Inspection Procedures (G-108) Root Cause/Incident Investigation (G-205)	Inspection – all programs
Characterization and Planning for Decommissioning (H-115S) MARSAME (H-120S) MARSSIM (H-121S) Visual Sampling Plan (H-500) RESRAD Overview (H-408) Advanced RESRAD Training Workshop (H-412) MILOS Area Training Workshop (H-413)	Inspection – all programs Inspection – 3900

- 3.3.2 In order to enhance the knowledge of the inspectors and reviewers and to improve the program, selected personnel shall complete the following training:
 - Internal Dosimetry (H-312S)
 - Environmental Monitoring & Air Sampling for Radioactive Materials (H-130S)
 - Health Physics Statistics (H-301S)
 - Respiratory Protection (H-311S)
- **3.4** Refresher Training
 - 3.4.1 Qualified materials license reviewers and inspectors must maintain their qualification by completing 24 hours of refresher training in a requalification schedule of 24 months. The beginning of each

requalification cycle will be determined using the month and year the inspector completed their initial qualification.

3.4.2 Refresher training may relate to various health and safety or security topics. Examples of training that may be considered include external training courses such as those for Preventative Radiological Nuclear Detection (PRND) or Radiological Emergency Preparedness (REP), directed self-study courses related to health and safety of security from the Health Physics Society (HPS), Conference of Radiation Control Program Directors (CRCPD), or other training approved by the RCPD.

Examples of other training that may be considered include:

- NRC-sponsored technical training
- State sponsored technical training
- Webinars sponsored by NRC, State or vendors
- External training courses provided by vendors or universities
- Lectures given at professional organizations
- State developed presentations in subjects related to health and safety, security, or regulation of radioactive materials

NOTE: License reviewers and inspectors may retake a course they had taken previously as refresher training. The RCPD should consider whether it would be beneficial for the license reviewer to retake the course, whether there have been changes in technology, regulations, or if the course has changed considerably since the last time the license reviewer took the course before allowing a course to be retaken as refresher training. If the RCPD allows the license reviewer to retake the course, the license reviewer must complete and pass the example, if the course has one, to receive credit for the course.

3.4.3 Before taking refresher training, Radioactive Materials Control Program staff should receive approval from the RCPD to confirm that the training will be credited as refresher training.

4.0 Records

- **4.1** Health Physicist Qualification Journal
- **4.2** Electronic records are found in Web-Based Licensing

5.0 Attachments to RMCPP 5.1

Attachment 5.1-1 Health Physics Qualification Journal

Applicability:

This Qualification Journal implements Radioactive Materials Control Program Procedure Section #. #, "Qualifications and Training" by documenting the qualifications and training of Radioactive Materials Control Program (RMCP) Health Physicists performing inspection at materials licensed facilities and processing licensing actions for radioactive materials licensees. The Qualifications Journal provides traceable documentation that the minimum requirements are met for each RMCP Health Physicist.

The Qualification Journal consists of a series of qualification guides and signature blocks. Each signature block is used to document task completion as indicated by the appropriate signature. The corresponding qualification guide establishes the minimum knowledge levels or areas of study that must be completed for each signature block. The trainee should complete the self-study section of the qualifications before starting on the other sections.

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT <mark>#. #-1</mark> Radioactive Materials Control Program Health Physicist Qualification Journal

NAME: _____

TITLE: _____

SELF STUDY

Trainee	Date
RCPD	Date
Trainee	Date
RCPD	Date
CONTROL REGULATIO	NS
Trainee	Date
RCPD	Date
Trainee	Date
RCPD	Date
Trainee	Date
RCPD	Date
	RCPD Trainee RCPD CONTROL REGULATION Trainee RCPD Trainee RCPD

D. Discussion of Selected NRC Bulletins and Information Notices	RCPD	Date	
NUREG-1556, "Consolidate Guidance About Materials Licenses"			
A. Review of NUREG-1556	Trainee	Date	
B. Discussion of NUREG-1556	RCPD	Date	

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

A. Medical Uses of Radiation Self-Study (H-317S)		
Dates Attended:		
B. Fundamentals of Health Physics Self-Study (H-122S)		
Dates Attended:	RCPD	
C. Transportation of Radioactive Materials Self-Study (H-308S)		
Dates Attended:	RCPD	
D. Inspection Procedures (G-108)		
Dates Attended:	RCPD	
E. Licensing Practices & Procedures (G-109)		
Dates Attended:	RCPD	
F. Safety Aspects of Industrial Radiography (H-305)		
Dates Attended:	RCPD	
G. Materials Control & Security Systems & Principles (S-201)		
Dates Attended:	RCPD	
H. Advanced Health Physics (H-201)		
Dates Attended:	RCPD	
I. Root Cause/Incident Investigation Training (G-205)		

Dates Attended: _____ RCPD_____

SPECIALIZED/ENHANCEMENT TRAINING

A. Irradiator Technology Course (H-31	5)
Dates Attended	RCPD
B. Safety Aspects of Well Logging (H-314)
Dates Attended	RCPD
C. MARSAME: Multi-Agency Radiati Equipment (H-120S)	on Survey Assessment of Materials and
Dates Attended	RCPD
D. Characterization and Planning for D	ecommissioning (H-115S)
Dates Attended	RCPD
E. Internal Dosimetry Self-Study (H-3	12S)
Dates Attended	RCPD
F. Environmental Monitoring & Air Sam	pling for Radioactivity Self-Study (H-130S)
Dates Attended	RCPD
G. Respiratory Protection (H-311)	
Dates Attended	RCPD
H. MARSSIM: Multi-Agency Radiation S	Survey and Sites Investigation Manual (H-121S)
Dates Attended	RCPD
I. Health Physics for Uranium Recover	ry (F-104)
Dates Attended	RCPD

J. Introductory Health Physics (H-117	S)
Dates Attended	RCPD
K. Fundamental Health Physics Lab (H	-122Lab)
Dates Attended	RCPD
L. Environmental Monitoring & Air San	npling for Radioactivity Lab (H-130Lab)
Dates Attended	RCPD
M. Health Physics Statistics Self-Study	(H-301S)
Dates Attended	RCPD
N. RESRAD OVERVIEW (H-408)	
Dates Attended	RCPD
O. Advanced RESRAD Training Worksho	op (H-412)
Dates Attended	RCPD
P. MILDOS-Area Training Workshop (H	-413)
Dates Attended	RCPD
Q. Visual Sampling (H-500)	
Dates Attended	RCPD

ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic	
1) Trainee observes an Inspector preparing for and inspection of a Program 01100-01120 licensee.	conducting an
Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee pr and records findings of selected portions of at lea 01100-01120 licensee inspections. 	• •
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their design prepares for and conducts an inspection, includin inspection findings and preparing, as necessary, correspondence for a Program 01100-01120 licer 	g recording of enforcement
Licensee:	Date:

RCPD: _____

B. Program 02110 – Medical Institution – Broad Scope

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 02110 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, ent correspondence for a Program 02110 licensee. 	ecording of
Licensee:	Date:
RCPD:	

C. Program 02120 – Medical Institution Written Required	Directive
 Trainee observes an Inspector preparing for and co inspection of a Program 02120 licensee. 	nducting an
Licensee:	_ Date:
Inspector:	-
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 02120 licensee inspections. 	
Licensee:	_ Date:
Inspector:	-
Licensee:	_ Date:
Inspector:	-
3) Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including inspection findings and preparing, as necessary, en correspondence for a Program 02120 licensee.	recording of
Licensee:	Date:
RCPD:	_

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D. Core Program 02121 – Medical Institution Wri Not Required	itten Directive
 Trainee observes an Inspector preparing for and co inspection of a Program 02121 licensee. 	nducting an
Licensee:	_ Date:
Inspector:	-
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 02121 licensee inspections. 	
Licensee:	Date:
Inspector:	-
Licensee:	_ Date:
Inspector:	-
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including inspection findings and preparing, as necessary, en correspondence for a Program 02121 licensee. 	recording of
Licensee:	Date:
RCPD:	_

E. Core Program 02230/02300 – HDR or Teletherapy

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02230/02300 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee preparation and records findings of selected portions of at least 02230/02300 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enf correspondence for a Program 02230/02300 license 	ecording of forcement
Licensee:	Date:
RCPD:	

F. Core Program 02231 – Medical Mobile Services Directive Required	s Written
 Trainee observes an Inspector preparing for and cor inspection of a Program 02231 licensee. 	nducting an
Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee preparation and records findings of selected portions of at least 02231 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
3) Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enf correspondence for a Program 02231 licensee.	ecording of
Licensee:	Date:
RCPD:	

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G. Core Program 02240 – Emerging Technologies

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prepa and records findings of selected portions of at least 02240 licensee inspections 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enf correspondence for a Program 02240 licensee. 	ecording of
Licensee:	Date:
RCPD:	

H. Core Program 02400 – Veterinary Nonhuman Subjects

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 02400 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, ent correspondence for a Program 02400 licensee. 	ecording of
Licensee:	Date:
RCPD:	

I. Core Program 02410 – In-Vitro Testing Laboratories

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 02410 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, ent correspondence for a Program 02410 licensee. 	ecording of
Licensee:	Date:
RCPD:	

J. Core Program 02500 – Nuclear Pharmacy

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prepared and records findings of selected portions of at least 02500 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enformation correspondence for a Program 02500 licensee. 	ecording of
Licensee:	Date:
RCPD:	

K. Core Program 03121 – Measuring Systems – Portable Gauges

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prep and records findings of selected portions of at least 03121 licensee inspections. 	
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
3) Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, ent correspondence for a Program 03121 licensee.	ecording of
Licensee:	Date:
RCPD:	

L. Core Program 03219 – Decontamination Services

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prepared and records findings of selected portions of at least 03219 licensee inspections. 	•
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enformation correspondence for a Program 03219 licensee. 	ecording of
Licensee:	Date:
RCPD:	

M. Core Program 03310/03320 – Industrial Radiography

1) Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prepa and records findings of selected portions of at least 03310/03320 licensee inspections. 	,
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designe prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enf correspondence for a Program 03310/03320 license 	ecording of orcement
Licensee:	Date:
RCPD:	

N. Core Program 03510 – Irradiators Self-Shielde equal to 10,000 Curies	d less than or
1) Trainee observes an Inspector preparing for and cor inspection of a Program 03510 licensee.	nducting an
Licensee:	Date:
Inspector:	
 Under the supervision of an Inspector, Trainee prepa and records findings of selected portions of at least 03510 licensee inspections. 	
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
 Under the observation of the RCPD, or their designed prepares for and conducts an inspection, including r inspection findings and preparing, as necessary, enf correspondence for a Program 03510 licensee. 	ecording of
Licensee:	Date:
RCPD:	

- A. Program 01100-01120 Academic
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 01100-01120 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

 Under the supervision of License Reviewers, Trainee process two Program 01100-01120 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 01100-01120 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

- B. Program 02110 Medical Institution Broad Scope
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02110 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02110 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02110 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

- C. Program 02120 Medical Institution Written Directive Required
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02120 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:		
Reviewer:		Date:
License:		
Reviewer:		Date:
License:		
Reviewer:		Date:
License:		
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02120 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02120 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

D. Program 02121 – Medical Institution Written Directive Not Required

1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02121 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02121 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02121 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

- E. Program 02230 High-Dose Rate Remote Afterloader
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02230 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02230 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02230 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

- F. Program 02231 Mobile Medical Services Written Directive Required
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02231 amendments.

Amendment Type:	
	Date:
Amendment Type:	
	Date:
Amendment Type:	
	Date:
Amendment Type:	
	Date:
Amendment Type:	
	Date:
Amendment Type:	
	Date:
	Amendment Type: Amendment Type: Amendment Type: Amendment Type:

2) Under the supervision of License Reviewers, Trainee process two Program 02231 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02231 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- G. Program 02240 Medical Therapy Other Emerging Technologies
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02240 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

 Under the supervision of License Reviewers, Trainee process two Program 02240 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02240 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- H. Program 02400 Veterinary Nonhuman Subjects
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02400 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02400 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02400 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- I. Program 02410 In-Vitro Testing Laboratories
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02410 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 02410 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02410 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- J. Program 02500 Nuclear Pharmacy
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 02500 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

 Under the supervision of License Reviewers, Trainee process two Program 02500 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 02500 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- K. Program 03212 Measuring Systems Portable Gauges
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 03212 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

 Under the supervision of License Reviewers, Trainee process two Program 03212 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 03212 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- L. Program 03219 Decontamination Services
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 03219 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 03219 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 03219 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:	
RCPD:		

- M. Program 03310/03320 Industrial Radiography
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 03310/03320 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:	<i></i>	Date:

 Under the supervision of License Reviewers, Trainee process two Program 03310/03320 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:	
Reviewer:		
License:	Date:	
Reviewer:		

3) The Trainee shall process a Program 03310/03320 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	Date:
RCPD:	

- N. Program 03510 Irradiators Self Shielded less than or equal to 10,000 Curies
- 1) Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

Under supervision of a License Reviewer, the Trainee shall be assigned processing of three to five selected Program 03510 amendments.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:

2) Under the supervision of License Reviewers, Trainee process two Program 03510 applications for license or applications for a license renewal in entirety and recommends the license for signature.

License:	Date:
Reviewer:	
License:	Date:
Reviewer:	

3) The Trainee shall process a Program 03510 application for license of license renewal in entirety, including preparing the license, tying down all license conditions and recommending the license to the RCPD for signature.

License:	 Date:	
RCPD:		

Qualification					
Training Completed	Date	OJT Completed	Date	Qualified Program	Date
		Inspections			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610-	
Inspect Procedures (G-108)		Fixed & Port. Gauges		03630, 03211-03213 03120/03121	
Transport of RadMat (H-308)		In-Vitro		02410	
Advanced HP (H-201)		Med Inst. – (Broad)		02110-02113	
Inspect Procedures (G-108) Med Uses of Rad (H-312S)		WD not required WD required		02121/02201 02120/02200	
Transport of RadMat (H-3123)		Mobile		02220/02231	
		HDR/Teletherapy		02230/02300	
		Other Med Uses		02240	
		Veterinary		02400	
Advanced HP (H-201)		Nuclear Pharmacy		02500	
Inspect Procedures (G-108)					
Med Uses of Rad (H-312S)		-			
Transport of RadMat (H-308)					
Advanced HP (H-201)		Ind. Radiography		03310/03320	
Inspect Procedures (G-108)				- '	
Saf. Asp. Ind. Rad (H-305)					
Med Uses of Rad (H-312S) Transport of RadMat (H-308)		Gamma Knife		02310	
Mat Con & Sec Sys (S-201)		-			
		-			
Advanced HP (H-201)		Irradiator		03521	
Inspect Procedures (G-108)		-			
Transport of RadMat (H-308) Irradiator Tech (H-315)		.			
		-			
Advanced HP (H-201)		Decomm. Facilities		03900	
Inspect Procedures (G-108)		-			
Transport of RadMat (H-308) MARSAME (H-120S)		Decon Services		03219	
		Licensing			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610-	
		<u>.</u>		03630, 03211-03213	
Lic Prac & Proc (G-109)		Fixed & Port. Gauges		03120/03121	
Transport of RadMat (H-308)		In-Vitro		02410	
Advanced HP (H-201)		Med Inst. – (Broad)		02110-02113	
Lic Prac & Proc (G-109)		WD not required		02121/02201	
Med Uses of Rad (H-312S)		WD required		02120/02200	
Transport of RadMat (H-308)		Mobile HDR/Teletherapy		02220/02231 02230/02300	
		Other Med Uses		02240	
		Veterinary		02400	
		Nuclear Pharmacy		02500	
Advanced HP (H-201) Lic Prac & Proc (G-109)		Nuclear Pharmacy		02000	
Med Uses of Rad (H-312S)					
Transport of RadMat (H-308)		-			

1			
Advanced HP (H-201) Lic Prac & Proc (G-109) Saf. Asp. Ind. Rad (H-305)	Ind. Radiography	03310/03320	
Med Uses of Rad (H-312S) Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)	Gamma Knife	02310	
Advanced HP (H-201) Lic Prac & Proc (G-109) Transport of RadMat (H-308) Irradiator Tech (H-315)	Irradiator 	03521	
Advanced HP (H-201) Lic Prac & Proc (G-109) Transport of RadMat (H-308)	Decomm. Facilities	03900	
MARSAME (H-120S)	Decon Services	03219	

4.6.3 Current Staff Qualification Program

With the formal establishment of the Agreement State Program, qualification of the current staff will be established in a manner based on RMCPP 5.1 but modified to account for the fact that Radioactive Materials Control Program work may begin soon, even immediately, after the Agreement is established. Current Senior Health Physicists and Health Physicists in the Radioactive Materials Control Program will be deemed fully qualified as documented in writing by the Radiation Program Director. This qualification is substantiated by significant evidence which includes their completion of all the core training courses identified in RMCPP 5.1, their accompaniment of NRC inspector, or qualified inspectors from other Agreement States, on inspections most types of licensees in Indiana, and their spending two weeks studying in person NRC staff license review activities conducted at the NRC Region III office.

Kaci Studer and Brenda Tubbs will serve as Senior Health Physicists and Daisy Coffman, Kevin Stahl, and Patrick Turner will serve as Health Physicists. All will be documented fully qualified at the time of the Agreement taking effect. This is documented in a letter from the Radiation Program Director in Appendix 4.6-1. All have documentation for their training and experience in their individual Qualification Journals. These Qualification Journals are in Appendix 4.6-2. Indiana is planning on all RMCP staff to accompany the NRC, and other Agreement State Inspectors, on their inspections many more times before completion of the Agreement. Details on the amount and types of inspections accompanied by RMCP staff are outlined in their current Qualification Journals located in Appendix 4.6-2. All RMCP staff will spend two weeks studying license review work by the NRC at Region III before completion of the Agreement.

Table 4.6-4 Current Staff Training Completion

Radioactive			License Reviewer/Inspector					
Materials Control Program Core Training Courses	Req'd For Licensing	Req'd for Inspection	Studer	Tubbs	Coffman	Stahl	Turner	Eckstein
G-108: Inspection								
Procedures		Yes		7/28/23	12/1/23	12/1/23		
G-109: Licensing								
Practices &								
Procedures	Yes			12/14/23	12/24/23			

G-205: Root		l						
Cause/Incident								
Investigation								
Training		Yes	2/17/23	5/5/23				
H-122S:								
Fundamentals of								
Health Physics Self								
Study			8/9/22	6/19/22	3/13/23	8/17/23	11/29/23	
H-201: Advanced			-,-,	-1 -1	-, -, -	-, , -	, -, -	
Health Physics	Yes	Yes						
H-305: Safety	105	103						
Aspects of Industrial								
Radiography	Yes	Yes	3/17/23	3/17/23				
H-308S:			0/1/20	0, 1, 1, 20				
Transportation of								
Radioactive								
Materials Self-Study	Yes	Yes	1/6/23	1/22/23	5/9/23		1/17/24	
H-317S: Medical			_/ =/ ==	_//	-,-,		_/ _ · / _ ·	
Uses of Radiation								
Self Study	Yes	Yes	7/28/23		8/4/23			
S-201: Materials								
Control & Security								
Systems & Principles	Yes	Yes		8/18/23	8/18/23			
Specialized and Enha				8/18/23	8/18/23			
F-104: Health		ig courses						
Physics for Uranium								
Recovery								
H-115S:								
Characterization and								
Planning for								
Decommissioning								
H-117S: Introductory								
Health Physics			6/10/22	6/10/22	3/2/23	6/19/23	11/21/23	
			0/10/22	0/10/22	5/2/25	0/15/25	11/21/23	
H-120S: Radiological								
Surveys in Support								
of Decommissioning							/ . /	
(MARSAME)							12/5/23	
H-121S: Multi-								
Agency Radiation								
Survey and Sites								
Investigation Manual							12/11/22	
(MARSSIM)							12/11/23	
H-122Lab:								
Fundamental Health					- 4 - 4-			
Physics Labs Course			11/4/22	1/27/23	6/16/23	1/26/24		
H-130Lab:								
Environmental								
Monitoring and Air								
Sampling for								
Radioactivity Lab				0/20/22				
Course				9/29/23				

H-130S: Environmental Monitoring & Air Sampling for Radioactivity Self- Study		11/3/23	9/5/23	12/20/23	11/22/23	2/1/24	
H-301S: Health Physics Statistics Self-Study Course		1/5/23	7/14/22		8/17/23		
H-311: Respiratory Protection							
H-312S: Internal Dosimetry Self-Study H-314: Safety Aspects of Well Logging		8/28/23	7/21/23				
H-315: Irradiator Technology Course							
H-408: RESRAD OVERVIEW							
H-412: Advanced RESRAD Training Workshop							
H-413: MILDOS-Area Training Workshop	 						
H-500: Visual Sampling Plan							

Appendix 4.6-1 Letter of Current Staff Qualification

Appendix 4.6-2 Current Staff Qualification Journals

Kaci Studer – Senior Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Health Physicist Qualification Journal

Kaci Studer

NAME: _____

Senior Health Physicist

TITLE: _____

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

I. Medical Uses of Radiation Self-Study (H-317S)				
Dates Attended:7/28/23	RCPD			
J. Fundamentals of Health Physics Sel	f-Study (H-122S)			
Dates Attended:8/9/22	RCPD			
K. Transportation of Radioactive Mater	rials Self-Study (H-308S)			
Dates Attended:1/6/23	RCPD			
L. Inspection Procedures (G-108)				
Dates Attended:	RCPD			
M. Licensing Practices & Procedures (C	G-109)			
Dates Attended:	RCPD			
N. Safety Aspects of Industrial Radiography (H-305)				
Dates Attended:3/17/23	RCPD			
O. Materials Control & Security System	ns & Principles (S-201)			
Dates Attended:	RCPD			
P. Advanced Health Physics (H-201)				
Dates Attended:	RCPD			
J. Root Cause/Incident Investigation	Training (G-205)			
Dates Attended:2/17/23	RCPD			
Page 508				

SPECIALIZED/ENHANCEMENT TRAINING

R. Irradiator Technology Course (H-31	5)
Dates Attended	RCPD
S. Safety Aspects of Well Logging (I	H-314)
Dates Attended	RCPD
T. MARSAME: Multi-Agency Radiatie Equipment (H-120S)	on Survey and Assessment of Materials and
Dates Attended	RCPD
U. Characterization and Planning for De	ecommissioning (H-115S)
Dates Attended	RCPD
V. Internal Dosimetry Self-Study (H-33	12S)
Dates Attended 8/28/23	RCPD
W.Environmental Monitoring & Air Sam	oling for Radioactivity Self-Study (H-130S)
Dates Attended <u>11/3/23</u>	RCPD
X. Respiratory Protection (H-311)	
Dates Attended	RCPD
Y. MARSSIM: Multi-Agency Radiation S	Survey and Sites Investigation Manual (H-121S)
Dates Attended	RCPD
Z. Health Physics for Uranium Recover	y (F-104)
Dates Attended	RCPD

AA.	Introductory Health Physics (H	-117S)	
Dates A	Attended 6/10/22	RCPD	
BB.	Fundamental Health Physics La	ab (H-122Lab)	
Dates A	Attended <u>11/4/22</u>	RCPD	
CC.	Environmental Monitoring & Ai	r Sampling for Radioactivity L	ab (H-130Lab)
Dates A	Attended	RCPD	
DD.	Health Physics Statistics Self-S	Study (H-301S)	
Dates A	Attended <u>1/5/23</u>	RCPD	
EE.	RESRAD OVERVIEW (H-408)		
Dates A	Attended	RCPD	
FF.	Advanced RESRAD Training Wo	orkshop (H-412)	
Dates A	Attended	RCPD	
GG.	MILDOS-Area Training Worksh	op (H-413)	
Dates A	Attended	RCPD	
HH.	Visual Sampling (H-500)		
Dates A	Attended	RCPD	

ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic

Trainee observes an Inspector preparing for and conducting an inspection of a Program 01100-01120 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

B. Program 02110 – Medical Institution – Broad Scope

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02120 licensee.

Licensee: Community Hospital of Anderson and Madison	Date: 4/24/23
County	
Inspector:Elizabeth Tindle-Engelmann Licensee: Inspector:	Date:

D. Core Program 02121 – Medical Institution Written Directive Not Required

Date: _____

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02121 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

E. Core Program 02230/02300 – HDR or Teletherapy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02230/02300 licensee.

Licensee: Community Hospital of Anderson and Madison	Date: 4/24/23
County	
Inspector: Elizabeth Tindle-Engelmann	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

F. Core Program 02231 – Medical Mobile Services Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02231 licensee.

Licensee:Mobile Medical	Date: 4/24/23
Inspector: _ Elizabeth Tindle-Engelmann	_
Licensee:	Date:
Inspector:	_
RCPD Approval:	Date:

G. Core Program 02240 – Emerging Technologies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

H. Core Program 02400 – Veterinary Nonhuman Subjects

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

I. Core Program 02410 – In-Vitro Testing Laboratories

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee:Antech Diagnostics	Date: 4/27/23
Inspector: Elizabeth Tindle-Engelmann	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

J. Core Program 02500 – Nuclear Pharmacy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

K. Core Program 03121 – Measuring Systems – Portable Gauges

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee: Thermo-Scan Energy Management Corporation	Date: 4/27/23
Inspector: _ Elizabeth Tindle-Engelmann	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:
	Date:

L. Core Program 03219 – Decontamination Services

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:
	Date:

M. Core Program 03310/03320 – Industrial Radiography

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:

Inspector:	
RCPD Approval:	Date:

N. Core Program 03510 – Irradiators Self-Shielded less than or equal to 10,000 Curies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03510 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

ON-THE-JOB TRAINING LICENSING

A. Program 01100-01120 Academic

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

B. Program 02110 – Medical Institution Broad Scope

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:	-	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

D. Program 02121 – Medical Institution Written Directive Not Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

E. Program 02230 – High-Dose Rate Remote Afterloader

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

F. Program 02231 – Mobile Medical Services Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

G. Program 02240 – Medical Therapy Other Emerging Technologies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

H. Program 02400 – Veterinary Nonhuman Subjects

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

I. Program 02410 – In-Vitro Testing Laboratories

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

J. Program 02500 – Nuclear Pharmacy

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
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K. Program 03121 – Measuring Systems – Portable Gauges

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

L. Program 03219 – Decontamination Services

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type:	
RCPD Approval:		Date:

M. Program 03310/03320 – Industrial Radiography

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

N. Program 03510 – Irradiators Self Shielded less than or equal to 10,000 Curies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

Qualification					
Training Completed	Date	OJT Completed	Date	Qualified Program	Date
		Inspections			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610- 03630, 03211-03213	
Inspect Procedures (G-108)		Fixed & Port. Gauges		03120/03121	
Transport of RadMat (H-308)		In-Vitro		02410	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S) Transport of RadMat (H-308)		Med Inst. – (Broad) WD not required WD required Mobile HDR/Teletherapy Other Med Uses Veterinary		02110-02113 02121/02201 02120/02200 02220/02231 02230/02300 02240 02400	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S) Transport of RadMat (H-308)		Nuclear Pharmacy		02500	

.....

Advanced HP (H-201) Inspect Procedures (G-108)	Ind. Radiography	03310/03320	
Saf. Asp. Ind. Rad (H-305) Med Uses of Rad (H-312S) Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)	Gamma Knife	02310	
Advanced HP (H-201) Inspect Procedures (G-108) Transport of RadMat (H-308) Irradiator Tech (H-315)	Irradiator 	03521	
Advanced HP (H-201) Inspect Procedures (G-108) Transport of RadMat (H-308)	Decomm. Facilities	03900	
MARSAME (H-120S)	Decon Services	03219	

Licensing			
Advanced HP (H-201)	All Broad – Except Med	01100-01120, 03610- 03630, 03211-03213	
Lic Prac & Proc (G-109)	Fixed & Port. Gauges	03120/03121	
Transport of RadMat (H-308)	In-Vitro	02410	
Advanced HP (H-201)	Med Inst. – (Broad)	02110-02113	
Lic Prac & Proc (G-109)	WD not required	02121/02201	
Med Uses of Rad (H-312S)	WD required	02120/02200	
Transport of RadMat (H-308)	Mobile	02220/02231	
	HDR/Teletherapy	02230/02300	
	Other Med Uses	02240	
	Veterinary	02400	
Advanced HP (H-201)	Nuclear Pharmacy	02500	
Lic Prac & Proc (G-109)			
Med Uses of Rad (H-312S)			
Transport of RadMat (H-308)			
		02240/02220	
Advanced HP (H-201)	Ind. Radiography	03310/03320	
Lic Prac & Proc (G-109)			
Saf. Asp. Ind. Rad (H-305)		03210	
Med Uses of Rad (H-312S)	Gamma Knife	02310	
Transport of RadMat (H-308)			
Mat Con & Sec Sys (S-201)			
Advanced HP (H-201)	Irradiator	03521	
Lic Prac & Proc (G-109)			
Transport of RadMat (H-308)			
Irradiator Tech (H-315)			
Advanced HP (H-201)	Decomm. Facilities	03900	
Lic Prac & Proc (G-109)			
Transport of RadMat (H-308)			
MARSAME (H-120S)	Decon Services	03219	

Brenda Tubbs - Senior Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Health Physicist Qualification Journal

Brenda D. Tubbs

NAME: _____

Senior Health Physicist

TITLE: _____

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

	Q. Medical Uses of Radiation Self-Study (H-317S)		
	Dates Attended:	RCPD	
	R. Fundamentals of Health Physics Sel	f-Study (H-122S)	
	Dates Attended: <u>06/19/2022</u>	RCPD	
	S. Transportation of Radioactive Mater	ials Self-Study (H-308S)	
	Dates Attended: 01/22/2023	RCPD	
	T. Inspection Procedures (G-108)		
	Dates Attended: 07/28/2023	RCPD	
	U.Licensing Practices & Procedures (G	-109)	
	Dates Attended: <u>12/14/2023</u>	RCPD	
	V. Safety Aspects of Industrial Radiog	raphy (H-305)	
	Dates Attended: 03/17/2023	RCPD	
	W.Materials Control & Security System	ns & Principles (S-201)	
	Dates Attended: <u>08/18/2023</u>	RCPD	
	X. Advanced Health Physics (H-201)		
	Dates Attended:	RCPD	
	K. Root Cause/Incident Investigation 7	Training (G-205)	
	Dates Attended: 05/05/2023	RCPD	
Page 5	523		

SPECIALIZED/ENHANCEMENT TRAINING

II. Irr	adiator Technology Course (H-31	5)
Date	s Attended	RCPD
JJ.	Safety Aspects of Well Logging (H-314)
Date	s Attended	RCPD
KK.	Radiological Surveys in Support	of Decommissioning (H-120)
Date	s Attended	RCPD
LL.	Root Cause/Incident Investigatio	n Training (G-205)
Date	s Attended <u>05/05/2023</u>	RCPD
MM.	Characterization and Planning fo	r Decommissioning (H-315)
Date	s Attended	RCPD
NN.	Internal Dosimetry Self-Study	(H-312S)
Date	s Attended <u>02/06/2023</u>	RCPD
00.	Environmental Monitoring & Ai	Sampling for Radioactivity Self-Study (H-130S)
Date	s Attended <u>08/06/2023</u>	RCPD
PP.	Respiratory Protection (H-311)	
Date	s Attended	RCPD
QQ.	Multi-Agency Radiation Survey a	nd Sites Investigation Manual (MARSSIM)
Date	s Attended	RCPD

RR. Health Physics for Uranium Recovery (F-104)

Dates Attended	RCPD
SS. Introductory Health Physics (H	-117S)
Dates Attended 06/01/2022	RCPD
TT. Fundamental Health Physics La	ab (H-122Lab)
Dates Attended 01/27/2023	RCPD
UU. Environmental Monitoring & Ai	r Sampling for Radioactivity Lab (H-130Lab)
Dates Attended 09/29/2023	RCPD
VV. Health Physics Statistics Self-S	Study (H-301S)
Dates Attended 07/14/2022	RCPD
WW. RESRAD OVERVIEW (H-408)	
Dates Attended	RCPD
XX. Advanced RESRAD Training Wo	orkshop (H-412)
Dates Attended	RCPD
YY. MILDOS-Area Training Worksho	op (H-413)
Dates Attended	RCPD
ZZ. Visual Sampling (H-500)	
Dates Attended	RCPD

ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic

Trainee observes an Inspector preparing for and conducting an inspection of a Program 01100-01120 licensee.

Licensee: Purdue University SUD-296 Inspector: Geoffrey Warren	Date: 7/11/23
Licensee: Purdue University SNM-142 Inspector: Geoffrey Warren	Date: 7/11/23
RCPD Approval:	Date:

B. Program 02110 – Medical Institution – Broad Scope

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee:	Date:
Inspector:	Ja
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02120 licensee.

Licensee: Ascension Macomb Oakland Hospital	Date: 11/29/2023
Inspector: Jason Von Ehr	11/29/2023
RCPD Approval:	Date:
D. Core Program 02121 – Medical Institution Writt Not Required	en Directive
Trainee observes an Inspector preparing for and conduc inspection of a Program 02121 licensee.	ting an
Licensee: Woodlawn Hospital 13-20338-01 Inspector: Geoffrey Warren	Date:7/14/23
Licensee: Lingareddy Divereddy, M.D. 21-32388-01	Date: 11/29/2023
Inspector: Jason VonEhr RCPD Approval:	Date:
E. Core Program 02230/02300 – HDR or Telethera	ру
Trainee observes an Inspector preparing for and conduc inspection of a Program 02230/02300 licensee.	ting an
Licensee: Providence Hospital, Providence Cancer Center 21-26632-01 Inspector: Jason VonEhr	Date: 11/28/23
RCPD Approval:	Date:

F. Core Program 02231 – Medical Mobile Services Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02231 licensee.

Licensee: _____ Date: _____

Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

G. Core Program 02240 – Emerging Technologies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

H. Core Program 02400 – Veterinary Nonhuman Subjects

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

I. Core Program 02410 – In-Vitro Testing Laboratories

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee:	_ Date:
Inspector:	
Licensee:	_ Date:
Inspector:	
RCPD Approval:	Date:

J. Core Program 02500 – Nuclear Pharmacy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee: Cardinal Health 34-31473-03MD Inspector: Geoffrey Warren	Date: 7/12/23
Licensee: NukeMed Inc. dba SpectronRx 13-32726-03 Inspector: Geoffrey Warren	Date: 7/14/23
RCPD Approval:	Date:

K. Core Program 03121 – Measuring Systems – Portable Gauges

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee: <u>SABIC Innovative Plastics Mr. Vernon, LLC 13-</u> <u>10455-01</u> Inspector: <u>Michael C. Reichard</u>	Date:3/21/23
Licensee: <u>Countrymark Refining and Logistics, LLC 13-</u> <u>26261-01</u> Inspector: <u>Michael C. Reichard</u>	Date: 3/22/23
Licensee: Alt & Witzig Engineering, Inc 13-18685-02 Inspector: <u>Michael C. Reichard</u>	Date: 3/22/23
Licensee: <u>Peabody Midwest Mining, LLC 13-26785-01</u> Inspector: <u>Michael C. Reichard</u>	Dare: 3/22/23
Licensee: Lehigh Cement Co 13-26609-01 Inspector: <u>Michael C. Reichard</u>	Date: 3/23/23
Licensee: Waupaca Foundry, Inc 48-15031-01 Inspector: Michael C. Reichard	Date: 3/23/23
RCPD Approval:	

L. Core Program 03219 – Decontamination Services

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

M. Core Program 03310/03320 – Industrial Radiography

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee: JRGO LLC 04-24888-01 Inspector: <u>Michael C. Reichard</u>	Date: 3/21/23
Licensee:	Date:
Inspector:	_
RCPD Approval:	Date:

N. Core Program 03510 – Irradiators Self-Shielded less than or equal to 10,000 Curies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03510 licensee.

Date:
10/25/2023
Date:
Date:

ON-THE-JOB TRAINING LICENSING

A. Program 01100-01120 Academic

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

B. Program 02110 – Medical Institution Broad Scope

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:	-	Date:

D. Program 02121 – Medical Institution Written Directive Not Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

E. Program 02230 – High-Dose Rate Remote Afterloader

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

Amendment Type: _	
	Date:
Amendment Type:	
	Date:
	Date:
	Amendment Type: _ Amendment Type: _

F. Program 02231 – Mobile Medical Services Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

G. Program 02240 – Medical Therapy Other Emerging Technologies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

H. Program 02400 – Veterinary Nonhuman Subjects

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

I. Program 02410 – In-Vitro Testing Laboratories

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

J. Program 02500 – Nuclear Pharmacy

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

K. Program 03212 – Measuring Systems – Portable Gauges

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

L. Program 03219 – Services Provider

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

M. Program 03310/03320 - Industrial Radiography

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

N. Program 03510 – Irradiators Self Shielded less than or equal to 10,000 Curies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

Qualification					
Training Completed	Date	OJT Completed	Date	Qualified Program	Date
Inspections					
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610-	
Page 535					

Inspect Procedures (G-108) Transport of RadMat (H-308)		Fixed & Port. Gauges In-Vitro	 03630, 03211-03213 03120/03121 02410	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S) Transport of RadMat (H-308)		Med Inst. – (Broad) WD not required WD required Mobile HDR/Teletherapy Other Med Uses Veterinary	02110-02113 02121/02201 02120/02200 02220/02231 02230/02300 02240 02400	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S) Transport of RadMat (H-308)	'	Nuclear Pharmacy	 02500	
Advanced HP (H-201) Inspect Procedures (G-108) Saf. Asp. Ind. Rad (H-305)	¹	Ind. Radiography	 03310/03320	
Med Uses of Rad (H-312S) Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)		Gamma Knife	 02310	
Advanced HP (H-201) Inspect Procedures (G-108) Transport of RadMat (H-308) Irradiator Tech (H-315)	¹	Irradiator	 03521	
Advanced HP (H-201) Inspect Procedures (G-108) Transport of RadMat (H-308)	[Decomm. Facilities	 03900	
MARSAME (H-120S)	(Decon Services	 03219	
		Licensing		
Advanced HP (H-201)	1	All Broad – Except Med	01100-01120, 03610- 03630, 03211-03213	
Lic Prac & Proc (G-109)	I	Fixed & Port. Gauges	 03120/03121	
Transport of RadMat (H-308)]	In-Vitro	 02410	
Advanced HP (H-201)	r	Med Inst. – (Broad)	02110-02113	
Lic Prac & Proc (G-109)	\	WD not required	 02121/02201	
Med Uses of Rad (H-312S)		WD required	 02120/02200	
Transport of RadMat (H-308)		Mobile	 02220/02231	
		HDR/Teletherapy Other Med Uses	 02230/02300 02240	
		Veterinary	 02400	
		Vetermary	 02100	
Advanced HP (H-201) Lic Prac & Proc (G-109) Med Uses of Rad (H-312S) Transport of RadMat (H-308)	I	Nuclear Pharmacy	 02500	
Advanced HP (H-201) Lic Prac & Proc (G-109) Saf. Asp. Ind. Rad (H-305)	¹	Ind. Radiography	 03310/03320	
Med Uses of Rad (H-312S) Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)		Gamma Knife	 02310	
Page 536				

Advanced HP (H-201) Lic Prac & Proc (G-109) Transport of RadMat (H-308) Irradiator Tech (H-315)	Irradiator 	03521	
Advanced HP (H-201) Lic Prac & Proc (G-109) Transport of RadMat (H-308)	Decomm. Facilities	03900	
MARSAME (H-120S)	Decon Services	03219	

Kevin Stahl - Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Health Physicist Qualification Journal

NAME: _____Kevin Stahl_____

TITLE: ___Health Physicist_____

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

	A. Medical Uses of Radiation Self-Stud	y (H-317S)	
	Dates Attended:	RCPD	
	B. Fundamentals of Health Physics Sel	f-Study (H-122S)	
	Dates Attended: 7/18/2023 – 8/17/2023 RCPD		
	C. Transportation of Radioactive Mater	ials Self-Study (H-308S)	
	Dates Attended:	RCPD	
	D. Inspection Procedures (G-108)		
	Dates Attended: 11/27/2023 - 12/1/2	2023 RCPD	
	E. Licensing Practices & Procedures (G	-109)	
	Dates Attended:	RCPD	
	F. Safety Aspects of Industrial Radiog	raphy (H-305)	
	Dates Attended:	RCPD	
	G. Materials Control & Security System	ns & Principles (S-201)	
	Dates Attended:	RCPD	
	H. Advanced Health Physics (H-201)		
	Dates Attended:	RCPD	
	L. Root Cause/Incident Investigation 1	raining (G-205)	
	Dates Attended:	RCPD	
Page 5	39		

SPECIALIZED/ENHANCEMENT TRAINING

M.Irr	adiator Technology Course (H-31	5)		
Date	s Attended	RCPD		
N.	Safety Aspects of Well Logging (I	H-314)		
Date	s Attended	RCPD		
О.	Radiological Surveys in Support	of Decommissioning (H-120)		
Date	s Attended	RCPD		
P.	Root Cause/Incident Investigatio	n Training (G-205)		
Date	s Attended	RCPD		
Q. Ch	aracterization and Planning for De	ecommissioning (H-315)		
Date	s Attended	RCPD		
R. In	ternal Dosimetry Self-Study (H-31	12S)		
Date	s Attended	RCPD		
S. En	vironmental Monitoring & Air Sam	oling for Radioactivity Self-Study (H-130S)		
Dates Attended 7/18/2023 – 11/22/2023 RCPD				
T. Respiratory Protection (H-311)				
Date	s Attended	RCPD		
U. Multi-Agency Radiation Survey and Sites Investigation Manual (MARSSIM)				
Date	s Attended	RCPD		

V. Health Physics for Uranium Recover	y (F-104)
Dates Attended	RCPD
W.Introductory Health Physics (H-1175	5)
Dates Attended <u>6/16/2023 – 6/19/2023</u>	RCPD
X. Fundamental Health Physics Lab (H-	122Lab)
Dates Attended <u>1/22/24 – 1/26/24</u>	RCPD
Y. Environmental Monitoring & Air Sam	ppling for Radioactivity Lab (H-130Lab)
Dates Attended	RCPD
Z. Health Physics Statistics Self-Study	(H-301S)
Dates Attended <u>7/18/23 - 8/17/23</u> RCPI	D
AA. RESRAD OVERVIEW (H-408)	
Dates Attended	RCPD
BB. Advanced RESRAD Training Wo	orkshop (H-412)
Dates Attended	RCPD
CC. MILDOS-Area Training Worksho	op (H-413)
Dates Attended	RCPD
DD. Visual Sampling (H-500)	
Dates Attended	RCPD
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ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic

Trainee observes an Inspector preparing for and conducting an inspection of a Program 01100-01120 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

B. Program 02110 – Medical Institution – Broad Scope

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee: Henry County Hospital	Date: 7/14/23
Inspector: Geoffrey Warren	
Licensee: Dupont Hospital	Date: 8/24/23
Inspector:	
RCPD Approval:	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02120 licensee.

Licensee: Reid Hospital and Health Care Services	Date: 11/14/23
Inspector: Debbie Piskura	11/11/23

Licensee:	Date:	
Inspector:		
RCPD Approval:	Date:	

D. Core Program 02121 – Medical Institution Written Directive Not Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02121 licensee.

Licensee: St Vincent Medical Group Avon/Noblesville	Date: 09/28/23
Inspector: Jason Draper	
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

E. Core Program 02230/02300 – HDR or Teletherapy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02230/02300 licensee.

Licensee: Reid Hospital and Health Care	Date: 11/14/23
Inspector: Debbie Piskura	
Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

F. Core Program 02231 – Medical Mobile Services Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02231 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

G. Core Program 02240 – Emerging Technologies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

H. Core Program 02400 – Veterinary Nonhuman Subjects

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

I. Core Program 02410 – In-Vitro Testing Laboratories

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:

Inspector:	 _	
RCPD Approval:	Date:	

J. Core Program 02500 – Nuclear Pharmacy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee:	_ Date:
Inspector:	_
Licensee:	Date:
Inspector:	_
RCPD Approval:	Date:

K. Core Program 03121 – Measuring Systems – Portable Gauges

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee: Materials Inspection and Testing	Date: 8/24/23
Inspector: Elizabeth Tindle-Engelmann Licensee: GME Testing	Date: 8/24/23
Inspector: Elizabeth Tindle-Engelmann	
Licensee:	_ Date:
Inspector:	_
RCPD Approval:	_ Date:

L. Core Program 03219 – Decontamination Services

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

M. Core Program 03310/03320 - Industrial Radiography

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

N. Core Program 03510 – Irradiators Self-Shielded less than or equal to 10,000 Curies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03510 licensee.

Licensee: IUPUI/IU Methodist Hospital	Date: 10/24/23
Inspector: Juan Alaya	
Licensee: QalTek Services	Date: 10/24/23
Inspector: Juan Alaya	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

ON-THE-JOB TRAINING LICENSING

A. Program 01100-01120 Academic

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
RCPD Approval:		Date:

B. Program 02110 – Medical Institution Broad Scope

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

D. Program 02121 – Medical Institution Written Directive Not Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

E. Program 02230 - High-Dose Rate Remote Afterloader

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

F. Program 02231 – Mobile Medical Services Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

G. Program 02240 – Medical Therapy Other Emerging Technologies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:	· ·	Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

H. Program 02400 – Veterinary Nonhuman Subjects

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

I. Program 02410 – In-Vitro Testing Laboratories

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

J. Program 02500 – Nuclear Pharmacy

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

K. Program 03212 – Measuring Systems – Portable Gauges

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:	· · · · · ·	Date:
RCPD Approval:		Date:

L. Program 03219 – Services Provider

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

M. Program 03310/03320 – Industrial Radiography

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	_ Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

N. Program 03510 – Irradiators Self Shielded less than or equal to 10,000 Curies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

Qualification					
Training Completed	Date	OJT Completed	Date	Qualified Program	Date
		Inspections			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610- 03630, 03211-03213	
Inspect Procedures (G-108) Transport of RadMat (H-308)		Fixed & Port. Gauges In-Vitro		03120/03121 02410	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S) Transport of RadMat (H-308)		Med Inst. – (Broad) WD not required WD required Mobile HDR/Teletherapy Other Med Uses		02110-02113 02121/02201 02120/02200 02220/02231 02230/02300 02240	

	Veterinary	02400	
		02400	
Advanced HP (H-201)	Nuclear Pharmacy	02500	
Inspect Procedures (G-108) Med Uses of Rad (H-312S)			
Transport of RadMat (H-3123)			
Advanced HP (H-201)	Ind. Radiography	03310/03320	
Inspect Procedures (G-108) Saf. Asp. Ind. Rad (H-305)			
Med Uses of Rad (H-312S)	Gamma Knife	02310	
Transport of RadMat (H-308)			
Mat Con & Sec Sys (S-201)			
Advanced HP (H-201)	Irradiator	03521	
Inspect Procedures (G-108)			
Transport of RadMat (H-308) Irradiator Tech (H-315)			
Advanced HP (H-201)	Decomm. Facilities	03900	
Inspect Procedures (G-108) Transport of RadMat (H-308)			
MARSAME (H-120S)	Decon Services	03219	
	Licensing		
Advanced HP (H-201)	All Broad – Except Med	01100-01120, 03610-	
· · · ·	· · ·	03630, 03211-03213	
Lic Prac & Proc (G-109) Transport of RadMat (H-308)	Fixed & Port. Gauges	03120/03121 02410	
	11 0100	02410	
Advanced HP (H-201)	Med Inst. – (Broad)	02110-02113	
Lic Prac & Proc (G-109) Med Uses of Rad (H-312S)	WD not required WD required	02121/02201 02120/02200	
Transport of RadMat (H-308)	Mobile	02220/02231	
· · · · <u> </u>	HDR/Teletherapy	02230/02300	
	Other Med Uses Veterinary	02240 02400	
		02400	
Advanced HP (H-201)	Nuclear Pharmacy	02500	
Lic Prac & Proc (G-109) Med Uses of Rad (H-312S)			
Transport of RadMat (H-308)			
	Ind Dadiaseshi	02210/02220	
Advanced HP (H-201) Lic Prac & Proc (G-109)	Ind. Radiography	03310/03320	
Saf. Asp. Ind. Rad (H-305)			
Med Uses of Rad (H-312S)	Gamma Knife	02310	
Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)			
, , , , _			
Advanced HP (H-201) Lic Prac & Proc (G-109)	Irradiator	03521	<u> </u>
Transport of RadMat (H-308)			
Irradiator Tech (H-315)			
Advanced HP (H-201)	Docomm Eacilities	03000	
Advanced HP (H-201) Lic Prac & Proc (G-109)	Decomm. Facilities	03900	
Transport of RadMat (H-308)			
MARSAME (H-120S)	Decon Services	03219	
Page 552			

Daisy Coffman - Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Health Physicist Qualification Journal

NAME: Daisy Coffman

TITLE: Health Physicist

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

A. Medical Uses of Radiation Self-Stud	y (H-317S)		
Dates Attended: _6/28/2023-8/4/202 B. Fundamentals of Health Physics Sel	_		
Dates Attended: 6/12/2023-6/16/202		RCPD	
C. Transportation of Radioactive Mater	ials Self-Study (H-3	308S)	
Dates Attended: 3/14/2023-5/9/2023		_ RCPD	
D. Inspection Procedures (G-108)			
Dates Attended: 11/27/2023-12/1/20	23	_RCPD	
E. Licensing Practices & Procedures (G	-109)		
Dates Attended: 12/10/2023-12/24/2023RCPD			
F. Safety Aspects of Industrial Radiog	raphy (H-305)		
Dates Attended:	RCPD		
G. Materials Control & Security System	ns & Principles (S-2	01)	
Dates Attended:8/14/2023-8/18/2023	3	_RCPD	
H. Advanced Health Physics (H-201)			
Dates Attended:	RCPD		
M.Root Cause/Incident Investigation	Fraining (G-205)		

Dates Attended: ______ RCPD_____

SPECIALIZED/ENHANCEMENT TRAINING

	N.	Irradiator Technology Course (H-315)		
	Date	s Attended	RCPD	
	О.	Safety Aspects of Well Logging (H-	-314)	
	Date	es Attended	RCPD	
	P.	Characterization and Planning for	Decommissioning (H-115S)	
	Date	es Attended	RCPD	
	Q.	Internal Dosimetry Self-Study (H-	312S)	
	Date	es Attended	RCPD	
	R. Environmental Monitoring & Air Sampling for Radioactivity Se			
(H-130S)			
	Date	Dates Attended 9/25/2023-12/20/2023_RCPD		
	S.	Respiratory Protection (H-311)		
	Date	es Attended	RCPD	
	Τ.	Multi-Agency Radiation Survey and (MARSSIM) (H-121S)	d Sites Investigation Manual	
	Dat	es Attended	RCPD	
	U.	Health Physics for Uranium Recover	ery (F-104)	
	Dat	es Attended	RCPD	
	V.	Introductory Health Physics (H-11	7S)	

Da	tes Attended <u>2/28/2023-3/2/2023</u>	RCPD
W.	Fundamental Health Physics Lab (H-122Lab)
Da	tes Attended <u>6/12/2023-6/16/2023</u>	RCPD
X.	Environmental Monitoring & Air Sa 130Lab)	ampling for Radioactivity Lab (H-
Da	tes Attended	RCPD
Y.	Health Physics Statistics Self-Stud	y (H-301S)
Da	tes Attended <u>1/8/2023-1/23/2024</u>	RCPD
Z.	RESRAD OVERVIEW (H-408)	
Da	tes Attended	RCPD
AA.	Advanced RESRAD Training Works	hop (H-412)
Da	tes Attended	RCPD
BB.	MILDOS-Area Training Workshop (H-413)
Da	tes Attended	RCPD
CC.	Visual Sampling (H-500)	
Da	tes Attended	RCPD

ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic

Trainee observes an Inspector preparing for and conducting an inspection of a Program 01100-01120 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

B. Program 02110 – Medical Institution – Broad Scope

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02120 licensee.

Licensee: Northwest Radiology	Date:
Inspector: Elizabeth Tindle-Engelmann	4/26/23
· · · · · · · · · · · · · · · · · · ·	
Licensee: Marion Hospital	Date:
	_9/27/23

Inspector: Jason Draper	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

D. Core Program 02121 – Medical Institution Written Directive Not Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02121 licensee.

Date: 4/26/2023
Date:
 Date:

E. Core Program 02230/02300 – HDR or Teletherapy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02230/02300 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

F. Core Program 02231 – Medical Mobile Services Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02231 licensee.

Licensee:	 Date:	
Inspector:		

Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

G. Core Program 02240 – Emerging Technologies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

H. Core Program 02400 – Veterinary Nonhuman Subjects

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

I. Core Program 02410 – In-Vitro Testing Laboratories

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

J. Core Program 02500 – Nuclear Pharmacy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee: NukeMed Inc., dba SpectronRx	Date: 07/21/2023
Inspector: Zahid Sulaiman	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

K. Core Program 03121 – Measuring Systems – Portable Gauges

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee: Gaunt & Son Asphalt, Inc.	Date: 09/27/2023
Inspector: Jason Draper	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

L. Core Program 03219 – Decontamination Services

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	_
Licensee:	Date:
Inspector:	_
RCPD Approval:	Date:

M. Core Program 03310/03320 – Industrial Radiography

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

N. Core Program 03510 – Irradiators Self-Shielded less than or equal to 10,000 Curies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03510 licensee.

-

ON-THE-JOB TRAINING LICENSING

A. Program 01100-01120 Academic

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

B. Program 02110 – Medical Institution Broad Scope

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

License:	Amendment Type:		_
Reviewer:		Date:	
License:	Amendment Type:		
Reviewer:		Date:	
RCPD Approval:		Date:	

C. Program 02120 – Medical Institution Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

D. Program 02121 – Medical Institution Written Directive Not Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
Page 563		

E. Program 02230 – High-Dose Rate Remote Afterloader

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

F. Program 02231 – Mobile Medical Services Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	_ Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

G. Program 02240 – Medical Therapy Other Emerging Technologies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

License:	Amendment Type:
Reviewer:	Date:
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License:	Amendment Type:	
Reviewer:	Date:	
RCPD Approval:	Date:	

H. Program 02400 – Veterinary Nonhuman Subjects

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

I. Program 02410 – In-Vitro Testing Laboratories

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

J. Program 02500 – Nuclear Pharmacy

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

License:	Amendment Type:
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Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

K. Program (03121) – Measuring Systems – Portable Gauges

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

L. Program 03219 – (Decontamination Services)

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

M. Program 03310/03320 – Industrial Radiography

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

License: Amendment Type:

Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

N. Program 03510 – Irradiators Self Shielded less than or equal to 10,000 Curies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
RCPD Approval:		Date:

Training Completed	Date	OJT Completed	Date	Qualified Program	Dat
		-			
		Inspections			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610- 03630, 03211-03213	
Inspect Procedures (G-108)		Fixed & Port. Gauges		03120/03121	
Transport of RadMat (H-308)		In-Vitro		02410	
Advanced HP (H-201)		Med Inst. – (Broad)		02110-02113	
Inspect Procedures (G-108)		WD not required		02121/02201	
Med Uses of Rad (H-312S)		WD required		02120/02200	
Transport of RadMat (H-308)		Mobile			
		HDR/Teletherapy		02230/02300	
		Other Med Uses Veterinary		02240 02400	
		vetermary		02400	
Advanced HP (H-201)		Nuclear Pharmacy		02500	
Inspect Procedures (G-108)		-			
Med Uses of Rad (H-312S) Transport of RadMat (H-308)		-			
		Ind Dadiagraphy		02210/02220	
Advanced HP (H-201) Inspect Procedures (G-108)		Ind. Radiography		03310/03320	
Saf. Asp. Ind. Rad (H-305)		-			
Med Uses of Rad (H-312S)		Gamma Knife		02310	
Transport of RadMat (H-308)					
Mat Con & Sec Sys (S-201)		-			
Advanced HP (H-201)		Irradiator		03521	
Inspect Procedures (G-108)					
Transport of RadMat (H-308)		-			
Irradiator Tech (H-315)		-			
Advanced HP (H-201)		Decomm. Facilities		03900	
Inspect Procedures (G-108)		_			
Transport of RadMat (H-308)					
MARSAME (H-120S)	. <u> </u>	Decon Services		03219	
Advanced HP (H-201)		Licensing All Broad – Except Med		01100-01120, 03610-	
				03630, 03211-03213	
Lic Prac & Proc (G-109)		Fixed & Port. Gauges		03120/03121	
Transport of RadMat (H-308)		In-Vitro		02410	
Advanced HP (H-201)		Med Inst. – (Broad)		02110-02113	_
Lic Prac & Proc (G-109)		WD not required		02121/02201	
Med Uses of Rad (H-312S)		WD required		02120/02200	
Transport of RadMat (H-308)		Mobile		02220/02231	
		HDR/Teletherapy		02230/02300	
		Other Med Uses		02240	
		Veterinary		02400	
Advanced HP (H-201)		Nuclear Pharmacy		02500	
Lic Prac & Proc (G-109)					

Med Uses of Rad (H-312S) Transport of RadMat (H-308)			
Advanced HP (H-201) Lic Prac & Proc (G-109)	Ind. Radiography	03310/03320	
Saf. Asp. Ind. Rad (H-305) Med Uses of Rad (H-312S) Transport of RadMat (H-308) Mat Con & Sec Sys (S-201)	Gamma Knife	02310	
Advanced HP (H-201) Lic Prac & Proc (G-109) Transport of RadMat (H-308) Irradiator Tech (H-315)	Irradiator 	03521	
Advanced HP (H-201) Lic Prac & Proc (G-109)	Decomm. Facilities	03900	
Transport of RadMat (H-308) MARSAME (H-120S)	Decon Services	03219	

Patrick Turner - Health Physicist

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Health Physicist Qualification Journal

	Patrick Turner
NAME:	

Health Physicist

TITLE: _____

Copies of formal training certifications or the basis for exemption to the specific course should be appended to the back of this document.

CORE TRAINING

	А.	Medical Uses	of Radiation Self-S	tudy (H-317S)	
	Date	s Attended: _		RCPD	
	B.	Fundamental	s of Health Physics	Self-Study (H-	
	122S	5)			
	Date	s Attended: _	<u>11/29/2023</u>	RCPD	
	C.	Transportatio	on of Radioactive Ma	aterials Self-Study (H-308S)	
	Date	s Attended: _	1/17/2024	RCPD	
	D.	Inspection P	rocedures (G-108)		
	Date	s Attended: _		RCPD	
	E. Licensing Practices & Procedure		actices & Procedures	es (G-109)	
	Dates Attended:			RCPD	
	F. Safety Aspects of Industrial Rac		ts of Industrial Rad	iography (H-305)	
	Date	s Attended:		RCPD	
	G. Materials Control & Security Sys		ntrol & Security Sys	tems & Principles (S-201)	
	Date	s Attended: _		RCPD	
	Н.	Advanced He	ealth Physics (H-201)	
	Dates Attended:			RCPD	
	I.	Root Cause/I	Incident Investigatio	on Training (G-205)	
Page 5	71				

Dates Attended: _____ RCPD_____

SPECIALIZED/ENHANCEMENT TRAINING

J. Irradiator Technology Course (H-315)			
	Dates Attended	RCPD	
K.	Safety Aspects of Well Logging (H-314)	
	Dates Attended	RCPD	
L.	Radiological Surveys in Support of Decommissioning (H-120)		
	Dates Attended	RCPD	
	M. Root Cause/Incident Investigatio	n Training (G-205)	
	Dates Attended	RCPD	
	N. Characterization and Planning for De	ecommissioning (H-315)	
	Dates Attended	RCPD	
	O. Internal Dosimetry Self-Study (H-32	12S)	
	Dates Attended	RCPD	
	P. Environmental Monitoring & Air Sam (H-130S)	oling for Radioactivity Self-Study	
	Dates Attended <u>2/1/2024</u>	RCPD	
	Q. Respiratory Protection (H-311)		
	Dates Attended	RCPD	
	R. Multi-Agency Radiation Survey and S (MARSSIM)	Sites Investigation Manual	
	Dates Attended 12/11/2023 Page 573	RCPD	

S.	Health	Physics	for	Uranium	Recovery	, ((F-104)
υ.	incurri	11195105	101	orumum	I CCOVCI y	/ \	1 104)

Dates Attended	RCPD	
T. Introductory Health Physics (H-1179	5)	
Dates Attended 11/21/2023	RCPD	
U. Fundamental Health Physics Lab (H-	-122Lab)	
Dates Attended	RCPD	
V. Environmental Monitoring & Air San 130Lab)	npling for Radioactivity Lab (H-	
Dates Attended	RCPD	
W.Health Physics Statistics Self-Study (H-301S)		
Dates Attended	RCPD	
X. RESRAD OVERVIEW (H-408)		
Dates Attended	RCPD	
Y. Advanced RESRAD Training Workshop (H-412)		
Dates Attended	RCPD	
Z. MILDOS-Area Training Workshop (H-413)		
Dates Attended	RCPD	

AA. Visual Sampling (H-500)

Dates Attended_____ RCPD _____

ON-THE-JOB TRAINING INSPECTIONS

A. Program 01100-01120 Academic

Trainee observes an Inspector preparing for and conducting an inspection of a Program 01100-01120 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

B. Program 02110 – Medical Institution – Broad Scope

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02110 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02120 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	

D. Core Program 02121 – Medical Institution Written Directive Not Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02121 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

E. Core Program 02230/02300 – HDR or Teletherapy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02230/02300 licensee.

Licensee:	Memorial Hospital 13-18881-01	Date: 12/12/2023
Inspector: _	Ryan Craffey	
Licensee: Inspector:		Date:
RCPD Appro	val:	Date:

F. Core Program 02231 – Medical Mobile Services Written Directive Required

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02231 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

G. Core Program 02240 – Emerging Technologies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02240 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

H. Core Program 02400 – Veterinary Nonhuman Subjects

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02400 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

I. Core Program 02410 – In-Vitro Testing Laboratories

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02410 licensee.

Licensee: Date	e:
Inspector:	
Licensee: Date	e:
Inspector:	
RCPD Approval: Date	e:

J. Core Program 02500 – Nuclear Pharmacy

Trainee observes an Inspector preparing for and conducting an inspection of a Program 02500 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

K. Core Program 03121 – Measuring Systems – Portable Gauges

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03121 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

L. Core Program 03219 – Decontamination Services

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03219 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

M. Core Program 03310/03320 – Industrial Radiography

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03310/03320 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Page 579	

spector:		
CPD Approval: _	Date:	
-FD Approvar	Date	

N. Core Program 03510 – Irradiators Self-Shielded less than or equal to 10,000 Curies

Trainee observes an Inspector preparing for and conducting an inspection of a Program 03510 licensee.

Licensee:	Date:
Inspector:	
Licensee:	Date:
Inspector:	
RCPD Approval:	Date:

ON-THE-JOB TRAINING LICENSING

A. Program 01100-01120 Academic

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 01100-01120 application for license or a license renewal in entirety.

Amendment Type:	
	Date:
Amendment Type:	
	Date:
	Date:

B. Program 02110 – Medical Institution Broad Scope

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02110 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

C. Program 02120 – Medical Institution Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02120 application for license or a license renewal in entirety.

License:	Amendment Type:		
Reviewer:		Date:	
License:	Amendment Type:		
Reviewer:		Date:	
RCPD Approval:		Date:	

D. Program 02121 – Medical Institution Written Directive Not Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02121 application for license or a license renewal in entirety.

License:	Amendment Type:		
Reviewer:		Date:	
License:	Amendment Type:		
Reviewer:		Date:	
RCPD Approval:		Date:	

E. Program 02230 – High-Dose Rate Remote Afterloader

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02230 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

F. Program 02231 – Mobile Medical Services Written Directive Required

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02231 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	_ Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

G. Program 02240 – Medical Therapy Other Emerging Technologies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02240 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

H. Program 02400 – Veterinary Nonhuman Subjects Page|582 Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02400 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

I. Program 02410 – In-Vitro Testing Laboratories

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02410 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
RCPD Approval:		Date:

J. Program 02500 – Nuclear Pharmacy

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 02500 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

K. Program 03212 – Measuring Systems – Portable Gauges

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03212 application for license or a license renewal in entirety.

License:	Amendment Type: _	
Reviewer:		Date:
License:	Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

L. Program 03219 – Services Provider

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03219 application for license or a license renewal in entirety.

License:	_ Amendment Type: _	
Reviewer:		Date:
License:	_ Amendment Type: _	
Reviewer:		Date:
RCPD Approval:		Date:

M. Program 03310/03320 - Industrial Radiography

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03310/03320 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

N. Program 03510 – Irradiators Self Shielded less than or equal to 10,000 Curies

Trainee is assigned directed review of selected licensing casework and observes a License Reviewer process a Program 03510 application for license or a license renewal in entirety.

License:	Amendment Type:	
Reviewer:		Date:
License:	Amendment Type:	
Reviewer:		Date:
RCPD Approval:		Date:

Qualification					
Training Completed	Date	OJT Completed	Date	Qualified Program	Date
		Inspections			
Advanced HP (H-201)		All Broad – Except Med		01100-01120, 03610-	
		Finad & Dant Conner		03630, 03211-03213	
Inspect Procedures (G-108)		Fixed & Port. Gauges In-Vitro		03120/03121 02410	
Transport of RadMat (H-308)		111-VILLO		02410	
Advanced HP (H-201)		Med Inst. – (Broad)		02110-02113	
Inspect Procedures (G-108)		WD not required		02121/02201	
Med Uses of Rad (H-312S)		WD required		02120/02200	
Transport of RadMat (H-308)		Mobile		02220/02231	
		HDR/Teletherapy		02230/02300	
		Other Med Uses		02240	
		Veterinary		02400	
Advanced HP (H-201) Inspect Procedures (G-108) Med Uses of Rad (H-312S)		Nuclear Pharmacy		02500	
Transport of RadMat (H-308)					
Advanced HP (H-201)		Ind. Radiography		03310/03320	
Inspect Procedures (G-108)					
Saf. Asp. Ind. Rad (H-305) Med Uses of Rad (H-312S)		Gamma Knife		02310	
Transport of RadMat (H-308)					
Mat Con & Sec Sys (S-201)					
Advanced HP (H-201)		Irradiator		03521	
Inspect Procedures (G-108)					
Transport of RadMat (H-308)					
Irradiator Tech (H-315)					
Advanced HP (H-201)		Decomm. Facilities		03900	
Inspect Procedures (G-108)					
Transport of RadMat (H-308)					

MARSAME (H-120S)	Decon Services	03219	
	Licensing		
Advanced HP (H-201)	All Broad – Except Med	01100-01120, 03610- 03630, 03211-03213	
Lic Prac & Proc (G-109)	Fixed & Port. Gauges	03120/03121	
Transport of RadMat (H-308)	In-Vitro	02410	
Advanced HP (H-201)	Med Inst. – (Broad)	02110-02113	
Lic Prac & Proc (G-109)	WD not required	02121/02201	
Med Uses of Rad (H-312S)	WD required	02120/02200	
Transport of RadMat (H-308)	Mobile HDR/Teletherapy	02220/02231 02230/02300	
	Other Med Uses	02240	
	Veterinary	02400	·
Advanced HP (H-201) Lic Prac & Proc (G-109)	Nuclear Pharmacy	02500	
Med Uses of Rad (H-312S)			
Transport of RadMat (H-308)			
		02210/02220	
Advanced HP (H-201) Lic Prac & Proc (G-109)	Ind. Radiography	03310/03320	. <u> </u>
Saf. Asp. Ind. Rad (H-305)			
Med Uses of Rad (H-312S)	Gamma Knife	02310	
Transport of RadMat (H-308)			
Mat Con & Sec Sys (S-201)			
Advanced HP (H-201)	Irradiator	03521	
Lic Prac & Proc (G-109)		05521	·
Transport of RadMat (H-308)			
Irradiator Tech (H-315)			
Advanced HD (H 201)	Decomm. Facilities	03900	
Advanced HP (H-201) Lic Prac & Proc (G-109)	Decomm. Facilities	03900	
Transport of RadMat (H-308)			
MARSAME (H-120S)	Decon Services	03219	
			

Courtney Eckstein – Radiation Program Director

Appendix 4.6-3 Current Staff Resumes

Kaci Studer – Senior Health Physicist

Kaci Elaine Studer Work Experience

05/2022 – Present	Senior Health Physicist – Indiana Department of Homeland Security
Present	 Developing the State of Indiana Agreement State Program Attending trainings for the radioactive materials control program, including licensing and inspection Shadowing NRC, and other agreement state, inspectors on various licensee inspections Developing and providing trainings to first responders in radiation safety and response Preparing DOT special permits for radiological shipments Assisting with Preventative Radiological/Nuclear
10/2020	Detection details
10/2020 – 05/2022	 Equipment Custodian – Summit Exercise and Training Contract support to the United States Department of Homeland Security, Countering Weapons of Mass Destruction Office, Mobile Deployment Detection Program
	 Maintain chemical, biological, nuclear, and radiological
	 detection equipment Provide just-in-time training in equipment usages and utilization for chemical, biological, nuclear, and radiological detection equipment Provide subject matter expertise to federal, state, and local partners during security operations Serve as a liaison between state and local clients and federal agencies during security operations
06/2018 -	Radiation Program Director – Indiana Department of
10/2020	 Homeland Security Serve as Radiation Safety Officer on Nuclear Regulatory Commission license for the Indiana Department of Homeland Security and Indiana State Department of Health. Develop and administer comprehensive radiation safety programs for the safe use of radioactive material, while ensuring worker dose is within federal regulations and as low as reasonably achievable Serve as the State Liaison Officer to the Nuclear Regulatory Commission for the State of Indiana to assure clear and frequent communication between the State of Indiana and NRC
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04/2014 - 06/2018	 Provide oversight of program budgets in collaboration with procurement and direct staff Assist in the development of business proposal (including staffing requirements, direct cost, benefit analysis, etc.) for State of Indiana to become a Nuclear Regulatory Commission Agreement State Develop and deliver training for state and local emergency responders regarding radiation basics, radiation protection, radiation transportation, radiation detection, and radiation response Serve as point of contact and subject matter expert for local and state agencies on radiation safety during both daily operations and in emergency response situations Radiological Transportation Program Manager – Indiana Department of Homeland Security Provided subject matter expertise to security efforts at large public events and venues. Examples include NCAA Men's Final Four, Indianapolis 500, Conference of Mayors, etc. Developed and delivered training for state and local
	emergency responders regarding Radiation Basics, Radiation Protection, Radiation Transportation,
	Radiation Detection, and Radiation ResponseProcessed Department of Transportation Special
	Permits for the one-way transport of materials not known to be radioactive but found to be radioactive
	 Conducted investigations of potential radioactive materials as detected by radiation monitoring devices at industrial/commercial facilities, as well as various citizen concerns
Education	
05/2014	 University of Illinois Springfield Master of Public Health, Environmental Health Graduate Certificate – Emergency Preparedness and Homeland Security
05/2006	 Avila University Bachelor of Science, Radiological Science
Training	
2022 – Present	 US Nuclear Regulatory Commission Agreement State Training Introductory Health Physics Self-Study Fundamental Health Physics Self-Study Environmental Monitoring & Air Sampling for Radioactive Self-Study Health physics Statistics Self-Study

- Transportation of Radioactive Materials Self-Study
- Internal Dosimetry Self-Study
- Inspection Procedures
- Fundamental Health Physics Lab Activities
- Safety Aspects of Industrial Radiography
- Root Cause/Incident Investigation Workshop

Brenda Tubbs - Senior Health Physicist

Brenda D. Tubbs

Work Experience

04/2023 – Present	 Indiana Department of Homeland Security Senior Health Physicist Assisting with the development of the Indiana Agreement State program. Training for radioactive materials control program licensing and inspection. Shadowed NRC inspectors on various licensee inspections. 	Indianapolis, IN
04/2022 - 04/2023	 Indiana Department of Homeland Security Health Physicist Training for radioactive materials control program licensing and inspection. Shadowed NRC inspectors on various licensee inspections. Prepared DOT special permits for radiological shipments. Assisted with RND details. 	Indianapolis, IN
2008 - 04/2023	 Indiana State Police Trooper Level VI (HRCQ Transuranic waste) inspector/Train-the-Trainer. Compliance Review Safety Investigator. 	Indianapolis, IN

Education

12/2021	Illinois Institute of Technology	Online
	МНР	Chicago, IL
12/2015	Indiana University East B.G.S.	Online
		Richmond,
		IN

Training

2022 - Present	 US Nuclear Regulatory Commission Agreement State Training: Introductory Health Physics Self- Study Fundamental Health Physics Self-Study Environmental Monitoring & Air Sampling for Radioactive Self- Study 	
	 Fundamental Health Physics Self-Study Environmental Monitoring & Air Sampling for Radioactive Self- Study Health physics Statistics Self- Study Transportation of Radioactive Materials Self-Study Internal Dosimetry Self-Study 	
	 Materials Control & Security Systems & Principles Inspection Procedures Licensing Practices & Procedures Environmental Monitoring & Air Sampling for Radioactive Lab Course 	

 Fundamental Health Physics Lab Activities Safety Aspects of Industrial Radiography Root Cause/Incident 	
Investigation Workshop	

<u> Kevin Stahl – Health Physicist</u>

KEVIN A. STAHL, MS

EDUCATION

Purdue University, West Lafayette, IN *Master's Degree, Health Physics, B.S. Nuclear Engineering,*

PROFESSIONAL EXPERIENCE

IDHS - Radioactive Materials Controls Program Indianapolis, IN Health Physicist

- Assist in annual program reviews of State NRC License
- Lead waste management and disposal of IDHS radioactive materials
- Conduct source inventory and leak testing
- Serve as equipment and technical expertise for RND event missions.

- Assist in giving radioactive emergency response training to first responders throughout the state

- Conduct investigations of rejected or reported radioactive material

Cardinal Health Centers for Theranostic Advancement Indianapolis, IN EHS Manager, RSO - Commercial Manufacturing Center EHS Manager, RSO - Innovation Center

RSO - Nuclear Pharmacy

- Serve as RSO for three facilities
- Conduct annual program reviews
- Train new hires for radiation safety and handling procedures
- Manage dosimetry of 100 employees
- Conduct dose reconstruction and investigations
- Manage calibration and daily testing of detection instrumentation

- Serve as SME for dose calibrators, liquid scintillation counters and radioactive material shipping

- Trained as backup nuclear pharmacy driver
- Develop hot cell shielding requirements for Ac-225 production line

- Created a functional glovebox system for opening a welded container of radioactive thorium safely,

allowing for remote handling and transfer into a hotcell line

- Maintain inventory and leak tests of several different isotopes.

- Train new Authorized Users
- Update and amend NRC licenses

- Serve as SME for effluent monitoring system for 1 Ra-223 system, and 2 Th-228 systems

Purdue University - REM West Lafayette, IN Health Physics Intern

- Conduct laboratory wipe and surveys as required by NRC license.
- Conduct liquid scintillation testing of contaminated equipment for release

- Construct and maintain a liquid HPGe system for specific research projects and assessments

- Assist in decommissioning of lab spaces after radioactive use was completed
 Designed the shielding around a new fluoroscopy surgery suite for biomedical
 - engineering building

<u> Daisy Coffman – Health Physicist</u>

Daisy M. Coffman

Work Experience

2/20/2023 - Present Indianapolis, IN Indiana, Department of Homeland Security

Health Physicist

- Training for Radioactive Materials Program Inspection and Licensing
- Complete and review online applications for Indiana Radioactive Materials registrations
- Work RND events for Public Health protection with Indianapolis Metro Police Department
- Develop and review Indiana agreement state application

05/23/2022-08/05/2022 Stan A. Huber Consultants Inc. Chicago, IL

Health Physics Intern

- Supervision of transportation and disposal contractor to ensure compliance with site radioactive materials license conditions and regulations
- Analyzed work area and site perimeter air sampling
- Performed radiological soil sampling via XRF and gamma spectroscopy

• Performed weekly clean area surveys of support zone and perimeter dose rate surveys

West Lafayette, IN

Education

08/2018-12/2022 Purdue University B.S., Radiological Health Sciences Minor in Physics

<u>Training</u>

US Nuclear Regulatory Agreement State Trainings:

Licensing Practices and Procedures

Inspection Procedures

Medical Uses of Radiation

Fundamentals of HP Lab

Materials Control & Security Systems

Transportation of Radioactive Materials

Health Physics Statistics

Industrial Radiography

Patrick Turner - Health Physicist

Patrick J. Turner

Work Experience		
11/2023 – Present	 Indiana Department of Homeland Security Health Physicist Training for radioactive materials control program licensing and inspection Prepared DOT special permits for radiological shipments 	Indianapolis, IN
5/2023 – 11/2023	 Eli Lilly and Co. Environmental Technician Lab packed chemicals for disposal Prepared hazardous waste for highway transportation Prepared hazardous waste manifests 	Indianapolis, IN
<u>Education</u> 08/2019 – 05/2023	Ball State University B.S., Physics	Muncie, IN
<u>Training</u> 2023 – Present	US Nuclear Regulatory Commission Agreement State Training: Introductory Health Physics Self-Study Fundamental Health Physics Self-Study MARSAME Self-Study MARSSIM Self-Study Transportation of Radioactive Materials Self- Study Environmental Monitoring and Air Sampling for Radioactivity Self-Study Internal Dosimetry Self-Study	

Courtney Eckstein – Radiation Program Director

Courtney Eckstein Work Experience

11/2022 -	Radiation Program Director – Indiana Department of
Present	Homeland Security
	Oversees Radiological/Nuclear response at the state lovel for Indiana
	level for Indiana
	 Assist in Rad/Nuc detection (RND) operations in Indiana, including assisting the Department of Energy
	(DOE) in training European allies in RND related work
	in Indianapolis
	 Oversees the upcoming Agreement State Program in
	Indiana that will regulate the uses, safety and
	security of Radioactive Materials in Indiana
	Oversees Radiological Emergency Preparedness
	Program (REP)
	• Regularly communicates with NRC, FEMA, CWMD, and
	DOE
	 FEMA Region V delegate for National Radiological
	Emergency Preparedness committee (NREP)
	 Counsil of State Government- Midwest Indiana
	delegate and currently on the committee to update
	governors on radiological advancements
	 Indiana representative to the State Liaison Officers to the NDC
	the NRC Bagion V Pennecentative for the National Padiological
	 Region V Representative for the National Radiological Emergency Preparedness Committee
	 Works daily with local responders to assist with
	training and response efforts
07/2021 -	REP Program Coordinator – Indiana Department of Homeland
02/2023	Security
02,2020	• Liaison between four nuclear powerplants for Ingestion
	Pathways in Indiana – two in Illinois, two in Michigan
	 Regularly communicate with FEMA
	 Assist Radiation Program Director with NRC materials
	 Work with stakeholders to develop, maintain, and revise the
	REP (Radiological Emergency Preparedness) plan for the state
	of Indiana
	 Assist regularly with RND missions for Secure the City and
	assist in transportation of radioactive material through
	Indiana. Works with DARPA, CWMD, and other federal
	agencies
	Joined the National REP Committee as Region V
	representative in December 2021

Education

08/2023	Naval Postgraduate School
	 Certificate, Executive Leadership
06/2022	Naval Postgraduate School
	 Certificate, Early REP Education
05/2021	Indiana University
	Master of Public Health
05/2019	University of Cincinnati
-	Bachelor of Arts, Health Communications
	 Study Abroad - Vietnam
	•

4.7 Event and Allegation Response Program Elements

This section of the application addresses how the State of Indiana Radioactive Materials Control Program will respond to radioactive materials events and allegations. Indiana has modeled its program elements after those in the NRC procedures SA-300 *Reporting Materials Events* and SA-400 *Management of Allegations*. The Indiana Radioactive Materials Control Program has four written procedures to address these elements: RMCPP 3.1 *Management of Allegations*, RMCPP 3.2 *Incident Response*, RMCPP 3.3 *Scrap Yard Incident Response*, and RMCPP 3.4 *Nuclear Materials Event Database (NMED) Input*. Section 4.7.1 of this application describes the procedure for responding to events and allegations and Section 4.7.2 describes procedures for identifying significant events and submittals for entry into the NMED.

4.7.1 Procedures for Responding to Events and Allegations

The procedures for responding to events and allegations are attached below. RMCPP 3.1 Management of Allegations describes how the Indiana Radioactive Materials Control Program will respond to allegations, while RMCPP 3.2 Incident Response describes the response actions for the broad range of radioactive materials incidents and RMCPP 3.3 Scrap Yard Incident Response describes the response to specific scrap yard incidents.

For event response, the procedures are consistent with, but not identical to, those of the NRC. They address immediate response and actions to mitigate an event; follow-up inspections and enforcement actions; notifications to licensing staff; reports to the incident file; and notification to other affected licensees of generic problems. The allegations procedure addresses allegation response, follow-up, and closeout. It provides for the protection of the identity of a person making an allegation and other confidential information.

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 3.1, Revision 0 Management of Allegations

Prepared By:	Date:
Reviewed By:	Date:
Approved By:	Date:
Effective Date:	

Revision	Date	Description of Changes
0		

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1.0 PURPOSE

1.1 Applicability

This procedure is to ensure that any allegation made against a licensee is properly addressed and to provide guidance to protect the identity of the alleger. Actions taken in response to an allegation include investigation, documentation, and enforcement, as appropriate. If, at any time, the need for criminal investigatory capacity is required, (for example thefts and/or terrorist activity, as described in Section 3.1.2) contact the Local Law Enforcement Agency (LLEA) and/or the Indiana State Police and/or other state and federal agencies such as the U.S. Federal Bureau of Investigation (FBI), as appropriate. The FBI should be notified if an event involves the possibility of theft or terrorist activities. The Indiana Department of Homeland Security (Department) shall promptly notify the Nuclear Regulatory Commission (NRC) Operations Center (301-819-5100) after contacting the appropriate LLEA and/or FBI in cases involving actual or attempted theft, sabotage, or diversion of radioactive materials as indicated in Appendix G of SA-300.

1.2 References

- 1.2.1 NRC Management Directive 8.8, "Management of Allegations"
- 1.2.2 NRC Inspection Manual Chapter 2800 "Materials Inspection Program"
- 1.2.3 SA-300, "Reporting Material Events"
- 1.2.4 Indiana Radioactive Materials Control Rule

1.3 Files

- 1.3.1 All allegation-related documentation is to be maintained in a secured Allegation File in the Radioactive Materials Control Program (RMCP).
- 1.3.2 Allegations Files are secured when not in use and access is controlled and limited to RMCP staff who are actively using the particular case file. Electronic Allegation Files shall be limited to RMCP staff required to address the allegation who have authorized access to the secured spaces.

1.4 Definitions

1.4.1 <u>Agency</u>: The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security (IDHS or Department).

- 1.4.2 <u>Allegation:</u> A declaration, statement, or assertion of impropriety or inadequacy associated with RMCP regulated activities, the validity of which has not been established. This term includes all concerns identified by individual or organizations regarding activities at a licensee's or applicant's facility. Excluded from this definition are inadequacies provided to RMCP staff members by a licensee's managers acting in their official capacity. Allegations regarding suspected improper conduct by an RMCP employee do not fall within the scope of this procedure and shall be promptly reported to the employee's immediate supervisor.
- 1.4.3 <u>Allegation File</u>: A secure hardcopy or electronic file that contains the documentation concerning the allegation, accessible to RMCP staff and secured by the RMCP.
- 1.4.4 <u>Alleger:</u> An individual or organization that makes an allegation. The alleger may be known or anonymous.
- 1.4.5 <u>Confidentiality:</u> The protection of the alleger's identity. Every effort will be made to protect information that could directly or otherwise identify an individual by name or the fact that a confidential source provided such information to the RMCP (see attachment 3.1-4).
- 1.4.6 <u>Confidential Source:</u> An individual who request and, to the extent possible, is granted confidentiality in accordance with 3.2 of these procedures and the Access to Public Records Act, Indiana Code 5-14-3.
- 1.4.7 <u>Investigation</u>: For purposes of this procedure, an activity conducted by the RMCP used to gather information related to the allegation by seeking confirmation to substantiate, evaluate, and resolve an allegation.
- 1.4.8 <u>Overriding Safety Issue:</u> An issue that may represent an actual or potential immediate and/or significant threat to public health, safety, or security, warranting immediate action by the licensee to evaluate and address the issue.
- 1.4.9 <u>Requirement:</u> A legally binding obligation such as a statute, regulation, license condition, or order.
- 1.4.10 <u>Secure Files:</u> Allegation Files are secured when not in use and access is controlled and limited to RMCP staff who are actively using the particular case file because they are required to address the allegation.
- 1.4.11 <u>Willfulness:</u> There are two types of willfulness:
 - <u>Deliberate Misconduct:</u> occurs when an individual voluntarily and intentionally (1) engages in conduct that the individual knows to be contrary to a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license; or (2) provides materially inaccurate or incomplete information to

a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license.

<u>Careless Disregard</u>: Refers to situations in which an individual acts with reckless indifference to at least on or three things: (1) the existence of a requirements, (2) the meaning of a requirements, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless proceeds to engage in conduct that the individual knows may cause a violation. Although unaware that the actions might cause a violation, the individual proceeds without ascertaining whether a violation would occur.

2.0 **RESPONSIBILITIES**

- **2.1** Health Physicist (HP)
 - 2.1.1 Any RMCP staff member may receive or recognize an allegation.
 - 2.1.2 Allegations may be communicated to the Department in person, by telephone, by e-mail or in print.
 - 2.1.3 An allegation also may be recognized by an RMCP staff member in information provided in a public forum such as television, radio, newspaper, internet, or social media.
 - 2.1.4 RMCP staff will be courteous, professional, and responsive to the alleger and are responsible for recording the initial allegation, any contact information provided, and immediately referring the allegation to a Senior Health Physicist or the Radiation Control Program Director.
 - 2.1.5 This staff member is also responsible for maintaining confidentiality of the alleger and all other confidential information, as allowed by the Access to Public Records Act, Indiana Code 5-14-3.
 - 2.1.6 This information must be documented in attachments 3.1-1 to 3.1-5, and the attachments filed, both electronically and in an Allegation File created specifically for each allegation, with access restricted to RMCP staff when evaluating the specific allegation.
 - 2.1.7 When designated as the Lead Investigator, the HP coordinates with the S/HP or RCPD for the processing and disposition of the allegation. Throughout the investigation the HP is required to respond in a timely manner commensurate with the seriousness of the allegation and in consultation with the S/HP or RCPD. The response to the allegation will

be determined using Attachments 3.1-1 and 3.1-3 to determine the impact and required response.

- 2.1.8 Prepares all records and reports concerning the allegation. Attachment 3.1-1 Initial Allegation Contact Log must be filled out in entirety, along with Attachment 3.1-3 Allegation Screening Form. These records and reports will be used if the allegation is required to be reported to the NRC and through the Nuclear Materials Event Database (NMED). The HP is responsible for discussing and providing a copy of Attachment 3.1-4 Acknowledgement Letter to Alleger.
- 2.1.9 Not all allegations will require immediate response. The HP must use Attachment 3.1-1 Initial Contact Log to determine if the reported allegation required immediate attention. The HP, in consultation with the S/HP and RCPD, will determine the required response to the allegation.
- **2.2** Senior Health Physicist (S/HP)
 - 2.2.1 Managers the response to allegation and maintains a filing system to track, resolve, and conduct periodic reviews of the allegations for their resolution/disposition (Allegation File).
 - 2.2.2 Informs the RCPD of the status of the investigation and recommends appropriate actions in response to allegations.
 - 2.2.3 Upon being informed of an incident through an inspection or investigation of the allegation, the S/HP will respond in accordance with RMCPP 3.2 Incident Response.
 - 2.2.4 Senior Health Physicist or the Radiation Control Program Director.
 - 2.2.5 This staff member is also responsible for maintaining confidentiality of the alleger and all other confidential information, as allowed by the Access to Public Records Ace, Indiana Code 5-14-3.
 - 2.2.6 When designated as the Lead Investigator, the S/HP coordinates with the RCPD for the processing and disposition of the allegation. Throughout the investigation the S/HP is required to respond in a timely manner commensurate with the seriousness of the allegation and in consultation with the RCPD. The response to the allegation will be determined using Attachments 3.1-1 and 3.1-3 to determine the impact and required response.
 - 2.2.7 Prepares all records and reports concerning the allegation. Attachment3.1-1 Initial Allegation Contact Log must be filled out in entirety, along with Attachment 3.1-3 Allegation Screening Form. These records and reports will be used if the allegation is required to be reported to the

NRC and through the Nuclear Materials Event Database (NMED). The HP is responsible for discussing and providing a copy of Attachment 3.1-4 Acknowledgement Letter to Alleger.

- 2.2.8 Not all allegations will require immediate response. The HP must use Attachment 3.1-1 Initial Contact Log to determine if the reported allegation required immediate attention. The HP, in consultation with the S/HP and RCPD, will determine the required response to the allegation.
- **2.3** Radiation Control Program Director (RCPD)
 - 2.3.1 Reviews and approves recommendations made by the HP and/or S/HP before actions are taken in response to allegations.
 - 2.3.2 Authorizes the release of the identities of allegers as provided in section 3.2 after consultation with legal counsel.
 - 2.3.3 Requests legal assistance, if required.

3.0 PROCEDURE

- **3.1** Initial Contact
 - 3.1.1 Evaluation is accomplished by technical review of the allegation, inspection, and information requested from the affected licensee, the individual informer, another Agreement State, or the NRC. As much information as possible is obtained and recoded from the alleger on the Initial Contact Log, (Attachment 3.1-1). If the notification is forwarded or received from the NRC, another state, or a local agency, use the same form, and record all the information from the agency, individual or organization contact. Note on the form the contact's information in case questions arise. For email, fax, regular mail, or any form of communication may attend the alleger's identity, RMCP staff must ensure the at the identity is protected as indicated in section 3.2 of this procedure.
 - 3.1.2 If the allegation involves discrimination on the basis of age, sex, race, etc., refer the alleger to the Indiana Civil Rights Commission (ICRC). If the allegation requires criminal investigatory capacity, notify and request assistance from the LLEA and/or the Indiana State Police, and/or other federal agency such as the FBI, as appropriate. Examples that may require criminal investigatory capacity would be an actual or attempted theft or threatened hijacking of a shipment or device

containing radioactive materials, or an incident involving radioactive materials that are subject to 10 CFR 37.57 reporting requirements.

- 3.1.3 If the alleger refuses to provide his/her name or other form of identification, then obtain as much information as possible and advise the alleger that he/she may submit a public records request to obtain information regarding the response to the allegation.
- 3.1.4 Address the issue of confidentiality with the alleger in accordance with section 3.2.
- 3.1.5 Inform that S/HP or RCPD of the allegation and submit completed Attachment 3.1-3. The alleger's identity, or information that could reveal that identity, should be imparted to staff on a need-to-know basis and should not be revealed to personnel outside the Department, unless as required by the Public Records law.
- 3.1.6 Allegations received will undergo an initial screening (see Attachment 3.1-1 & 3.1-3). Generally, action will not be taken to determine the validity of an allegation, nor will an allegation be discussed with licensees or other affected organizations, until after the allegation has been discussed with the S/HP, RCPD, and IDHS General Council. If those parties determine that an allegation proves to be unsubstantiated (unconfirmed), the alleger will be notified of the findings of the allegation disposition and the allegation management process will be terminated.
- 3.1.7 Allegations received by the RMCP staff, are given a sequential number (INA-24-001) and an Allegation File is created. Electronic documents are placed in files accessible only to RMCP staff. Hardcopy records are scanned to electronic files where they will be secure.
- 3.1.8 Provide the initial notification to the alleger by phone and document with a letter (Attachment 3.1-5) to the alleger. Include in the notification that the Department will evaluate the licensee's activities and response, and that the alleger will be informed of the final disposition of the allegation.
- 3.2 Disclosure of Alleger's Identity
 - 3.2.1 RMCP will make all reasonable efforts to maintain as confidential any information provided by the alleger that meets the criteria below. However, RMCP cannot guarantee confidentiality. Disclosure of an alleger's identity may be made in accordance with 3.2.2 and 3.2.3 below. RMCP will mark all information deemed confidential as such on both hard copy and electronic files. Prior to terminating initial contact with the alleger, inform the alleger of the degree to which their identity can be protected, including the following:
 - 3.2.1.1 Confidential information including that which would reveal that identity, will be shared with RMCP staff on a need-to-know

basis. Confidential information that needs to be protected includes, but is not limited to the following:

- 3.2.1.1.1 Birthdate
- 3.2.1.1.2 Date and place of birth
- 3.2.1.1.3 Social Security Number
- 3.2.1.1.4 State issued drivers identification number
- 3.2.1.1.5 Medicare card
- 3.2.1.1.6 Hospital medical records number
- 3.2.1.1.7 Passport
- 3.2.1.1.8 Mother's maiden name
- 3.2.1.1.9 Biometric records
- 3.2.1.1.10 Educational records
- 3.2.1.1.11 Financial records
- 3.2.1.2 All confidential information including information regarding the alleger's identity will be stored in a secure file electronically and the hard copy file will be locked at all times and under the control of the RCPD, in the same manner as Allegation Files.
- 3.2.1.3 Hard copy Allegation Files are stored in a locked location and access is controlled and limited to RMCP staff. Electronic Allegation Files are limited to RMCP staff required to address the allegation and authorize access to the electronically secured space.
- 3.2.1.4 Inspection reports and correspondence with licensees, other agreements states, federal agencies (including NRC), other organizations, or individuals will contain no confidential information or information that could lead to the identification of the alleger or confidential source.
- 3.2.1.5 The alleger's identity and all confidential information regarding the alleger's identity will be disclosed outside of the RMCP, except under the conditions stipulated in section 3.2.2.
- 3.2.2 Inform the alleger that disclosure of his or her identity or of confidential information may occur on the criteria listed in Attachment 3.1-2.
- 3.2.3 Obtain approval from the RCPD with consultation with the Radiation Control Program Director and IDHS General Counsel prior to any mandated disclosure.
- 3.2.4 Regardless of means by which an allegation is made, if the alleger's identity is known, then inform the alleger by letter within 30 working days of the degree to which his or her identity can be protected as described in 3.2.1 through 3.2.3 using Attachment 3.1-5 Acknowledgement Letter to Alleger.

- 3.2.5 If requested by the alleger, inform the alleger that a non-disclosure statement (Attachment 3.1-2) is available and will be sent within 30 working days.
- **3.3** Controlling Allegations
 - 3.3.1 Allegations should be addressed according to the guidelines listed below:
 - 3.3.1.1 Overriding safety issues shall be addressed immediately,
 - 3.3.1.2 High safety significance should be addressed
 - expeditiously, usually within 30 working days,
 - 3.3.1.3 Low safety significance should be addressed as priorities and resources permit, usually within 6 months of receipt.
 - 3.3.2 Action by the RCPD or designee
 - 3.3.2.1 Appoint a Lead Investigator for the allegation.
 - 3.3.2.2 Ensure an Allegation File is opened for the allegation.
 - 3.3.2.3 With the assistance of the Lead Investigator, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine if an overriding safety issue exists.
 - 3.3.2.4 An allegation is a declaration, statement, or assertion of impropriety or inadequacy associated with RMCP regulated activities, the validity of which has not been established. This term includes all concerns identified by individuals or organizations regarding activities at a licensee's or applicant's facility or in the public domain. Examples of allegations are: 3.3.2.4.1 Potential wrongdoing by a licensee, staff, or
 - contractor;
 - 3.3.2.4.2 A concern about a safety-conscious work environment problem at a facility;
 - 3.3.2.4.3 Deliberately falsifying records;
 - 3.3.2.4.4 Bypassing safety interlocks.

If multiple allegations are made, as described above, the RCPD and S/HP must determine the priority of the allegations.

- 3.3.2.5 Any allegation determined to be an overriding safety issue will cause an immediate evaluation by the RMCP. This evaluation may include the RCPD, a legal representative, and other members of the RMCP staff. All discussions with a legal representative concerning suspected wrongdoing shall be documented and filed within the Allegation File, and, if appropriate, the licensee's folder.
- 3.3.2.6 As necessary, brief the RCPD on the evaluation findings and recommendations.

Upon finding of an incident, immediately implement RMCPP 3.3 *Incident Response*.

- 3.3.3 Evaluation by Lead Investigator
 - 3.3.3.1 In consultation with the S/HP, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine of an overriding safety issue exists.
 - 3.3.3.2 Determine, in conjunction with the S/HP, the actions necessary for resolution of the allegation including an investigation, enforcement actions (per RMCPP 2.5), etc.
 - 3.3.3.3 Identify additional resources required for resolution of the allegation.
 - 3.3.3.4 Develop a schedule for the resolution of each allegation consistent with the inspection schedule; unless the priority of the allegation causes immediate action.
 - 3.3.3.5 With the approval of the S/HP, implement actions necessary for resolution of the allegation.
 - 3.3.3.6 If an inspection is performed, focus should be placed not only on the particular allegation, but also on the overall area of concern, including safety culture. If the Lead Investigator receives notification of the finding of an incident, implement RMCPP 3.2 Incident Response and advise inspection staff of immediate actions taken to mitigate the incident and notify the S/HP.
- **3.4** Referral of Allegations to Licensees

The decision whether or not to refer an allegation to the licensee will be made upon the recommendation of the Lead Investigator with the approval of the RCPD and based on the considerations delineated in 3.4.1 and 3.4.2. If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee, to confirm the issue in writing of the reported allegation and to request pertinent information. In this instance, the 30-day waiting period (see subsection 3.4.3 following) will be waived.

- 3.4.1 Prohibitions on Referrals
 - Do not refer the allegation to the licensee if any of the following apply:
 - 3.4.1.1 The evaluation of the allegation would be compromised because of knowledge gained by the licensee.
 - 3.4.1.2 The allegation is made against the licensee's management or those parties who would normally receive and address the allegation.

- 3.4.1.3 The allegation is based on information received from a federal agency that does not approve of the information being released to the licensee.
- 3.4.1.4 Allegation involving willfulness.

Note: If the above criteria conflicts with those for public release as described in Attachment 3.1-2, discuss the referral with legal counsel.

3.4.2 Referral Criteria

Consider the following when determining whether to refer an allegation(s) to a licensee:

- 3.4.2.1 Could the release of information bring harm to the alleger or confidential source?
- 3.4.2.2 Has the alleger or confidential source objected to the release of the allegation to the licensee?
- 3.4.2.3 What is the licensee's history of addressing allegations?
- 3.4.2.4 What is the likelihood that the licensee will effectively investigate, document, and resolve the allegation?
- 3.4.2.5 Is there any other relevant reason to withhold the information?
- 3.4.3 Informing the Alleger
 - 3.4.3.1 Prior to referring an allegation to a licensee, make all reasonable efforts to inform the alleger of the intent to refer, unless there is an overriding safety issue.
 - 3.4.3.2 If the alleger or confidential source cannot be reached by telephone, then inform the alleger by letter of the intent to refer the allegation to the licensee.
 - 3.4.3.3 If the alleger objects to the referral or does not respond to the letter within 30 calendar days, and the factors described in section 3.4.1 and 3.4.2 concerning the referral prohibitions and allowances and 3.3.2.5 concerning an overriding safety issue have been considered, then refer the allegation to the licensee.
- 3.4.4 Referral Letter
 - 3.4.4.1 Referrals should be made by RCPD or designated staff.
 - 3.4.4.2 If a referral of an allegation is to be made to the licensee, then ensure that referral letter contains the following:
 - 3.4.4.2.1 A complete description of the elements of the allegation.
 - 3.4.4.2.2 A statement that the referral is a result of an allegation against the licensee.
 - 3.4.4.2.3 A request to the licensee to thoroughly review the elements of the allegation in a manner that is objective,

of sufficient scope, and sufficient depth to resolve the allegation.

- 3.4.4.2.4 A written report of the results of the review must be submitted to the Department within 10 working days of receipt by the licensee of the referral letter.
- 3.4.4.3 If the allegation was received in writing, then do not include a copy or the original written information from the alleger.
- 3.4.4.4 Ensure a copy of the referral letter is entered into the Allegation File.
- 3.4.5 Licensee Response
 - 3.4.5.1 The RMPD or designee is responsible for determining whether the licensee response is adequate and for directing further actions to be taken in response to the license's review of an allegation.
 - 3.4.5.2 Evaluation of the adequacy of licensee's response is completed by considering, at a minimum, all the following factors:
 - 3.4.5.2.1 Was the evaluation conducted by an entity independent of the organization in which the alleged event occurred?
 - 3.4.5.2.2 Was the evaluator competent in the specific functional area in which the alleged event occurred?
 - 3.4.5.2.3 Was the evaluation of adequate depth to establish to scope of the problem?
 - 3.4.5.2.4 Was the scope of the evaluation sufficient to establish that the alleged event or problem was not a systemic defect?
 - 3.4.5.2.5 If the allegation was substantiated, did the evaluation consider the root cause and generic implications of the allegation?
 - 3.4.5.2.6 Was the licensee's corrective action sufficient to prevent, alleviate, or correct deficiencies in both the specific and generic instances, and in the short and long term?
 - 3.4.5.3 If the licensee's response is adequate, then notify the licensee within 30 working days that the response is adequate and that no further action is required. The response will be incorporated in the closeout letter to the alleger or confidential source.
 - 3.4.5.4 If the licensee's response is considered to be inadequate, then determine the additional actions required to resolve the allegation, including an investigation, enforcement actions (per RMCPP 2.5), etc.

- 3.4.5.5 Ensure a copy of both the licensee's response and the Department's response letter are entered into the Allegation File.
- **3.5** Investigations

If the allegations cannot be referred to the licensee (see subsection 3.4.1); is not resolved by the licensee; or, involves possible willfulness, an investigation shall be performed, preferably by the Lead Investigator. The investigation may be included as part of a routine inspection or may involve only the allegation(s).

- 3.5.1 When conducting an investigation in response to an allegation, use all of the following techniques:
 - 3.5.1.1 Inspect the issue, not the alleger.
 - 3.5.1.2 Avoid prejudgment.
 - 3.5.1.3 Do not communicated that the specific issue was raised by an alleger (see subsection 3.4.4).
 - 3.5.1.4 Take extensive notes and obtain copies of pertinent records, if possible.
 - 3.5.1.5 Interview employees regarding relevant procedures and activities.
 - 3.5.1.6 Verify any assertions may by the licensee.
- 3.5.2 If investigation of the allegation is determined to have a negative impact on public health or safety, immediately take action to mitigate the incident and immediately notify the RCPD or designee (see RMCPP 3.2 *Incident Response*)
- 3.5.3 Document the results of the investigation in a written report and submit to RCPD or designee.
- 3.5.4 Ensure a copy of the investigation report is entered into the Allegation File.
- 3.5.5 Send a closeout letter to the alleger, if possible, documenting the results of the investigation.
- 3.6 Close Out
 - 3.6.1 The RCPD or designee shall determine when there is sufficient information to close out the allegation and indicate in the investigation report or licensee response letter satisfactory response.
 - 3.6.2 The Allegation File should be update and closed. If appropriate, a copy of all information should be placed in the licensee's file.
 - 3.6.3 If requested and reviewed by RCPD or designee, a letter should be forwarded to the alleger or confidential source of the findings of the allegation indicating that it has been considered closed.
 - 3.6.4 Regardless of whether an investigation was conducted in response to the allegation or not, the Lead Investigator should place a note in the licensee's file.

- 3.6.5 If an incident was found through inspection or investigation, ensure all notifications required to NRC and NMED were made in accordance with RMCPP 3.2 *Inspection Response*. Refer to RMCPP 3.2 for follow up guidelines. Refer to RMCPP 2.5 *Enforcement, Escalated Enforcement, and Administrative Actions* if enforcement actions are necessary. If the cause was a possible generic problem, notify other affected licensees.
- **3.7** Coordinating with Other Agencies In the case of complaints or allegations involving other local, state, or federal agency's jurisdiction, the Health Physicist should withhold the information from the licensee and elevate the concerns to the attention of the S/HP or RCPD while still onsite.

3.8 Attachments



ATTACHMENT #3.1-1 Radioactive Materials Control Program Initial Allegation Contact Log

NAME: _____

TITLE: _____

INDIANA DEPARTMENT OF

HOMELAND SECURITY Radioactive Materials Control Program



INITIAL ALLEGATION CONTACT LOG

INSTRUCTIONS:

This log is to be used to record the information gathered in an allegation against a licensee or registered user.

Has the individual been informed of the conditions regarding confidentiality. YES NO

ALLEGER INFORMATION:	
Individual's full name:	Telephone number:
Position or relationship to the facility or activity involved:	Alleger's employer:
Home mailing address:	Facility/location:

What sort of activities or practices did this involve? What have they observed? Use back for additional information.

NATURE AND DETAILS OF THE ALLEGATION:

How long has this activity been occurring?	Description of Concern	
Is this a current or past unsafe practice?		
How did the individual find out about the concern?		
Date(s) and times of occurrence:		
Are there other individuals that should be contacted for additional information?		

(list names, addresses, phone numbers if available)

What records does the individual think should be reviewed?	What records doe	es the individual	I think should	be reviewed?
--	------------------	-------------------	----------------	--------------

Has the individual raised the concerns with his/her management? Yes What action has been taken? No Why not?

** If the allegation involves discrimination because of age, sex, race, etc., inform the alleger that they should contact the State of Indiana XXXXX at (xxx)xxx-xxxx.

** If this allegation was forwarded from another agency, indicate who the contact was that provided the notification: Agency:

Telephone:

Region/Office:

Name:

ACTIONS TO BE TAKEN:

Refer this to the Radiation Control Program Director

If this issue was referred to another agency, please list the name of agency:

ADDITIONAL COMMENTS OR INFORMATION:

	_



ATTACHMENT #3.1-2 Radioactive Materials Control Program Nondisclosure Statement

NAME: _____

TITLE: _____

Nondisclosure Statement

I have information that I wish to provide in confidence to the Indiana Department of Homeland Security (IDHS), Radioactive Materials Control Program (RMCP). I request that the RMCP not reveal that I am the source of the information.

During an inquiry or investigation, the RMCP will make its best effort to avoid actions that would clearly be expected to result in disclosure of my identity.

My identity may be divulged outside the RMCP in any one or more of the following situations:

When disclosure is necessary because of an overriding safety issue. The RMCP staff (1)will attempt to contact me prior to any disclosure.

(2) When a court orders such disclosure.

When the RMCP request disclosure for enforcement proceedings. (3)

(4) In response to a legislative request. While such a request will be handled on a caseby-case basis, the RMCP will make its best effort to limit the disclosure to the extent possible.

When requested by a federal or state agency in furtherance of its statutory (5) responsibilities and the RMCP finds that furtherance of the public interest requires such release.

When the State of Indiana Attorney General or a local or state law enforcement (6) agency is pursuing an investigation, my identity may be disclosed without my knowledge or consent.

When I have taken actions that are inconsistent with and override the purpose of (7) protecting my identity.

When I have taken actions that are inconsistent with and override the purpose of (8) protecting my identity.

Disclosure is mandated by the Access to Public Records Act (APRA), Indiana Code 5-(9) 14-3.

My identity will be withheld from the RMCP staff, except on a need-to-know basis. Consequently, I acknowledge that if I have further contact with RMCP personnel, I cannot expect that those people will be cognizant of my desire to remain anonymous, and it will be my responsibility to bring that point to their attention if I desire similar treatment for the information provided to them.

I have read and fully understand the information above.

Signature: _____Date: _____Date: _____

Address:

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ATTACHMENT #3.1-3 Radioactive Materials Control Program Allegation Screening Form

NAME: _____

TITLE: _____

ALLEGATION SCREENING FORM

- a) Is there an immediate safety concern that must be quickly addressed?
- b) Is the allegation a specific safety or quality issue or a generalized concern?
- c) Has the staff previously addressed this issue or a similar issue?
- d) Has there been a substantial number of allegations on similar concerns?
- e) What is the time sensitivity of the allegation and what immediate actions are necessary?
- f) What is the potential for wrongdoing, and will investigative assistance be needed?
- g) Does the allegation package contain sufficient information for a thorough evaluation? If not, identify the additional information needed.
- h) Can the issues be adequately addressed by a routine technical inspection? If not, determine the best way to address the issues.
- i) Identify any peripheral issues that could develop.
- j) Are any licensing actions or enforcement actions pending that could be affected by the allegation? When an allegation involved a case with pending licensing action, the HP or S/HP working on the case should be promptly notified.
- k) Can inspection resources be effectively utilized pursuing the issue of is the allegation to vague of frivolous?
- Is further consideration of the allegation required? If not, inform the alleger in a courteous and diplomatic manner of the rationale for not considering it further. Consult the Radiation Control Program Director and the IDHS General Council for a final decision before doing so.

- m) Can licensee resources reasonably be used in resolving the allegation to conserve staff resources?
- n) Does the allegation have the potential to require escalated enforcement action?



ATTACHMENT #3.1-4 Radioactive Materials Control Program Handling of Information and Files

NAME: _____

TITLE: _____

Handling of Information and Files

Upon receipt of an allegation and during the investigation of an allegation, the alleger may expect that his/her identify will be protected. While the RMCP cannot withhold information in the situations outlined in Attachment 3.1-2, the RMCP will take all reasonable steps to minimize the use of the alleger's identity and/or any identifiable information. Basic program rules to protect the identity of the alleger and other identifiable information are outlined below.

1) Restrict staff discussions to those individuals who truly need-to-know.

The alleger's identity and other information that would reveal their identity should be restricted to only those RMCP staff that are involved in the investigation.

2) Restrict access to the hardcopy and computer files by storing in a secure file.

All information regarding the alleger's identity and other confidential information will be stored in the specific Allegation File. The Allegation File will be maintained in a secured filing cabinet and an electronic folder accessible only those working directly with the investigation. When an electronic or paper copy is in use, the RMCP staff member using the file is responsible for always controlling access to it when the file is not locked up or closed electronically.

3) Protect access to information during work.

Files are not left lying open if the work area is not occupied. Computer screens are not left open if the work area is not occupied. At the end of the day, the hardcopy Allegation File is placed in the secured filing cabinet. Computer files are saved on the secured computer space. Drafts are not developed outside this computer space. Field notes, received forms, etc. are kept secured or are disposed of.

4) Be wary of emails if you must use them.

Emails are to be sent encrypted and being very careful to enter the correct email address. Prior to sending emails including documents/attachments, calls should be made to alert the recipient and a read receipt should be requested to confirm the email was received.



ATTACHMENT #3.1-5 Radioactive Materials Control Program Acknowledgement Letter to Alleger

NAME: _____

TITLE: _____

Acknowledgement Letter to Alleger

<Utilize Department of Health Letterhead>

Date

Mr. John Doe

1234 ABC Street

Anytown, IN 46XXX

Dear Mr. Doe:

This letter refers to your contact with <specify individual> of the Indiana Department of Homeland Security (IDHS), Radioactive Materials Control Program (RMCP) on <specify date>, in which you expressed concern related to <specify licensee/company/etc.>. <Specify concern e.g., you were concerned that you used a Troxler portable gauge without receiving proper training and transported the device in your personal vehicle.>

In addition, according to your contact with RMCP staff, we understand that you did/did not object to having your allegation referred to <specify licensee/company/etc.>.

Specify actions taken in response and include detailed information such as: On October 18th RMCP staff performed a routine health and safety inspection of Company X and focused on an investigation of your allegation. During this investigation, RMCP staff determined that you logged out the Troxler portable gauge at the Sample Jobsite in July prior to your August 2nd training certificate. Specify any other relevant information found related to the allegation such as: We were also able to determine that authorized users including yourself were allowed to perform work with the portable gauge without being issued dosimetry, which is a violation of the license.>

<Specify agency actions such as: subsequently, the IDHS has issued violations based upon the inspection and investigation.>

If you have any questions or further concerns, please contact me at <specify contact number> or <specify email address>.

Sincerely,

Name

Title



Radioactive Materials Control Program Procedure 3.2, Revision 0 Incident Response

Prepared By:

Reviewed By:

Approved By:

Date:

Date:

Date:

Effective Date:

Revision	Date	Description of Changes
0		

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Incident Response

4.0 PURPOSE

- **4.1** Applicability
 - 4.1.1 This applies to all Indiana Department of Homeland Security, Radioactive Materials Control Program (RMCP) staff responding to an incident involving real or suspected radioactive materials. This procedure does not apply to a known or suspected terrorist incident. If

terrorism is known or possible, contact the Local Law Enforcement Agency (LLEA) and/or the Indiana State Police, and/or the U.S. Federal Bureau of Investigation (FBI), as appropriate.

- 4.1.2 This addresses preparation for responding to a radiological incident and an abnormal occurrence (AO), which is any unscheduled incident or event which the NRC/RMCP determines to be significant from the standpoint of public health and safety.
- 4.1.3 This procedure describes radiation detection instruments and other equipment potentially required for response to a radiological incident, safety precautions for RMCP staff and other responders during a response effort and options for identifying unknown radioactive material in the field and laboratory.
- 4.1.4 This procedure establishes guidelines for voluntary reports on lost and stolen events involving any types of radioactive material, as well as situations that cannot be specifically tied to a reporting requirement (such as "found" sources that were not reported as lost, material contaminated with radioactive material, and landfill alarm trips).
- 4.1.5 This procedure establishes notification requirements to other federal (including NRC), state, and local agencies as well as event notification through the Nuclear Materials Events Database (NMED) and notification of a possible generic problem to other affected licensees, etc.
- 4.2 References
 - 4.2.1 Indiana Radioactive Materials Control Rules
 - 4.2.2 NRC Procedure, SA-300, "Reporting Material Events"
- 4.3 Definitions
 - 4.3.1 Abnormal Occurrence (AO): An unscheduled incident or event significant from the standpoint of public health or safety.
 - 4.3.2 Agency: The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security.
 - 4.3.3 Apparent Violation: A potential noncompliance with a regulatory requirement that has not yet been formally cited as a violation or order.
 - 4.3.4 Deviation: A licensee's failure to satisfy a non-legally binding commitment (e.g. failure to tie-down a commitment during licensing and the licensee has not implemented that commitment.)
 - 4.3.5 Escalated Enforcement Action: An enforcement action for any Severity Level I, II, or III violations. Violations with willful aspects (i.e. careless disregard or deliberate misconduct) will typically be considered for escalated enforcement.

4.3.6 Immediate Notification: For this procedure, notification is required to be made to the Indiana Department of Homeland Security

5.0 **RESPONSIBILITIES**

- **5.1** Health Physicist (HP)
 - 5.1.1 Informs the S/HP of all radioactive materials incidents.
 - 5.1.2 Assumes the lead role in immediate response as required to incidents involving radioactive materials and coordinates with the S/HP or the Radiation Control Program Director (RMCP).
 - 5.1.3 Immediately responds to incidents involving radioactive materials, as directed by the RCPD or designee.
 - 5.1.4 Assists the RCPD or designee with incident response and documentation, including report preparation, as needed.
- **5.2** Senior Health Physicist (S/HP)
 - 5.2.1 Notifies the RCPD of radiological incidents.
 - 5.2.2 Assigns staff to respond to incidents involving radioactive materials.
 - 5.2.3 Coordinates immediate response effort during normal working hours.
 - 5.2.4 In coordination with the RCPD and general counsel, makes decisions to impound radioactive materials found in the public domain.
 - 5.2.5 Advises the RCPD whether legal assistance is required.
 - 5.2.6 Ensures that notifications are made of reportable and required reports as indicated in Attachment 3.2-4, and SA-300 "Reporting Materials Events," including immediate, 24-hour, and 5 to 30-dat event reporting requirements.
 - 5.2.7 Has the responsibility to ensure that written documentation of reportable incidents is completed and for assuring the quality of the reports to the Nuclear Materials Events Database (NMED) within the appropriate time period as required by the incident. Abnormal occurrences should be managed in accordance with NRC's Management Directive 8.1 "Abnormal Occurrence Reporting Procedures."
 - 5.2.8 If necessary and in consultation with the RCPD, request federal assistance from the NRC Headquarters Operations Officer (HOO) at (301) 816-5100.
- **5.3** Radiation Control Program Director (RCPD)
 - 5.3.1 Final authority, if needed, for radiological incident response activities (conflict resolution).

- 5.3.2 Requests legal assistance, if required.
- 5.3.3 Coordinates immediate response effort outside normal working hours.

6.0 **PROCEDURE**

- **6.1** Incident Type and Classification
 - 6.1.1 Transportation Incident: An incident which occurs in association with any activity involving the movement of radioactive materials by a motorized conveyance on roadways, to include trucks, planes, automobiles, etc. This does not include movement of materials at a facility by forklift, hand-truck, or other transfer method. Such incident would be considered as a fixed facility incident.
 - 6.1.2 Fixed Facility Incident: An incident which occurs in association with any activity involving radioactive material at a fixed location. This would include temporary work sites (soil testing and non-destructive testing of welds), manufacturing sites (thickness gauges, etc.), or any other location which does not involve the movement of radioactive materials by a motorized conveyance on roadways as indicated above.
 - 6.1.3 Terrorism Incident: An incident which occurs in association with any deliberate act of sabotage or destruction which includes the use of radioactive materials. This type of incident may include transportation or fixed facility, but due to the initiating event, will require coordination of response actions to ensure crime scene issues are considered.
 - 6.1.4 Incident Classification: Level I an incident in which no release of radioactive materials has occurred. This is determined by visual assessment of the incident scene. If there is not a high confidence level by the response personnel in declaring a Level I incident, it should default to a Level II incident.
 - 6.1.5 Incident Classification: Level II an incident in which there may be a release of radioactive materials. This is determined by visual assessment of the incident scene. Level II would be declared when there is reasonable doubt of the integrity of the containment of the radioactive materials (package shows significant damage, but there is no visible sign of material release).
 - 6.1.6 Incident Classification: Level III an incident in which there is a release of radioactive material. This is determined by visual assessment of the incident scene. There must be a high level of confidence by the response personnel before declaring a Level III incident.
- **6.2** Initial Notification When the Indiana Department of Homeland Security is notified that an incident has occurred, the Radiation Section's on-call staff member will obtain as much information as possible in order to determine the level of response

required. If upon notification of the radioactive material incident, the on-call staff member, with consultation with the RCPD, will contact the applicable agencies listed in Attachment 3.2-4 for assistance. Not all incidents will require an immediate response. If immediate response is not required, the on-call staff member will notify the appropriate program director (i.e. transportation program manager will be notified for transportation incidents; REP program director will be notified for Nuclear Power Plant related incidents; the S/HPs within the RMCP will be notified for incidents involving licensed materials; etc.) The appropriate response can be ascertained by obtaining as much information as possible and based on the guidance from the program's response plan and/or in Appendix A of SA-300 "Reporting Materials Events." In the event that multiple simultaneous incidents are being reported, the RCPD or designee will coordinate the response activities to ensure the incidents are properly categorized and prioritized. Incident may be received in a number of ways, including in-person, phone, email, letter, news media, and/or internet social media. If the incident is assigned to RMCP staff, the incident is screened to determine the level of response required. RMCP personnel should use this section as guidance when responding to byproduct, source, or special nuclear material incidents. Radiological material incidents should be recorded on Attachment 3.2-1 Radiological Incident Notification Form and the incident reported in accordance with Attachment 3.2-4 Procedure for Reporting Events. For major radiological emergencies, IDHS radiation program staff should coordinate with other state agencies, the NRC 24-hour Headquarters Operations Center Officer at (301) 816-5100, the Radiation Emergency Assessment Center/Training Site (REAC/TS) at (865) 576-1005, and EPA Region 5 at (312) 353-2000.

The below procedures should be performed for events classified as Significant Events, meaning events identified as having generic concerns or issues with a significant potential to impact public health and safety and/or the environment, requiring immediate (within 4 hours) or 24-hour reporting as specified in SA-300 Appendix A. For example:

- Multiple occurrences of an event tracked as a performance measure (medical events, overexposures, lost or stolen sources of concern);
- A single occurrence of an event tracked as a strategic goal (deaths, loss of organ function, significant releases to the environment);
- Events involving possible generic concerns or issues (equipment malfunctions, equipment failure, inadequate user procedures, software problems); or
- Consequences or casual factors not previously seen in the event assessment.
- 6.2.1 Obtain as much of the following information as possible:

- 6.2.2 For incidents involving quantities of Category 1 and Category 2 radioactive materials, make the required notifications in accordance with the provisions of 10 CFR 37.57.
- 6.2.3 Inform the S/HP and RCPD of the incident. If the S/HP or RCPD is unavailable, notify any other RMCP staff.
 - 6.2.3.1 Criteria for determining the level of response required follows the reporting requirements listed in SA-300, based on the relative risk to public health and safety and the factors in 3.2.3.2. The primary responsibility for responding to an incident remains with the licensee. However, the RMCP may give advisory support and may assist the licensees in diagnosing the situation and determining potential courses of action.
 - 6.2.3.2 Factors that should be considered for determining the appropriate response include:
 - Potential to escalate.
 - Location of incident.
 - Potential for exposure or contamination.
 - Media interest.
 - Type of release
 - Involvement of other responders.
 - Request for specific type of assistance.
- 6.2.4 Upon receipt of a notification of an incident, advise the notifier on proper measurements to limit exposure and minimize the spread of contamination.
- 6.2.5 As necessary, keep the public informed thought IDHS Public Affairs office. Attachment 3.2-2 Radiological Incident Response Question and Answer Sheet may be helpful and can be provided to the IDHS Public Affairs office. Relative to communication with the public, consider the following factors:
 - Extent of public risk and perception of the risk.
 - Extent of media interest.
 - Confidence in validity of information reported to the Department.
 - Reassessment of the measures that have been taken (e.g., health physics and medical services that have been made available to the public).
 - Coordination of information among the NRC, federal agencies, and state and local agencies. Ensure that other federal agencies are informed of any information to be released to the media or the public.
 - Assurance of correctness of information provided to the news media and public.

- 6.2.6 Examples of reportable events from SA-300 are included in Attachment 3.2-5.
- 6.2.7 The notifications to be made to NRC are contained in Attachment 3.2-6.
- 6.3 On Scene Response
 - 6.3.1 When possible, a minimum of two people should provide immediate response to a radiological incident.
 - 6.3.2 The following equipment should be obtained and transported to the incident scene for immediate response:
 - Appropriate survey instrumentation,
 - An instrument capable of field identification of unknown isotopes,
 - Personally assigned dosimetry,
 - Cellular phone,
 - Other instruments and supplies, as necessary.
 - 6.3.3 Site approach for immediate response team:
 - Approach the incident site/material from upwind.
 - Turn on exposure rate instrument before approaching the incident site.
 - Obtain current information from on scene personnel.
 - Coordinate response efforts prior to approaching the material.
 - Ask for a shipping manifest if applicable.
 - If there is the potential for contamination, wear plastic booties and gloves.
 - Establish a 2mR/hr. exclusion zone around the material if not already done.
 - Determine who may enter the exclusion zone and under what conditions.
 - 6.3.4 Document the following, as it occurs:
 - Date and time of all major activities related to the incident.
 - Model and serial numbers of all instruments used.
 - Calibration date of all instruments used.
 - Names of responders.
 - A physical description of the incident site.
 - Location or orientation of any materials.
 - Background radiation levels.
 - Survey results.
 - Amount of material present.
 - Any markings or inscriptions associated with the material.
 - Disposition of the material.
 - Names, phone numbers, and addresses of all individuals involved, for follow-up when performed.
 - 6.3.5 Determine if material needs packaging. If the material must be bagged, double bag the material. Survey the outer surfaces of packaging for

contamination prior to transport and take appropriate precautions should external contamination be measured.

- 6.3.6 After the material has been safely packaged or ensured to be in safe condition, do the following:
 - Determine best location for temporary storage.
 - Ensure that decontamination issues are addressed.
 - Initiate attempt to locate owner of material.
 - Contact the RCPD or designee for direction and authorization for management of the material (see Attachment 3.2-3 Impoundment Guidelines.)
 - If no owner can be found, notify the RCPD or designee and inquire whether or not to impound the item. Disposal options will be investigated at this time.
- 6.3.7 Materials being transported for analysis or storage must be packaged to meeting Department of Transportation (DOT) requirements.
- 6.4 Report
 - 6.4.1 The HP assigned to the incident shall prepare a report within 15 days documenting all information gathered, the disposition of the material, and a list of all the parities involved. The report is required for all incident response, including phone consultation for reportable incidents.
 - 6.4.2 Provide a copy of the report to the S/HP and RCPD.
 - 6.4.3 The S/HP shall assure the quality and completeness of the report and ensure that a copy of the report, analysis results, and all notes and related paperwork are properly filed in accordance with SA-300. This report and any subsequent follow-up reports should be utilized to forward data to NMED and to the NRC in accordance with SA-300 "Reporting of Materials Events" as well as any other federal, state, or local agency, as necessary.
 - 6.4.4 Input incident data to the local NMED and forward event reports to the NRC, as necessary. For more information on reporting events, see Attachment 3.2-4 Procedure for Reporting Events.
- 6.5 Follow-up
 - 6.5.1 In consultation with the RCPD, or designee, determine if any wholebody counts, bioassays, or personnel dose determination are warranted, and if medical assistance is required or referral to Oak Ridge Radiation Emergency Assistance Center (REAC/TS) for analysis is necessary. See NRC Inspection Manual Chapter 1360 'Use of Physicians and Scientific Consultants in the Medical Consultant Program" for guidance.
 - 6.5.2 In consultation with the S/HP, determine if training or information for any individuals involved in the incident is warranted.
 - 6.5.3 In consultation with the S/HP determine the need for a follow-up inspection and/or any enforcement actions against the licensee. This

incident should be addressed during the next routine inspection. If it is determined that enforcement actions are required, refer to RMCPP 2.5 Enforcement, Escalated Enforcement, and Administrative Actions.

- 6.5.4 Ensure a copy of the incident report is in the licensee file and make notification to the appropriate RMCP staff, as necessary.
- 6.5.5 Make notifications to appropriate federal and state agencies specified in section 5.0, including the NRC and NMED within the appropriate time period of any new information and status of event including final close of the event.
- 6.5.6 In consultation with S/HP and RCPD, determine the need to notify other licensees of the problem if a known or possible general fault is involved that could affect those licensees.

7.0 RECORDS

- **7.1** Records include completed attachments from this procedure, other documents related to incidents and NMED-related documents.
- **7.2** Efforts will be made to maintain records primarily in an electronic form. Those that are paper will be scanned electronically and may be kept as paper or shredded after determination as to what is best for the particular record and its form for regulatory purposes.
- 8.0 COMMUNICATING EVENTS TO THE APPROPRIATE STATE AND FEDERAL AGENCIES
 - **8.1** Events and allegations may be reported to the Indiana Radioactive Materials Control Program at 301 W. Washington St E-208, Indianapolis, IN 46204, or via the IDHS Watchdesk at (317)233-6615.
 - 8.2 US. NRC Region 3, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532-4352.
 - **8.3** NRC Headquarters Operation Officer (HOO) (301) 816-5000.
 - **8.4** U.S. EPA Region 5, 77 W. Jackson Blvd, Chicago, IL 60604, (312) 353-2000.
 - **8.5** Oak Ridge Institute for Science and Education, Radiation Emergency Assistance Center/Training Site (ORISE REAC/TS) (865) 576-1005.

9.0 Attachments to RMCPP 3.2

Attachment 3.2-1 Radiological Incident Notification Form

Attachment 3.2-2 Radiological Incident Response Question & Answer Sheet

Attachment 3.2-3 Impoundment Guidelines

Attachment 3.2-4 Procedure for Reporting Events

Attachment 3.2-5 Examples of Reportable Events

Attachment 3.2-6 Event Reporting Schedule



ATTACHMENT #3.2-1 Radioactive Materials Control Program Radiological Incident Notification Form

NAME: _____

TITLE: _____

RADIOLOGICAL INCIDENT NOTIFICATION FORM			
Contact Information	Incident Number:		
Name:	Notification Date/Time:		
Incident Reported By:	On-site Contact:		
Title/Organization:	Title/Organization:		
Phone Number:	Phone Number:		
Location of Incident (Include Di	rections):		
Description of Incident:			
Radiation Assessment:			
1. Why do you believe radioactive material is involved?			
2. Describe the radioactive material including packaging.			
3. Did you observe any writing or inscriptions on the materials?			
4. Are shipping papers available?			
5. Are there any indications of a po broken source housing, leaking	ossible spread of contamination based on meter readings, packaging, etc.?		

6. Has the source or contaminated area been isolated or access to the area restricted?

7. What other agencies or personnel are involved?



ATTACHMENT #3.2-2 Radioactive Materials Control Program Radiological Incident Response Question and Answer Sheet

NAME: _____

TITLE: _____

RADIOLOIGICAL INCIDENT RESPONSE QUESTION AND ANSWER SHEET

What is a radiological incident?

A radiological incident is an emergency involving radioactive materials. Examples of radiological incidents include situations where radioactive materials are lost, stolen, or involved in a transportation accident. In most cases, radiological incidents can be successfully resolved by emergency responders with state assistance.

What state assistance is available to respond to a radiological incident?

The Indiana Department of Homeland Security, Radiation Program, is available on a 24-hour basis to support and advise emergency responders during an incident involving radioactive materials. IDHS emergency response resources include highly trained personnel and specialized radiation monitoring equipment. IDHS Radiation Program staff can be quickly dispatched to provide assistance remotely, and if needed, on-site assistance at the scene of a radiological incident.

How are radioactive materials regulated to minimize public risk?

Radioactive materials are stringently regulated by state and federal government agencies by licensing or registration. Devices and products containing radioactive materials are required to incorporate safety features that minimize the exposure risk to the public from a radiological incident.

What should I do if involved in a radiological incident?

Remain calm. Follow instructions given by on-scene officials. Indiana Department of Homeland Security Radiation staff will quickly assess the situation and recommend any further actions. Most radiological incidents do <u>not</u> result in harmful levels of radiation exposure to the public.

Where can I get more information?

Indiana Department of Homeland Security, Radiation Programs - hazmat@dhs.in.gov

Center for Disease Control and Prevention - <u>https://www.cdc.gov/nceh/radiation/emergencies/index.htm</u>

Nuclear Regulatory Commission - <u>https://www.nrc.gov/about-nrc/emerg-preparedness/prepare-</u> <u>for-radiological-emerg.html</u>



ATTACHMENT #3.2-3 Radioactive Materials Control Program Impound Guidelines

NAME: _____

TITLE: _____

IMPOUNDMENT GUIDELINES

Management will consider the following questions before approving a request to impound radioactive materials.

Regulatory Control:

- Are the radioactive materials under the direct control and responsibility of a licensee?
- Are the materials in a controlled location?
- Are the materials directly and negatively impacting public health and safety?
- Is there a possible public perception problem with the current location?

Physical/Chemical Form:

- What is the isotope and physical/chemical form of the material?
- Are other hazardous or explosive materials involved?
- What is the activity of the material?

Physical Condition:

- Are the materials intact, crushed, leaking, or damaged in some way?
- Are the materials concentrated or dispersed over a large area?
- Are the materials separate or part of a larger device?

Amount:

• What is the volume of the material?

Transportation:

• Can the material be transported safely?

Waste Management:

• Does managing the material involve simple storage or is any processing involved in disposing of the materials?

Alternatives:

- Are there any safe and reasonable alternatives to the State impounding the material?
- Is there a temporary storage location and responsible party available?



ATTACHMENT #3.2-4 Radioactive Materials Control Program Procedure for Reporting Events

NAME: _____

TITLE: _____

PROCEDURE FOR REPORTING EVENTS

This is a procedure for determining if an event is reportable to the Indiana Department of Homeland Security and steps that need to be taken. Immediate notification to the Local Law Enforcement Agency (LLEA) is required after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material (see Appendix A to Part 37 – Category 1 and Category 2 Radioactive Materials)

Indiana Department of Homeland Security: (317) 233-6615 Option 2 Local Law Enforcement Agency: 911

IMMEDIATE (WITHIN 4 HOURS OR LESS) NOTIFICATION

Reports of removable contamination on packages > limits in 10 CFR 71.87	10 CFR 20.1906(d)(1)
Radiation levels on packages > limits in 10 CFR 71.47	10 CFR 20.1906(d)(2)
Reports of lost, stolen, or missing licensed materials ≥ 1000 times Appendix C to 10 CFR Part 20 value under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.	10 CFR 20.2201(a)(1)(i)
Exposure (real or threated) \geq TEDE of 25 rem (0.25 Sv), or lens dose equivalent \geq 75 rem (0.75 Sv), or shallow dose equivalent to the skin or extremities \geq 250 (2.5 Gy)	10 CFR 20.2202(a)(1)
Release where an individual could have an intake \geq 5 time the annual limit on intake (ALI) over 24 hours.	10 CFR 20.2202(a)(2)
Events involving prevention of immediate protective actions, necessary to avoid exposures to radiation, radioactive materials, or releases of radioactive material that could exceed regulatory limits.	10 CFR 30.50(a) (Byproduct Material) 10 CFR 40.60(a) (Source Material) 10 CFR 70.50(a) (Special Nuclear Material)
Well logging source rupture	10 CFR 39.77(a)
Theft or loss of radioactive materials, radiation overexposures, or excessive levels and concentrations of radiation.	10 CFR 39.77(b)
Events involving failure of licensees to comply with the applicable requirements of the Department of Transportation regulations in 49 CFR.	10 CFR 71.5
Events involving hazardous materials, including radioactive materials per 49 U.S.C 5103(a) require the immediate reporting of incidents involving hazardous materials that result in an individual's death, injury requiring hospitalization, evacuation of	49 CFR 171.15(b)(1)

the general public for at least one hour, the operational flight pattern or routine of a aircraft is altered, or the closure of one or more major transportation facility or artery for at least one hour.	
Fire, breakage, spillage, or suspected radioactive contamination that occurs involving the shipment of radioactive material.	49 CFR 171.15(b)(2)
 Unauthorized entry resulting in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. Immediate notification to the LLEA As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the IDHS RMCP via phone. In no case shall the notification to IDHS be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion. 	10 CFR 37.57
 Any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and to notify the LLEA as appropriate. As soon as possible, but not later than 4 hours after notifying the LLEA as appropriate. As soon as possible, but no later than 4 hours after notifying the LLEA, the licensee shall notify the IDHS RMCP via phone. 	10 CFR 37.57

24 HOUR EVENT REPORTING

Release where, had an individual been present for 24 hours, individual could have intake of > 1 times occupational ALI over 24 hours.	10 CFR 20.2202(b)(2)
Events involving unplanned contamination that: (i) requires access to the contaminated area, by workers or the pubic to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; (ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; and (iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.	10 CFR 30.50(b)(1) (byproduct material) 10 CFR 40.60(b)(1) (source material) 10 CFR 70.50(b)(1) (special nuclear material)

Events in which equipment is disabled or fails to function as designed when: (i) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; (ii) the equipment is required to be available and operable when it is disabled or fails to function; and (iii) no redundant equipment is available and operable to perform the required safety function.	10 CFR 30.50(b)(2) (byproduct material) 10 CFR 40.60(b)(2) (source material) 10 CFR 70.50(b)(2) (special nuclear material)
Events requiring unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.	10 CFR 30.50(b)(3) (byproduct material) 10 CFR 40.60(b)(3) (source material) 10 CFR 70.50(b)(3) (special nuclear material)
Events involving unplanned fire or explosion affecting the integrity of the material, device or container, or equipment containing licensed material when the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for that material, and the damage affects the integrity of the licensed material or its container.	10 CFR 30.50(b)(4) (byproduct material) 10 CFR 40.60(b)(4) (source material) 10 CFR 70.50(b)(4) (special nuclear material)
Events involving irradiators not reported under other reporting requirements: source stuck in an unshielded position, and fire or explosion in a radiation room, damage to source racks, failure of the cable or drive mechanism used to move the source racks, inoperability of the access control system, detection of source by radioactive material, etc.	10 CFR 36.83(a)(1) through (10)

NEXT CALENDAR DAY REPORTING

Notifications and reports of medical events involving administration and use of byproduct material, except for patient intervention events, that result in certain doses listed in the regulations	10 CFR 35.3045
Events involving an unauthorized dose of 50 mSv (5 rem) to an embryo/fetus or a nursing child, or unintended permanent functional damage to an organ or a physiological system of a nursing child.	10 CFR 35.3047

5 DAY REPORTING

Reporting of leaking sealed source or guide tube, leak test results ≥ 0.005 microcuries (185 Bq)	10 CFR 34.27(d)
Reports of leak test results that demonstrate the	10 CFR 35.3067 (medical uses)
presence of 0.005 microcuries (185 Bq) or more of	10 CFR 39.35 (well logging)
removable contamination from a sealed source.	

30 DAY REPORTING

Reports of lost, stolen, or missing licensed material > 10 times Appendix C to 10 CFR Part 20 value and is still missing at this time (i.e., within 30 days it becomes known to the licensee).	10 CFR 20.2201(a)(1)(ii)
Radiation doses, releases, or concentrations of radioactive material that exceed the limits of 10 CFR 20	10 CFR 20.2203(a) (list of reportable events)
Immediately suspend operation of a device if there is a failure of or damage to the shielding or an indication of a failure of or damage to the shielding, or the on-off mechanism or indicator, or upon detection of 0.005 microcuries (185 Bq) or more of removable radioactive material.	10 CFR 31.5(c)(5)
Radiography source disconnection, inability to retract source, or component failure (critical to safe operation of device).	10 CFR 34.101(a)

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT #3.2-5 Radioactive Materials Control Program Examples of Reportable Events

NAME: _____

TITLE: _____

EXAMPLES OF REPORTABLE EVENTS

Immediately reportable	Stolen Portable Moisture Density Gauge
under 10 CFR	Licensee [Name] [License Number] reported that a
20.2201(a)(1)(i)	[Manufacturer] [Model #] [Serial #] portable gauge
	containing 10 millicuries of cesium-137 and 50 millicuries
	of americium-241: beryllium was stolen from the
	licensee's vehicle parked at the licensee's facility
	[Address]. The gauge was padlocked in its original
	carrying case. The Indiana Department of Homeland
	Security is following the incident and working with local
	authorities to develop a press release. Local law
	enforcement and the FBI have been notified. Follow-up
	information will be provided to NRC on the recovery of
	the stolen gauge and entered into NMED.
Immediately reportable	Shipment of Brachy therapy Sources Received with
under 10 CFR	Radiation Levels Exceeding Regulatory Limits
20.1906(d)(2)	A medical licensee [Name] [License Number] reported
	receiving a shipment of two packages containing cesium-
	137 brachytherapy sources. Radiation surveys of the
	packages found radiation levels of 250 millirem per hour
	on one package, which exceeds the IDHS and Federal
	limit at the external surface of a package of 200 millirem
	per hour. The third and final package was received two
	days late with radiation levels of 400 millirem per hour at
	the surface of the package. The shipper has retained a
	consultant to determine the cause of the elevated
	radiation levels. IDHS will keep NRC informed of the
	results of the consultant's review of the event.
Reportable within 24 hours under 10 CFR	Exposure to Non-radiation Worker at a Licensed Facility
20.2202(b)(1)(i)	A licensee [Name] [License Number] reported to IDHS
20.2202(D)(1)(1)	RMCP that a non-radiation worker had received an
	exposure as a result of picking up a 5-curie americium-
	241: beryllium neutron source used for well logging and
	placed it in his pocket. The worker, a temporary
	contractor's employee, was cleaning a well logging tool at
	the licensee's facility. (The licensee was under the
	assumption that all the source material had been
	removed from the equipment.) While cleaning the tool,
	the source fell out and the worker picked it up and placed
	it in his pocket. The worker was not a radiation worker
	and had no knowledge of what the object was.
	Preliminary calculations performed by [identify
	Consultant/Contractor] indicate that the individual may

	baya received a doce of 4 6 rem. The licenses's
	have received a dose of 4-6 rem. The licensee's Radiation Safety Officer (RSO) is investigating the incident. IDHS plan so to keep NRC informed of the ongoing results of the investigation.
Reportable within 24 hours under 10 CFR 30.50(b)(2)	Radiography Camera Source Unable to Retract A licensee [Name] [License Name] reported the inability to retract a 2.072 TBq (56 Ci) Ir-192 source ([Source Model #], [Serial #]) into the radiography exposure device ([Manufacturer], Model #], [Serial #]) on [Date]. The radiographers had used a double gear control assembly throughout the day without problem. Later, the radiographers cranked out the source to conduct an exposure and were unable to retract the source. The radiographers removed the cover plate on the control assembly and pulled the drive cables to retract the source into the exposure device. The device was locked, and the drive cable was disconnected from the source pigtail. The radiation area was repositioned and maintained throughout the incident. The source had been extended for approximately three minutes. The exposure device was physically inspected and determined to be in good working condition. The double gear control assembly was returned to the manufacturer. The manufacturer stated that they were unable to replicate the failure. However, they did note that the gears offered a large amount of resistance, had impurities, and that the drive cable was out of tolerance.
Reportable by next calendar day under 10 CFR 35.3045(a)(1)(i) and within 24 hours under 10 CFR 30.50(b)(2)	Medical Event Involving a Gamma Knife Malfunction A licensee [Name] [License Number] reported that a patient only received 5% of the prescribed dose during a gamma knife procedure performed on [Date]. The RSO stated that while conducting a single fraction exposure to the patient, the computer screen froze. The patient was immediately removed from the gamma knife unit ([Manufacturer], [Model #], [Serial #]), which contained Co-60 sources ([Source Model #], [Serial #]) with a total activity of 102.34 TBq (2766Ci). The patient was prescribed to receive 2,000 cGy (rad) to one location and 1,500 cGy (rad) to a second location, both to be delivered simultaneously. The referring physician and patient were notified of the event. The service provider for the gamma knife responded and replaced the control unit. The manufacturer stated that the event occurred due to a computer programming problem. The timer that froze is used to display the total run time of the treatment and

	does not control any part of the treatment. They also stated that the treatment would have run normally had the technician not stopped it and the patient would have received the prescribed dose. The manufacturer is resolving the problem in their latest upgrade to the system.
Reportable by next calendar day under 10 CFR Part 35.3045 Note: May be classified as a potential AO.	Medical Event Involving Prostate Brachytherapy A licensee [Name] [License Number] reported a medical event involving a patient treated for prostate cancer. The treatment included the implanting of 65 I-125 brachytherapy seeds ([Manufacturer], [Model #]), containing a total activity of 0.814 GBq (22 mCi), in the patient's prostate for a prescribed therapeutic radiation dose of 14,500 cGy (rad). The prostate gland only received approximately 500 cGy (rad). The seeds were implanted on [Date] using real time dosimetry under ultrasonic guidance. On [Date], the patient returned to the facility for a 30-post implant CT scan. The scan showed that the implanted seeds, although in an appropriate pattern, were placed outside the intended target. The Licensee's Radiation Oncology Group determined that an additional quality assurance review was warranted. IDHS RMCP performed a reactive inspection during the week of [Date]. Initially, a malfunction of the ultrasound unit was suspected. That unit was re-evaluated and was determined to be working properly. The cause was determined to be human error. An unintended dose to the penile bulb of approximately 16,100 cGy (rad) was received, where no does was anticipated. The Radiation Oncology Department suspended prostate brachytherapy treatments. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure the urologist and radiation oncologist clearly identifies the prostate gland and the surrounding anatomy. The treatment will be cancelled if the prostate gland and surrounding anatomy cannot be visualized adequately.

Indiana Department of Homeland Security Radioactive Materials Control Program



ATTACHMENT #3.2-6 Radioactive Materials Control Program Event Reporting Schedule for Agreement States

NAME: _____

TITLE: _____

IMMEDIATE

REPORTABLE EVENT NOTIFICATION	AGREEMENT STATE REPORTING SCHEDULE	REPORTING METHODS TO NRC ⁴
NOTIFICATION	TO NRC	TO NICE
Significant reportable	Agreement States	Report initial
events requiring	should report to NRC	information to the NRC
immediate	immediately of	Operations Centers⁵
notification (i.e.,	notification by an	(301) 816-5100
within 4 hours or	Agreement State	FAX#:(301) 816-5151
less ²) by Agreement	licensee	Email:
State licensees.		HOO.HOC@nrc.gov

24 HOURS

Significant reportable events requiring notification within 24 hours or less, or next calendar day, by Agreement state licensees.	Agreement States should report to NRC within 24 hours of notification by an Agreement State licensee.	Report initial information to the NRC Operations Centers⁵ (301) 816-5100 FAX#:(301) 816- 5151 Email: HOO.HOC@nrc.gov
Events involving theft or terrorist activities should be reported to the FBI ³ .	Agreement States should consider reporting to the FBI within 24 hours of notification.	Report initial information to the NRC Operations Centers⁵ (301) 816-5100 FAX#:(301) 816- 5151 Email: HOO.HOC@nrc.gov

5 to 60 DAYS

5 to 60 days	Agreement States	NMED Local Agreement
reportable events	should provide 5 to	State Software or
requiring greater than	60-day notification	NMED website at
240hour notification by	within the same	https://nmed.inl.gov/ or

Agreement state licensee and event follow-up reports.	to the Agreement States, and any follow- up reports should be	Mail: U.S. NRC, Branch Chief of RMSB/MSSA, Mail Stop T-8-E24, Washington, DC 20555
	provided in a timely manner ⁶ .	

VOLUNTARY

Lost, stolen, or abandoned sources reported to the Agreement and Non- Agreement States that are non-AEA or unlicensed material and not covered by the above two categories.	Voluntary reporting by the Agreement States and Non-Agreement States. ⁷	NMED website at https://nmed.inl.gov/ or Mail: U.S. NRC, Branch Chief of RMSB/MSSA, Mail Stop T-8-E24, Washington, DC 20555
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¹*Privacy Act Information – Personal or confidential information should not be included in event descriptions (e.g., names, personal addresses, or-social security-numbers.)*

²For example, events involving lost, actual or attempted theft, sabotage, or diversion of radioactive materials or devices containing "high-risk" sources in quantities greater than or equal to the quantities of concern (i.e., quantities greater than or equal to Category 2 sources listed in the International Atomic Energy Agency's Code of Conduct and as outlined in reporting requirements in 10 CFR Part 20.2201.)

³A revision to the U.S. Code assigns lead responsibility for material events involving possible theft or terrorist activities to the Federal Bureau of Investigation (FBI).

⁴Sample fax to the NRC Operations Center is available in Appendix D of FSME procedure SA-300.

⁵The NRC Operations Center staff will promptly notify the appropriate Region Duty Officer (RDO) and Headquarters staff of Agreements State events. Therefore, no separate notification to other NRC staff by an Agreement State is necessary.

⁶An example of the minimum basic event information required for a complete record is provided in Appendix E of SA-300.

⁷Voluntary reporting is a joint national effort of the NRC and the Conference of Radiation Control Program Directors (CRCPD) to track certain non-AEA, unlicensed or nonreportable AEA lost and found radioactive material.

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 3.3, Revision 0 Scrap Yard Incident Response

Prepared By:

Reviewed By:

Approved By:

Date:

Date:

Date:

Effective Date:

Revision	Date	Description of Changes	
0			

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5.0 ATTACHMENTS TO RMCPP 3.3

None

Scrap Yard Incident Response

1.0 PURPOSE

- **1.1** Applicability
 - 1.1.1 Applies to all Indiana Department of Homeland Security Radiation

Program staff responding to a scrap yard incident involving real or suspected radioactive materials.

- **1.1.2** Describes options for determining the appropriate type of response to a scrap year incident by Radiation Program (RP) staff.
- **1.1.3** Addresses preparations for a site response to a scrap yard incident.
- 1.1.4 Describes appropriate radiation detection instruments and other equipment potentially required for use during a site response to a scrap yard incident.
- **1.1.5** Describes safety precautions for RP staff and other responders during a site response effort to a scrap yard incident.
- **1.1.6** Establishes guidelines for managing, including impounding radioactive material that is, or could be, a threat to public health and safety.

1.2 References

- 1.2.1 Indiana Radioactive Materials Control Program Rules
- 1.2.2 U.S. DOT Special Permit SP 10656
- 1.2.3 SA-300 "Reporting Material Events"

1.3 Definitions

- **1.3.1** Agency: The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security.
- **1.3.2** Radiation Program: All IDHS radiation focused staff; includes both Radioactive Materials Control Program (RMCP) staff and Radiation Response staff (i.e., REP Coordinator, Radiological Transportation/RND Program Manager, and Emergency Preparedness Specialist)

1.3.3 U.S. DOT Special Permit SP 10656: (Also called "DOT Exemption" form)

is a form signed by the authorized Radiation Program staff that

authorizes the one-way transportation in commerce of (rail or motor

vehicle) shipments of scrap metal and related metal recycled material

which have been found, during or at the conclusion of transportation, or

during inspection of the shipment following receipt, to contain

unexpected and unidentified radioactive material or contamination

2.0 **RESPONSIBILITIES**

- 2.1 On-call Radiation Program Staff members
 - 2.1.1 Receive initial notification from the scrap facility, via the Watchdesk, of potential discovery of radioactive material.
 - 2.1.2 Complete all immediate documentation required, including, but not limited to, DOT SP 10656, instructions to scrap yard, etc.
 - 2.1.3 If warranted due to public health and safety, provide immediate response to incidents involving radioactive materials, as directed by the RCPD or designee.
 - 2.1.4 If necessary, notifies the NRC and inputs report into NMED.
- 2.2 Assigned Radiation Program Staff member.
 - 2.2.1 Conducts on-site response.
 - 2.2.2 Determines appropriate remedial action of any identified radioactive material.
 - 2.2.3 Determines if notifications should be made to the NRC withing the time period specified in RMCPP 3.2 Incident Response and Attachment 3.2-4 Procedure for Reporting Events.
 - 2.2.4 Coordinate landfill disposal with Indiana Department of Environmental Management, if appropriate.
 - 2.2.5 Ensures a complete report is prepared documenting the incident response, including all notes, pictures, forms, surveys, and analysis results.
- 2.3 Radiation Control Program Director (RCPD)
 - 2.3.1 Final authority within the RMCP for radiological incident response activities (conflict resolution)

- 2.3.2 Requests legal assistance, if required.
- 2.3.3 Requests federal assistance, if required.

3.0 PROCEDURE

- 3.1 Initial Notification
 - 3.1.1 If a radiation portal monitor, or hand-held detector, at a scrapyard detects radiation, the scrap yard will notify IDHS RP staff via the IDHS Watchdesk at (317) 233-6615.
 - 3.1.2 IDHS RP will assign two individuals to provide on-call support for all radiological incidents 27/7/365. Radiation Response will provide the primary on-call individual and the RMCP will provide the secondary oncall individual. Response staff will provide response for any unknown radioactive materials; RMCP staff will provide response to any know licensed material and will provide assistance to the Response staff for any unknown radioactive material.
 - 3.1.3 Once notification is received, obtain as much of the following information as possible:
 - Caller's name, affiliation, and location
 - Phone number where caller can be reached.
 - Location of the incident
 - Overall description of the incident, including any injuries.
 - Indications that radioactive material is involved.
 - Any writing or inscription on visible materials.

- Radiation readings on sides of vehicle and in driver compartment containing scrap, or other survey results.
- Type of survey instrumentation used.
- Other agencies or personnel involved.
- 3.1.4 Determine the level of immediate response required. Factors that should be considered include:
 - Likelihood of health and safety concerns such as significant personnel radiation exposure or personal or environmental contamination.
 - Location of incident.
 - Impact of facility (i.e., ability to secure material and maintain safety of workers and the public).
 - Potential for exposure or contamination.
 - Security of storage area.
 - Media interest
 - Involvement of other responders.
 - Request for specific type of assistance.
 - Training and experience of scrap yard personnel.
- 3.1.5 Advise the caller on proper measures to limit exposure and minimize the spread of contamination (e.g., isolate vehicle, do not disturb load, etc.)

Note: People should not handle contaminated or high exposure rate materials unless trained, qualified and aware of the hazards. If there is any doubt, isolate the material until Radiation Program staff or other authorities can attend the materials safely.

- 3.2 Determining Use of U.S. DOT Special Permit SP 10656
 - 3.2.1 Ask the scrap yard if they will accept or reject the load containing potential radioactive materials.
 - 3.2.2 Issue a U.S. DOT Special Permit SP 10656 to the shipper that allows transportation of the load back to point of origin or another predesignated location.
 - 3.2.2.1 Radiation readings are needed for SP 10656 form.
 - 3.2.2.2 The reading may be supplied by scrap yard personnel or others if RP staff believe they are accurate.
 - 3.2.2.3 The Special Permit is available from the Conference of Radiation Control Program Directors (CRCPD) at:

https://crcpdpro.wpenginepowered.com/document/dot-10656-fillableform/

- 3.2.3 If warranted, the on-call staff member schedules a site visit to the scrap facility, point of origin, or the designated location by Radiation Program staff to assess the incident.
- 3.3 On Scene Response
 - 3.3.1 If possible, a minimum of two people should respond to a scrap yard incident including a member of the RP staff.

3.3.2 Prior to use, all instruments shall be battery and source checked and

have a current calibration. Obtain the following equipment:

- Appropriate survey instrumentation.
- An instrument capable of field identification of unknown isotopes.
- Personally assigned dosimetry.
- Cellular phone
- Other instruments and supplies, as necessary.

3.3.3 Upon arrival:

- Obtain current information from facility personnel.
- Turn on exposure rate instruments before approaching.
- Wear safety equipment (boots, hard hat, gloves), as necessary.
- Wear contamination clothing, as appropriate.
- Perform radiation surveys.
- Establish a 2mR/hr. exclusion zone if required and not already done.
- Determine who may enter the exclusion zone and under what conditions.
- 3.3.4 Determine level of resources needed.
 - 3.3.4.1 IF RP resources are available to resolve the incident,

evaluate the scrap load, determine the cause of alarm, and advise the facility, as appropriate.

- 3.3.4.2 If RP resources are unavailable:
 - Advise the facility to obtain the services of a health physics contractor to investigate the load, determine cause of alarm, and assist with radioactive material management.
 - Inform contractor to provide results of investigation to the Indiana Department of Homeland Security Radiation
 Programs at <u>hazmat@dhs.in.gov</u>.
- 3.3.5 Document the following:
 - Date and time of all major activities related to the incident.
 - Model and serial numbers of all instruments used.
 - Calibration date of all instruments used.
 - Names of responders.
 - A physical description of the incident site.
 - Location or orientation of any materials.
 - Background radiation levels.
 - Survey results.
 - Activity of material.
 - Amount of material present.
 - Any markings or inscriptions associated with the material.
 - Disposition of the material.

- Names, phone numbers, and addresses of all individuals involved, in case follow-up is required.
- 3.3.6 If radioactive material is removed from the load, determine if material needs packaging. If it does, double bag the material and incorporate any other US DOT transportation packaging requirements.
- 3.3.7 After the material has been safety packaged or ensured to be in safe condition, od the following:
- 3.3.8 Materials being transported for analysis or storage must be packaged to meet US DOT requirements.
- 3.4 Report
 - 3.4.1 The report shall be prepared within 15 days of the notification, documenting all information gathered, the disposition of the material, and a list of parties involved. The report is required for scrap yard incidents response, including phone consultation for reportable incidents.
 - 3.4.2 Provide a copy of the report to RCPD.
 - 3.4.3 The RCPD or designee shall ensure that a copy of the report, analysis results, and all notes and related paperwork are properly filed.
 - 3.4.4 If required, input incident data to the Nuclear Materials Events Database (NMED) and forward event reports as specified in Appendix A of SA-300 "Reporting Materials Events."

3.5 Follow-up

3.5.1 Replace all inventories supplies used from the response kit.

- 3.5.2 In consultation with RCPD or designee, determine if any whole-body counts, bioassays, or personnel dose determinations are warranted.
- 3.5.3 In consultation with RCPD or designee, determine if training or information for any individuals involved in the incident is warranted.
- 3.5.4 If appropriate, obtain copy of reports by any health physics contractors involved in the incident.
- 3.5.5 If the owner is a IDHS Radioactive Materials Control Program licensee, consult with the RCPD and the S/HP to determine if a follow up inspection and/or any enforcement actions against the licensee. The next inspection should address this item. If it is determined that enforcement actions are required, refer to RMCPP 2.5 Enforcement, Escalated Enforcement, and Administrative Actions.
- 3.5.6 In consultation with the RCPD, if the owner is found and not an IDHS RMCP licensee, determine need to notify the appropriate regulatory agency.
- 3.5.7 Ensure that any notifications required to be made to any federal, state, and local agencies are made within the appropriate time period, updated of any new information and notified of the final close.

4.0 RECORDS

- 4.1 RMCPP 3.2 Attachment 3.2-1 Radiological Incident Notification Form
- 4.2 Local NMED Database: Provide an electronic NMED report to the NMED contractor by using the local NMED Agreement State software from the NMED website or following the upload function instructions on the NMED website.
- 4.3 As much as possible, records should be electronically filed. Where possible, paper records should be scanned to be filed electronically.

5.0 Attachments to RMCPP 3.3

None

4.7.2 Procedures for Identifying Significant Events and Submittals for Entry into

the Nuclear Material Event Database

The State of Indiana has modeled its procedures for identifying significant events and submittals for entry into the Nuclear Medical Event Database (NMED) on the SA-300 Handbook Nuclear Material Event Reporting in the Agreement State. This is done in RMCPP 3.4 Nuclear Material Event Database (NMED) Input, which is attached in this section of the application. It describes how Indiana will generate event reports and submit them to NMED within required time frames and as required by regulation. Responsibilities are assigned for the completion of reports and for ensuring the quality of reports. Criteria are included for identifying abnormal occurrences that are reportable, and guidance is provided for notification, follow-up and closeout of reports.

Indiana Department of Homeland Security Radioactive Materials Control Program



Radioactive Materials Control Program Procedure 3.4, Revision 0 Nuclear Material Events Database (NMED) Input

Prepared By:

Date:

Reviewed By:	Date:
Approved By:	Date:

Effective Date:

Revision	Date	Description of Changes
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Nuclear Materials Event Database (NMED) Input

1.0 PURPOSE

To provide guidance for Indiana Department of Homeland Security (IDHS) Radioactive Materials Control Program (RMCP) licensing and inspection personnel on the proper reporting requirements for incidents involving lost, stolen, misplaced, orphan or damaged sources, medical events, and other incidents involving radioactive material to the NRC via the Nuclear Material Events Database (NMED). All RMCP staff members involved with the reporting of events to NMED shall use the guidance of SA-300 "Handbook on Nuclear Material Events Reporting in the Agreement States"

2.0 BACKGROUND

From SA-300 "At the request of the Conference of Radiation Control Program Directors (CRCPD), the Nuclear Material Events Database (NMED)...captures voluntary reports on lost and stolen events, for any type of nuclear material, as well as situations that cannot be specifically tied to a reporting requirement (such as 'found' sources that were not reported lost, materials contaminated with radioactive material, and landfill alarm trips). The reported information aids in understanding why the events occurred and in identifying actions to help ensure public and occupational safety and security, and improves the overall effectiveness of the NRC and Agreement State regulatory programs."

Guidance is provided on:

- 1. Reporting events requiring notification within 24 hours to the NRC Operations Center;
- 2. Providing 5 to 30-day notification and follow-up event information;
- 3. A schedule for event reporting;
- 4. Reporting formats; and
- 5. Providing event information for events meeting the abnormal occurrence (AO) criteria.

Note: An accident or event will be considered an AO if it involves a major reduction in the degree of protection of public health or safety, security, and/or the environment. This type of incident or event would have a moderate or severe impact and could include, but need not be limited to the following:

- 1. Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the RMCP;
- 2. Major degradation of essential safety-related equipment; or
- 3. Major deficiencies in design, construction, or use of management controls for facilities or radioactive material licensed by or otherwise regulated by the RMCP.

3.0 REPORTING EVENTS REQUIRING NOTIFICATION WITHIN 24 HOURS

The RMCP shall report events requiring notification within 24 hours to the NRC Operations Center Headquarters Operations Officer (HOO). Information should be initially reported to the HOO by telephone at (301) 816-5100. Follow-up information for the event may also be provided to the HOO by fax at (301) 816-5151 or by email at HOO.HOC@nrc.gov.

3.1 NMED Record for Events Reported Within 24 Hours

The NMED contractor uses the initial event notification (EN) information, which was provided to the NRC Operations Center from the RMCD, to establish a record in the national NMED database. The NMED contractor will reference the IDHS event reporting identification number in the record. The RMCP event report identification number will be reflected in the "Reference" field of the NMED record and will be used to ensure any subsequent updates are correctly associated with the initial event record. In addition, each event entered into NMED is assigned a unique NMED item number.

3.2 5 to 60-Day Event Reporting

The RMCP shall report events that require reporting within 5 to 60 days to the NRC. These reports may be provided in writing by mail or electronically. NRC staff encourages Agreement States to electronically report these events using the local NMED Agreement State software or the document "Upload" program on the NMED website.

A. Assign Event Report Identification Number

The IDHS event report identification number should appear on all reports, including preliminary, initial notification reports (e.g., EN's), and any follow-up reports. The event report identification number should consist of the two-letter state agency ID (IN), two-digit year corresponding to the reporting year, and a sequentially assigned four-digit ID number. The event report identification number should be referenced by the IDHS for all telephone, electronic, or written notifications involving each specific event. The S/HPs will keep a log of event reports up to date.

B. Basic Event Information

Appendix E of SA-300 provides a listing of the minimum event information that should be provided. When submitting an initial event report, provide as much information as known at the time the report is prepared regarding the items listed in the Appendix.

C. Electronic Reporting to NMED

The RMCP may provide an electronic NMED report to the NMED contractor by using the NMED Agreement State software, which may be downloaded from the NMED website, or by using the document "Upload" function on the NMED website.

D. Access to NMED

A search of the nationally collected data is available on the NMED website with several drop-down, point-and-click menus available. To obtain access to NMED, contact the NRC NMED Project manager at <u>NMEDNRC@nrc.gov</u>.

E. Written Event Reports

Written event reports should be sent to the Branch Chief, RMSB at the address listed in Appendix C of SA-300. Reports should be provided in an optical character recognition (OCR) format. Include an event report cover page for all written event information provided to the NRC. Department personnel should refrain from providing information that is considered confidential (e.g., personal privacy, proprietary, or security related information, including sensitive unclassified non-safeguards information (SUNSI)). If such information is required to describe the event, the RMCD should provide a bracketed copy of the information that deletes such information.

3.3 Reporting Follow-up Event Information

Follow-up information for NMED reports (e.g., providing additional information regarding initial event reports) should provide the results of the investigation as to what, where, when and how the event or conditions occurred. The following items should be provided when reporting follow-up information:

- A. On a monthly basis, follow up reports through the closeout of the event should be provided in writing to the Radioactive Materials Safety Branch Chief at the address listed in Appendix C of SA-300 or electronically to the NMED contractor via the NMED website. A complete event report should include all investigative information obtained through closeout of the event.
- B. When providing follow-up event information, provide document(s), or clear reference to documents on file that the RMCP used to generate the NMED event report (e.g., a licensee inspection report dated mm/dd/yyy), if applicable and appropriate.

C. Provide any foll-up event information that revises earlier information or provides additional information on a given event to ensure a complete historical record.

3.4 Radiological response Assistance Available to the States

The RMCP may request radiological emergency response assistance by contacting the NRC's Operation Center. The Federal Government, upon request, has the capability to provide assistance to state in responding to radiological emergencies. Under the National Response Framework, NRC is the coordinating agency for domestic incident management for incidents involving nuclear materials or facilities licensed by the NRC or Agreement States.

3.5 Voluntary Reporting or Lost, Stolen and Abandoned Sources

The RMCP should follow the guidelines provided above in section 3.2, "5 to 60-Day Reporting" to report any lost, stolen, and abandoned non-Atomic Energy Act and unlicensed material.

3.6 Reporting Theft or Terrorist Activity

The U.S. Federal Bureau of Investigation (FBI) notification should be considered in an event involves the possibility of theft or terrorist activities. The RMCP will promptly notify the NRC Operations Center (i.e, the HOO) after contacting the appropriate Local Law Enforcement Agency (LLEA) and/or the FBI in cases involving actual or attempted theft, sabotage, or diversion of radioactive material containing quantities greater than or equal to the quantities of concern of radioactive material as indicated in Appendix G of SA-300. The RMCP should consider notifying the FBI or LLEA in all cases of actual theft, sabotage, or diversion and possible terrorism of radioactive materials, regardless of the quantity of radioactive material involved. This includes intentional use of radioactive material that could be used in an unauthorized malevolent manner that could lead to serious consequences. The RMCP should coordinate with the NRC, their communication with other local, Federal and State agencies, to ensure that shared information is accurate and consistent. Based on health and safety significance the RMCP should also consider the issuance of a press release. If it is not clear whether and event should be categorized as a possible theft or terrorist activity, the RMCP should contact the NRC Headquarters Operations Center for assistance in determining if the event should be reported.

If an event involves suspicious activity involving the possibility of theft, sabotage, or diversion, or the actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 licensed material, as defined in Appendix A of 10 CFR 37, the RMCP shall promptly notify the NRC's Operation Center at (301) 816-5100 within 4 hours of the event notification, after contacting the appropriate local law enforcement authority.

4.0 CLOSING AND COMPLETING EVENTS

4.1 Events Closed in NMED

The RMCP should notify the NMED contractor when the event record has been officially closed (i.e., no further follow-up is planned and/or no additional information is expected). The RMCP should ensure that the record contains all pertinent technical information, including follow-up information before closing the record.

4.2 Record Compete in NMED

A "complete record" refers to an NMED record that contains a specified minimum set of information. This minimum set of information is defined in Appendix E of SA-300 and may also be found on the NMED website under "Help." Once the minimum information is provided, the NRC/NMED contractor marks the NMED record as "complete." A "complete" record still remains open in NMED until the RMCP has indicated the record should be closed.

5.0 AGREEMENT STATE SAFETY REVIEWS OF MATERIAL EVENT REPORTS

5.1 Agreement State Review of Material Events for Safety Significance and Generic Assessment.

The RMCP should review events occurring in Indiana, or related to products registered or licensed in Indiana, to identify any event that may involve generic concerns or issues or could have significant impact on public health and safety, security, and/or the environment. Events that warrant such a review include:

- A. Multiple occurrences of an event (e.g., medical events, overexposures, lost or stolen sources of concern), or
- B. A single occurrence of a significant or serious event (e.g., deaths, loss of organ function, significant release to the environment), or

- C. Events involving possible generic concerns or issues (e.g., equipment malfunctions, equipment failures, inadequate user procedures software problems), or
- D. Consequences or causal factors not previously seen in the event assessment process.
- **5.2** Actions Agreement States May Take after Review of Significant Events Events identified as having a significant potential risk to public health and safety, security, and/or the environment may receive additional RMCP or NRC management review. The RMCP should continue to follow-up and review material events through the closure of the vent, which includes checking to see that the final report information has been entered into NMED. Based on potential risks identified as a result of event review and analyses, the RMCP may take actions to reduce potential risks identified as a result of issuing safety-related notifications to licensees. The RMCP is encouraged to share with the NRC and other states any findings, assessments, or trending studies. These can be forwarded to the NMED Project Manager for posting on the NMED website, or distribution in the NMED newsletter and/or Agreement State Letter.

6.0 ABNORMAL OCCURRENCE GUIDELINES AND CRITERIA

RMCP staff should routinely screen events against the Abnormal Occurrence (AO) criteria as part of their routine program. Section 208 of the Energy Reorganization Act of 1974 defines an AO as an unscheduled incident or event that the NRC has determined to be significant from the standpoint of public health or safety. The RMCP will follow SA-300 Section 7 "Abnormal Occurrence Guidelines and Criteria" to routinely screen events against the AO criteria as part of the routine incident response. Any events identified as potential Abnormal Occurrences should be reported to the NRC in accordance with SA-300.