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, Amendment Request or Renewal
RMCPP 1.2	License Termination/Revocation
RMCPP 1.3	NRC Licenses Affected by Agreement States
RMCPP 1.4	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, Amendment Request or Renewal* is in Section 4.3.5.

RMCPP 1.2 *License Termination/Revocation*, RMCPP 1.3 *NRC License Affected by Agreement States,* and RMCPP 1.4 *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
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
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
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
OUO	Official Use Only
P-32	Phosphorous-32
PET	Positron Emission Tomography
PII	Personally Identifiable Information
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
TBq	Terabecquerel
Tc-99m	Technetium-99m
T	Time
TEDE	Total Effective Dose Equivalent
TI	Transport Index
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: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html

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
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
21	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 a renewal to an existing license. 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: (317) 232-2222

Email Address: RMCP@dhs.in.gov

Mailing Address: 302 West Washington, E-208

Indianapolis, IN 46204

Attn: Radioactive Materials Control Program

Table 4.3-2: NRC and Department Forms

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

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, Amendment Request or Renewal* to provide means by which the technical quality of licenses is assured. The elements include primary review, secondary review by two different qualified license reviewers, and supervisory review. The primary and secondary reviews 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 ensure 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, Amendment Request or Renewal, RMCPP 1.2 License Termination/Revocation, RMCPP 1.3 NRC Licenses Affected by Agreement States, and RMCPP 1.4 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, Amendment Request or Renewal

Effective Date:

Revision	Date	Description of Changes
0		

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Attachment 1.1-2 Risk Significant Radioactive Material Checklist*

Attachment 1.1-3 Checklist for Requests to Withhold Information from Public Disclosure

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

Attachment 1.1-8 Review of Initial Application and Request for Amendment Flowchart

Attachment 1.1-9 Sample Letter for Expired License

Attachment 1.1-10 Sample Renewal Letter for 90-day Notification

Attachment 1.1-11 Sample Letter for Receipt of Renewal Application-Timely Filed

***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, license amendments and renewals (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 1.1 *Review of Initial Application for License, Amendment Request or Renewal* and termination is covered by RMCPP 1.2 *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 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.

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 Title 290 Indiana Administrative Code Article 3. *Standards for Protection Against Radiation*

1.2.2 Indiana Code Title 10, Article 19, Chapter 12 *Nuclear Regulatory Agreement*

1.2.3 NUREG-1556 Volume 20, *Consolidated Guidance About Materials Licenses*.

1.2.4 Title 10 of the Code of Federal Regulations (10 CFR)

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 Any Deficiency Letters;

1.3.4 License Transmittal Letter;

1.3.5 Any Requests for Additional Information (RAI);

1.3.6 Financial assurance documents.

1.4 Definitions

1.4.1 **Department:** Department of Homeland Security as established by IC 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 Department Form 313.

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 **Expedited Amendment:** When a request is made by the licensee that requires an amendment to be completed in a timely manner this process can be covered for a renewal of a license when there has not been a significant change to the scope of the licensed program.

1.4.7 **License Review:** The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.

1.4.8 **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:

- 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 of control, authorized use, and/or user(s), Radiation Safety Officer (RSO), address, etc.
- A request for termination of a license; and/or,
- Financial Assurance.

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 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 RMCPP 1.1-4 *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 RMCPP 1.1-1 *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 RMCPP 1.1-1 *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. Pre-licensing 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 of Category 1 and 2 materials as identified in 10 CFR Part 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 ensure 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 RMCPP 1.1-4 *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 **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.

1.4.20 **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 Radiation Support Specialist

2.1.1 Receives, logs, and acknowledges the receipt of an application and informs the applicant that the application is considered to be timely if that is the case.

2.1.2 Notifies a licensee that their license(s) will expire in 90 days and sends appropriate guidance document(s).

2.1.3 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.

2.2 Health Physicist (HP)

2.2.1 Completes the license renewal review in the time frame specified in RMCPP 1.1.

2.2.2 Performs secondary reviews of license applications, renewals and amendments as needed, but only for which the HP was not the primary reviewer. Secondary review is documented using the Licensing Job Aid (Attachment 1.1-4 in RMCPP 1.1).

2.2.3 Maintains computer-based files and tracks the application for a license during processing.

2.2.4 Responds to requests for license applications and amendments by transmitting an application (Department Form 313), internet address of the regulations, and a copy of, or reference to, specific guidance within 30 days of the licensing actions.

2.2.5 Reviews the application, amendment or renewal, determines if it is complete, requests additional information as needed, and prepares the license, amendment or renewal for secondary review and license or amendment approval by the Radiation Control Program Director (RCPD) or designee.

2.2.6 Recommends whether an application is deficient and should be denied either with or without prejudice.

2.2.7 Provides findings during the primary or secondary review of license applications, amendments and renewals to the Senior Health Physicist or RCPD as appropriate.

2.2.8 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
E – Expedited	As Soon As Possible	Assigned by S/HP License Expiration
H – High	90 days	New RSO New Authorized User New Use* Possible Violations License Termination
M - Medium	180 days	Initial License Renewal – In Entirety New Equipment New Change Practice
L – Low	180 days	Delete AU or RSO

2.3 Senior Health Physicist (S/HP)

2.3.1 Generally, manages the Radioactive Materials Control Program and for license applications, amendments, and renewals assigns the licensing actions to a qualified Health Physicist.

2.3.2 May perform primary or secondary reviews of license applications, amendments and renewals.

2.3.3 May initiate consultation with and seek concurrence of the IDHS General counsel on license application, amendment or renewal denials, with or without prejudice.

2.3.4 Performs supervisory reviews of license applications, amendments and renewals.

2.3.5 Provides information on important findings in the renewal application to the Radiation Control Program Director.

2.3.6 Approves and signs licenses, amendments and renewals in absence of RCPD.

2.3.7 The responsibilities of the S/HP may be designated to the RCPD in the S/HP's absence.

2.4 Radiation Control Program Director (RCPD)

2.4.1 Approves and signs licenses and license amendments.

2.4.2 May perform license reviews if qualified as a license reviewer for the license type.

2.4.3 Following consultation with, and concurrence of, the IDHS General Counsel, denies, with or without prejudice, license applications, amendments or renewals.

2.4.4 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. Designation of responsibilities from the RCPD to the S/HP will be provided in writing, including timeframe of delegation, duties delegated, and to whom the responsibilities are delegated.

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:

3.1.1.2 Issue an acknowledgement of receipt within 30 working days of the receipt and make an entry for such in Web-Based Licensing (WBL).

3.1.1.3 Confirm that all necessary sections of the application (Department Form 313) are completed, and the form has been signed by the applicant's certifying official.

3.1.1.4 Confirm that attachments identified by the applicant are included in the submittal.

3.1.1.5 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 or control).

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; formal letters may be necessary.

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 Department Form 313 (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 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 by the Senior Health Physicist or the RCPD if necessary.

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 1.2).
- 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.

Under no circumstances will a license be issued if the location of use and mailing address is incorrect.

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. This checklist includes a credentialed NSTS user updating the licensee's information on NSTS.

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) may be warranted to complete the license review. .

3.2.3 The reviewer shall use the Licensing Job Aid (Attachment 1.1-4) to verify all aspects of the license review have been completed.

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 or S/HP who will conduct the Administrative Qualitative Checklist and approve or deny the license application or amendment.

3.2.7 If the RCPD or S/HP approves issuance of the license or license amendment, the prepared license will be signed by the RCPD or S/HPs in the absence of the RCPD.

3.2.8 Submitted and referenced information may be tied-down to the license. A tie-down license condition is used for commitments that are not already specifically identified on the license. License reviewers should use standard license conditions whenever possible.

3.2.9 Before issuing a license or license amendment with nonstandard conditions, reviewers should verify with the IDHS General Counsel and RCPD, or designee, that the non-standard condition: (1) doesn't conflict with regulatory requirements, (2) has a clear meaning for both the RMCP and the regulated community, and (3) is permitted by law. In addition, reviewers should ensure that all parties have the same understanding of all license conditions, especially any conditions unique to a particular license.

3.2.10 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).

3.3.4 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 Department Form 313. The request should be accompanied by a letter on company letterhead including 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 If the primary review of the amendment request is determined to be a significant change of scope and/or size, the license reviewer, in collaboration with the S/HP, will work with the licensee to determine if a license renewal would be a more appropriate route.

3.4.3 A request to add an Authorized User to a license shall be accompanied by records of the individual's training and qualifications meet all applicable regulations outlined in 10 CFR., especially as related to the AU's uses of radioactive materials.

3.4.4 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.

3.4.5 A request to add or replace a Radiation Safety Officer (RSO) or Chair of the Radiation Safety Committee (RSC) shall include training and experience, duties, responsibilities, and if appropriate, availability and delegation of authority. (Reference: NUREG-1556 Volume 11, *Consolidated Guidance About Materials Licenses*)

3.4.6 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.

3.4.7 Expedited amendments are conducted on a need-to-need basis and should be completed in a timely manner depending on the scope of the request. The expedited amendment process is conducted when a request is made by a licensee for new users

or uses, such as a new modality. They are granted by the RCPD or S/HP in absence of the RCPD.

3.4.8 A checklist to address requests for Risk-Significant Radioactive Material Checklist, (Attachment 1.1-2), must also be completed when the amendment includes any radioisotope that equals or exceeds the quantity values listed in the Risk-Significant Radioactive Material Table in Attachment 1.1-2 and has not been subject to a security order or additional requirements for increased controls. This checklist includes reviewing the National Source Tracking System (NSTS) to ensure the licensee information is as accurate as possible. 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 commitments as appropriate. The RCPD or S/HP shall sign in absence of the RCPD to approve the amendment.

3.5 Processing a Request for Possession Only License

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 without a license amendment, communicate to the licensee that it may proceed with decommissioning and license termination. Unless the licensee is lacking an essential safety element, such as a Radiation Safety Officer or Authorized User, the licensee does not need to be amended to authorize possession only. If the expiration date has not passed, and the licensee is lacking an RSO, AU, or other essential element necessary to allow the continued uses listed on the license, the license should be amended to limit activities to possession only. (Note that: (1) A Possession only authorization also allows limited decommissioning activities such as final closeout surveys and waste disposal; and (2) Expired licenses do not need to be amended because by rule, decommissioning is the only activity authorized.) If the license is amended to “possession only” for purposes of termination, where ancillary decommissioning is the only activity authorized, change the program code to POSESSION ONLY, WITH INTENT TO DISPOSE.

3.5.4 If the licensee is not authorized to conduct the types of activities needed for decommissioning its site, i.e. missing or incomplete decommissioning plan, no adequate financial assurance, etc., the licensee must provide the missing documentation for review, and the license must be approved and amended prior to decommissioning commencing. If a Decommissioning Plan is approved, as part of the review, amend the license to allow decommissioning and change the program code to DECOMMISSIONING.

3.5.5 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 checklist A.8 in NUREG-1556 Volume 20, *Guidance About Administrative Licensing Procedures*. 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 License Expiration

3.6.1 Ninety (90) days prior to a license's expiration date, the licensee shall be notified of the pending expiration date using Attachment 1.1-10 and that if an application for renewal is postmarked at least 30 days prior to the expiration date, the application will be timely.

3.6.2 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.

3.6.3 If the application is found to be timely, the licensee is informed by letter that activities authorized by the current license may continue until processing of the renewal has been completed. This letter (Attachment 1.1-11) must be issued within 30 working days of the receipt.

3.6.4 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 1.1-9.

3.6.5 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.

3.6.6 Processing of terminated licenses is covered in RMCPP 1.2, *License Termination/Revocation*.

3.7 License Renewal

3.7.1 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.

3.7.2 License renewal requests are conducted similarly to new license application with the time frame being 180 days.

3.7.3 The license reviewer should determine whether conditions exist to necessitate an expiration date of less than 15 years.

3.7.4 The license renewal package should be reviewed to determine if any significant changes have been requested.

3.7.5 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.

3.8 Handling of Information

3.8.1 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.

3.8.2 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 IC 5-14-3-4(a)(4) that includes the following guidance:

3.8.2.1 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.

3.8.2.2 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 IC 5-14-3-4 "withhold from public disclosure under IC 5-14-3-4", 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 3.8.2 of this section.

3.8.3 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 IC 5-14-3-4;
- 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.

3.8.4 Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with IC 5-14-3 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 IC 5-14-3.

3.9 Assuring the Technical Quality of Licensing Actions

3.9.1 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).

3.9.2 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*.

3.9.3 License reviewers should compare similar Indiana radioactive materials licenses as a means to provide an additional quality check to ensure completeness.

3.9.4 The final review to assure the technical quality of licensing actions is the supervisory review. It is conducted by the Senior Health Physicist, or Radiation Control Program Director in absence of the SHP, before approving the licensing action.

3.10 Exemptions

3.10.1 The RCPD may grant exemptions if the exemption(s) does not result in significant risk to the health and safety of the public, and safeguards that provide equivalent levels of protection are implemented.

3.10.2 Each individual exemption request will be evaluated on a case-by-case basis utilizing the current guidance in NUREG 1556, Volume 20, *Guidance About Administrative Licensing Procedures*. The license reviewer will inform the RCPD as soon as practical upon receipt of an exemption request.

3.10.3 Legal may review the exemptions for form and statute as requested by the RCPD prior to issuing the exemption.

3.10.4 NUREG-1556, Volume 20 specifies certain exemptions which require coordination with the NRC for approval. In these cases, the RCPD will request assistance through the NRC Regional State Agreements Officer (RSAO) for processing the exemption request.

4.0 Records

4.1 Records to be Maintained

Applications for license, including attachments, are kept in the license file on the restricted drive 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.

4.2 Records Retention

4.2.1 Web Based Licensing is the primary electronic file repository.

4.2.2 Records are also kept on Microsoft teams and on the restricted drive with access only to RMCP staff.

4.2.3 Hard copies can be destroyed after verification of electronic records for completeness and legibility.

4.2.4 Two license applications and supporting documents shall be kept at all times.

4.2.5 All related records can be deleted seven years after the license is terminated.

5.0 Attachments to RMCPP 1.1

Attachment 1.1-1 Pre-Licensing Checklist*

Attachment 1.1-2 Risk-Significant Radioactive Material Checklist*

Attachment 1.1-3 Checklist for Requests to Withhold Information from Public Disclosure

Attachment 1.1-4 License Review Job Aid

Attachment 1.1-5 Administrative Qualitative Checklist

Attachment 1.1-6 Program Codes

Attachment 1.1-7 Department Form 313 Application for Radioactive Materials License

Attachment 1.1-8 Review of Initial Application and Request for Amendment Flowchart

Attachment 1.1-9 Sample Letter for Expired License

Attachment 1.1-10 Sample Renewal Letter for 90-day Notification

Attachment 1.1-11 Sample Letter for Receipt of Renewal Application-Timely Filed

*These are maintained separately as Security-Related Materials

Indiana Department of Homeland Security
Radioactive Materials Control Program

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

This document is maintained separately as security-related materials

Indiana Department of Homeland Security
Radioactive Materials Control Program

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

This document is maintained separately as security-related materials

Indiana Department of Homeland Security
Radioactive Materials Control Program

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

Name: License Number:	
To request that the Department withhold information contained in an application form public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with IC 5-14-3. The applicant should submit 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 addresses 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, 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.

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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*;
b. NUREG-1757 Volume 1 & 2 *Consolidated Decommissioning Guidance*;
c. NUREG-1757 Volume 3 *Financial Assurance, Recordkeeping, and Timeliness*;
d. 10 CFR 35 Medical use of Byproduct Material;
e. RMCPP 1.1-1.4 and RMCPP 1.4; and
f. NRC Medical License Toolkit https://www.nrc.gov/materials/miau/med-use-toolkit.html

3. Determine if subject to:

a. Financial Assurance;
   i. Determine if the licensee's possession limits are above quantities and specified bounds to require financial assurance. If changes to the possession limits prompt new requirements, ensure that the application contains the appropriate documents. For those licensees that must provide a financial assurance instrument, ensure the instrument is adequate for the licensee's specific situation.

   ii. The licensee can choose between surety, insurance, or guarantee mechanisms including surety bonds, letters of credit, insurance policies, parent company guarantees, self-guarantees or an external sinking fund. Refer to NUREG-1757, Volume 3 *Guidance on The Acceptance Criteria for Each Modality*.

   iii. The licensee must have an anti-bankruptcy waiver or something similar that still guarantees payment in the event of a bankruptcy.

   iv. The RMCP staff review ensures that sufficient funds will be available to carry out decommissioning activities and site control and maintenance (if applicable) in a safe and timely manner.

   v. The RMCP staff should ensure that the licensee submits a 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. Check that the adjustments are resubmitted at the time of renewal when the amounts or types of material at the facility change. Licensees may be required to prepare a DFP rather than a certification of financial assurance depending on the type of license possessed and characteristics of the materials possessed, as discussed in Section A.1 of NUREG-1757 Volume 3.

vi. Financial Assurance will be reviewed at intervals not to exceed 3 years.

(References: NUREG-1757 Volume 3, NUREG-1556 Volume 20)

b. Emergency Plan;

i. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in § 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(i) In evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

ii. Any changes to the emergency plan that decrease the effectiveness of the plan must have Department approval before implementation, pursuant to 10 CFR 30.34(f).

iii. Service licensees are not in a position to establish all of the site-specific response measures necessary to execute an effective emergency plan for a temporary jobsite. However, in accordance with 10 CFR 30.34(f) and 10 CFR 30.32(i), it may be necessary for service providers to have an emergency plan or evaluation. Therefore, a license condition should be included for a decommissioning service provider license to specify that prior to handling licensed material at any one site in quantities requiring an emergency plan under 10 CFR 30.32(i), the decommissioning service provider must either obtain approval by the department of an evaluation demonstrating that an emergency plan is not required or submit written

confirmation that licensee personnel have been trained and will follow an existing emergency plan for the temporary jobsite.

Information regarding the need for an emergency plan is described in NUREG-1556 Volumes. (Reference: Regulatory Guide 3.67, *Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities*, Revision 1, NUREG-1556 Volume 20)

c. Decommissioning Timeliness Rule;

   i. Licensees should submit a notification of cessation of operations. The licensee should decommission all or part of its facility if it has not conducted license activities for a period greater than 24 months. See technical guidance for reviewing decommissioning licenses in NUREG-1757 Volume 1-3.

   ii. A licensee must submit a Decommissioning Plan (DP), to support the decommissioning of its facility when it is required by license condition, or if the department has not approved the procedures and activities necessary to carry out the decommissioning and these procedures could increase the potential health and safety impacts to the workers or the public. During the Decommissioning Plan RMCP staff will review the final status surveys and verify that the licensee has demonstrated that the site, area, or building meets the radiological criteria for license termination. A Decommissioning Plan 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 NUREG-1757 Volume 2 Section for guidance on the acceptable format and content of this report.

   iii. Decommissioning Plans will be reviewed at intervals not to exceed 3 years.

(Reference: NUREG-1757 Volume 1 & 2 *Consolidated Decommissioning Guidance*, NUREG-1556 Volume 20, 10 CFR 30.35(e)).

d. Change of Control

   i. Control of licensed activities is in the hands of the authority who decides how and when the license will be used. The licensee should

provide full information and obtain the Departments written consent prior to transferring the control of the license. The reviewer should also verify whether any financial assurance documents are affected by the change of control and ensure the Pre-licensing checklist has been completed. See Regulatory Issue Summary (RIS) 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees" for further information on change of control. (Reference: NUREG-1556 Volume 15 *Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses*)

4. For amendments and renewals, compare with previous license. Review licensee inspection/enforcement history.

5. For new licenses and change of ownership or control, ensure that the Pre-licensing 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. For previous NRC licenses refer to:

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

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

8. Review license tie downs and inspection documentation.

9. Ensure that the review of the application includes the following commonly missed items:

a. Application signed by upper management;

b. 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;

c. Training and experience records for all Authorized Users (AUs);

d. Preceptor and attestation statements for all new AUs, RSOs, and Authorized Medical Physicists (AMPs);

e. Training and experience records, duties, responsibilities, and the availability of the RSO;

f. Training and experience records for the Radiation Safety Committee Chair, if appropriate;

g. Records to be retained and responsibility for records retention assigned;

h. 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;

i. Procedures for receipt of radioactive material, especially to include off-hours and weekends.

10. 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 (Department 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.

11. Notify the Radiation Control Program Director immediately with concerns and/or violations identified during the review.

12. Ensure completed Department forms are included and signed by licensee management:

Department form 313 – New Licenses Department form 313 – License Renewal (or equivalent); and
Department form 314 – License Termination

13. Ensure that sealed source model numbers are registered and that the requested sealed source models and requested uses are consistent with that listed on the current certificate in the Sealed Source and Device Registry.

14. Confirm manufacturer, possession limit, AUs and all information is current

15. Complete security related information and mark as appropriate.

16. Draft license in WBL and compare with similar licenses.

17. Confirm license expiration date on license.

18. Confirm proper program code and inspection priority.

19. Draft Cover Letter.

20. Use Administrative Qualitative Checklist for Licensing Actions.

21. Ensure the RCPD signs license or S/HP in the RCPD absence.

22. Ensure the document will be properly delivered by email.

23. Email letter and license.

24. Use Administrative Quality Checklist for Licensing Actions for QA/QC review of letter and license.

Indiana Department of Homeland Security
Radioactive Materials Control Program

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.

7. 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 Web Based Licensing (WBL) is filled out and correct (Program Codes, Contact, RSO, Address, etc.).

11. Error reduction techniques are utilized, such as re-read/proofread/secondary review after printing or prior to emailing the license.

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 1.1-6 to RMCPP 1.1, Revision 0:
INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES
From OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
PROGRAM CODE DESCRIPTIONS AND INSPECTION PRIORITIES

Program Code	Priority Code	Category Title
01100	3	Academic Type A Broad, 1-5 Locations
01110	5	Academic Type B Broad, 1-5 Locations
01120	5	Academic Type C Broad, 1-5 Locations
02110	2	Medical Institution Broad, 1-5 Locations
02120	3	Medical Institution Written Directive (WD) Required, 1-5 Locations
02121	5	Medical Institutions WD Not Required, 1-5 Locations
02200	3	Medical Private Practice WD Required, 1-5 Locations
02201	5	Medical Private Practice WD Not Required, 1-5 Locations
02210	3	Eye Application Strontium-90, 1-5 Locations
02220	3	Mobile Medical Service WD Not Required, 1-5 Locations
02230	2	High-Dose Rate Remote After loader HDR, 1-5 Locations
02231	2	Mobile Medical Service WD Required, 1-5 Locations
02240	2	Medical Therapy Other Emerging Technology, 1-5 Locations
02300	5	Teletherapy, 1-5 Locations
02310	2	Gamma Stereotactic Radiosurgery, 1-5 Locations
02400	5	Veterinary Non-human Subjects, 1-5 Locations
02410	5	*in-Vitro* Testing Laboratories, 1-5 Locations
02500	2	Nuclear Pharmacies, 1-5 Locations
02511	5	Medical Product Distribution - 32.72 Prepared Radiopharmaceuticals, 1-5 Locations
02513	5	Medical Product orstribution-32.74- Sources and Devices, 1-5 Locations
02600		Production or PET Radioactive Drugs - 30.320) (Secondary Code)
02700	5	Radium-226 luminous Products & Sources up to 10 Times 31.12(a)(4) & 151
02710	3	Radium-226 Luminous Products & Sources Greater Than 10 Times 31.12(a)(4) & 151
03110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only
03112	3	Well Logging Byproduct Only - Tracers Only
03113	3	Field Flooding Studies
03120	5	Measuring Systems Fixed Gauges, 1-5 Locations
03121	5	Measuring Systems Portable Gauges, 1-5 Locations

Program Code	Priority Code	Category Title
03122	5R	Measuring Systems Analytical Instruments, 1-5 Locations
03123	5R	Measuring Systems Gas Chromatographs, 1-5 Locations
03124	5R	Measuring Systems Other, 1-5 Locations
03130	5	Inspection Systems, 1-5 Locations
03140	2	Industrial Diagnostic Systems, 1-5 Locations
03210	2	Radionuclide Production Using an Accelerator
03211	2	Manufacturing and Distribution Broad Type A, 1-5 Locations
03212	5	Manufacturing and Distribution Broad Type B, 1-5 Locations
03213	5	Manufacturing and Distribution Broad Type C, 1-5 Locations
~~0~~3214	5	Manufacturing and Distribution 1-5 Locations Other,
03215	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226, 1-5 Locations
03218	3	Nuclear Laundry
03219	3	Decontamination Services
03220	5R	Leak Test Service Only, 1-5 Locations
03221	5	Instrument Calibration Services Only - Sources Less than Or Equal To 100 Curies, 1-5 Locations
03222	5	Instrument Calibration Services Only - Source Greater than 100 Curies, 1-5 Locations
03225	5	Other Services - Source Less Than or Equal to 100 Curies
03226	2	Other Services - Source Greater Than 100 Curies
03231	2	Waste Disposal Burial
03232	3	Waste Disposal Service Prepackaged Only
03233	2	Waste Disposal Service Incineration
03234	2	Waste Disposal Service Processing and/or Repackaging
03235		Incineration, Non-commercial (Secondary Code)
03236	2	Waste Treatment Service (Other Than Compaction)
03240	5	General License Distribution - 32.51
03241	5	General License Distribution - 32.53
03242	5	General License Distribution - 32.57
03243	5	General License Distribution - 32.61
03244	5	General License Distribution - 32.71

Program Code	Priority Code	Category Title
03250	5	Exempt Distribution - 32.11: Exempt Concentrations and Items
03251	5	Exempt Distribution- 32.14: Certain Items
03252	5	Exempt Distribution - 32.17: Resins
03253	5	Exempt Distribution- 32.18: Small Quantities
03254	5	Exempt Distribution - 32.22: Self-luminous Products
03255	5	Exempt Distribution - 32.26: Smoke Detectors
03256	5	Exempt Distribution - 32.21: Carbon-14 Urea Capsules
03257	5	Exempt Distribution - 32.30: Certain Industrial Devices
03310	2	Industrial Radiography Fixed Location, 1-5 Locations
03320	1	Industrial Radiography Temporary Job Sites, 1-5 Locations
03510	5	Irradiators Self Shielded Less Than Or Equal To 10,000 Curies
03511	5	Irradiators Other less Than Or Equal To 10.000 Curies
03520	5	Irradiators tors Self Shielded Greater Than 10,000 Curies
03521	2	Irradiators - Other Greater than 10,000 Curies
03610	3	Research and Development Broad - Type A, 1-5 Locations
03611	5	Research and Development Broad - Type B, 1-5 Locations
03612	5	Research and Development Broad - Type C, 1-5 Locations
03613	2	Research and Development Broad - Multisite - Multiregional, 1-5 Locations
03620	5	Research and Development Other
03710	5	Civil Defense
03800	3	Byproduct Material Possession Only - Permanent Shutdown, 1-5 Locations
03810	3	Byproduct Material Standby - No Operations, 1-5 Locations
03900	D'	Decommissioning of Byproduct Material Facilities
04010	2	Manufacturing and Distribution Broad Type A, 6-10 Locations

Program Code	Priority Code	Category Title
04011	2	Manufacturing and Distribution Broad Type A, More than 20 Locations
04012	5	Manufacturing and Distribution Broad Type B, 6-10 Locations
04013	5	Manufacturing and Distribution Broad Type B, More than 20 Locations
04014	5	Manufacturing and Distribution Broad Type C, 6-10 Locations
04015	5	Manufacturing and Distribution Broad Type C, More than 20 Locations
04110	5	Manufacturing and Distribution Broad OTHER, 6-10 Locations
04111	5	Manufacturing and Distribution OTHER, More than 20 Locations
04112	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226, 6-20 Locations
04113	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226, More than 20 Locations
04114	5R	Power Sources with Byproduct Material- Manufacturing & Distribution, 6-20 Location
04115	5R	Power Sources with Byproduct Material– Program Code 04114 Manufacturing & Distribution, More than 20
04116	2	Pacemaker-Byproduct Manufacturing and Distribution, 6-20 Locations
04117	2	Pacemaker-Byproduct Manufacturing and Distribution, More than Locations
04210	2	Nuclear Pharmacies, 6-20 Locations
04211	2	Nuclear Pharmacies, More than Locations
04212	5	Medical Product Distribution–32.72 Prepared Radiopharmaceuticals, 6-20 Locations
04213	5	Medical Product Distribution–32.72 Prepared Radiopharmaceuticals, More than Locations
04214	5	Medical Product Distribution – 32.74 Sources and Devices, 6-20 Locations

Program Code	Priority Code	Category Title
04215	5	Medical Product Distribution – 32.74 Sources and Devices, More than 20 Locations
04310	2	Industrial Radiography Fixed Location, 6-20 Locations
04311	2	Industrial Radiography Fixed Location, More than 20 Locations
04312	1	Industrial Radiography Temporary Job Sites, 6-20 Locations
04313	1	Industrial Radiography Temporary Job Sites, More than 20 Locations
04410	5	Veterinary, 6-20 Locations
04411	5	Veterinary, More than 20 Locations
04412	5	In-Vitro Testing Laboratories, 6-20 Locations
04413	5	In-Vitro Testing Laboratories, More than 20 Locations
04414	5	Measuring Systems Fixed Gauges, 6-20 Locations
04415	5	Measuring Systems Fixed Gauges, More than 20 Locations
04416	5	Measuring Systems Portable Gauges, 6-20 Locations
04417	5	Measuring Systems Portable Gauges, More than Locations
04418	5R	Measuring Systems Analytical Instruments, 6-20 Locations
04419	5R	Measuring Systems Analytical Instruments, More than 20 Locations
04420	5R	Measuring Systems Gas Chromatographs, 6-20 Locations
04421	5R	Measuring Systems Gas Chromatographs, More than 20 Locations
04422	5R	Measuring Systems Other, 6-20 Locations
04423	5R	Measuring Systems Other, More than 20 Locations
04424	5R	Leak Test Service Only, 6-20 Locations
04425	5R	Leak Test Service Only, More than 20 Locations

Program Code	Priority Code	Category Title
04426	5	Instrument Calibration Services Only, Source Less Than or Equal to 100 Curies, 6-20 Locations
04427	5	Instrument Calibration Services Only, Source Less Than or Equal to 100 Curies, More than 20 Locations
04428	5	Instrument Calibration Service Only, Source Greater Than 100 Curies, 6-20 Locations
04429	5	Instrument Calibration Service Only, Source Greater Than 100 Curies, More than 20 Locations
04430	3	Byproduct Material Possession Only–Permanent Shutdown, 6-20 Locations
04431	3	Byproduct Material Possession Only–Permanent Shutdown, More than 20 Locations
04432	3	Byproduct Material Standby–No Operations, 6-20 Locations
04433	3	Byproduct Material Standby–No Operations, More than Locations
04434	5R	Power Sources with Byproduct Material, 6-20 Locations
04435	5R	Power Sources with Byproduct Material, More than 20 Locations
04436	5	Inspection Systems, 6-20 Locations
04437	5	Inspection Systems, More than 20 Locations
04438	2	Industrial Diagnostic Systems, 6-20 Locations
04439	2	Industrial Diagnostic Systems, More than 20 Locations
04510	5	Teletherapy, 6-20 Locations
04511	5	Teletherapy, More than 20 Locations
04512	2	Gamma Stereotactic Radiosurgery--, 6-20 Locations
04513	2	Gamma Stereotactic Radiosurgery--, More than 20 Locations
04610	3	Research and Development Broad Type A, 6-20 Locations
04611	3	Research and Development Broad Type A, More than Locations
04612	5	Research and Development Broad Type B, 6-20 Locations

Program Code	Priority Code	Category Title
04613	5	Research and Development Broad Type B, More than 20 Locations
04614	5	Research and Development Broad Type C, 6-20 Locations
04615	5	Research and Development Broad Type C, More than 20 Locations
04616	2	Research and Development Broad-Multisite-Multiregional, 6-20 Locations
04617	2	Research and Development Broad-Multisite-Multiregional, More than 20 Locations
04618	3	Academic Type A Broad, 6-20 Locations
04619	3	Academic Type A Broad, More than 20 Locations
04620	5	Academic Type B Broad, 6-20 Locations
04621	5	Academic Type B Broad, More than 20 Locations
04622	5	Academic Type C Broad, 6-20 Locations
04623	5	Academic Type C Broad, More than 20 Locations
04710	2	Medical Institution Broad, 6-20 Locations
04711	2	Medical Institution Broad, More than 20 Locations
04810	3	Medical Institution – Written Directive Required, 6-20 Locations
04811	3	Medical Institution – Written Directive Required, More than 20 Locations
04812	5	Medical Institution – Written Directive Not Required, 6-20 Locations
04813	5	Medical Institution – Written Directive Not Required, More than 20 Locations
04814	3	Medical Private Practice – Written Directive Required, 6-20 Locations

Program Code	Priority Code	Category Title
04815	3	Medical Private Practice- Written Directive Required, More than 20 Locations
04816	5	Medical Private Practice- Written Directive Not Required, 6-20 Locations
04817	5	Medical Private Practice- Written Directive Not Required, More than 20 Location
04818	3	Eye Applicator Strontium-90, 6-20 Locations
04819	3	Eye Applicator Strontium-90, More than 20 Locations
04820	3	Mobile Medical Service – Written Directive Not Required, 6-20 Locations
04821	3	Mobile Medical Service – Written Directive Not Required, More than Locations
04822	2	High Dose Remote Afterloader, 6-20 Locations
04823	2	High Dose Remote Afterloader, More than 20 Locations
04824	2	Mobile Medical Service – Written Directive Required, 6-20 Locations
04825	2	Mobile Medical Service – Written Directive Required, More than 20 Locations
04826	2	Medical Therapy – Other Emerging Technology, 6-20 Locations
04827	2	Medical Therapy – Other Emerging Technology, More than 20 Locations
04828	5R	Pacemaker – Byproduct AND/OR Special Nuclear Material Medical Institution, 6-20 Locations
04829	5R	Pacemaker – Byproduct AND/OR Special Nuclear Material Medical Institution, More than 20 Locations
06101	1	Low-level Waste Storage - Other (Secondary Code)
11200	5	Source Material Other Less than 150 Kilograms
11210	5R	Source Material Shielding
11220	5	Source Material Military Munitions Indoor Testing
11221	5	Source Material Military Munitions Outdoor Testing

Program Code	Priority Code	Category Title
11230	5	Source Material General License Distribution - 40.34
11231	5	Source Material General License Distribution - 40.54
11240	5	Exempt Distribution – Source Material Distribution – 40.52
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
11820	2	Source Material – Water Treatment
11900	D	Decommissioning of Source Material Facilities
21131	1	Medical Isotopes Production Facility
21133	1	Hot Cell Operations - Other than Reactor Fuel
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	5R	Power Sources with Byproduct Material and/or Special Nuclear Material
22131	5	Power Sources with Special Nuclear Material
22135	5R	Power Sources with Byproduct Material - Manufacturing & Distribution
22136	5R	Power Sources with Special Nuclear Material - Manufacturing & Distribution
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

Program Code	Priority Code	Category Title
22160	5R	Pacemaker-Byproduct, and/or Special Nuclear Material - Medical Institution
22161	5R	Pacemaker - Byproduct, and/or Special Nuclear Material - Individual
22162	2	Pacemaker – Byproduct Material –Manufacturing and Distribution

Indiana Department of Homeland Security
Radioactive Materials Control Program

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

INSTRUCTIONS

See the appropriate **NUREG-1556** Consolidated Guidance https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html , 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

OR

RMCP@dhs.in.gov

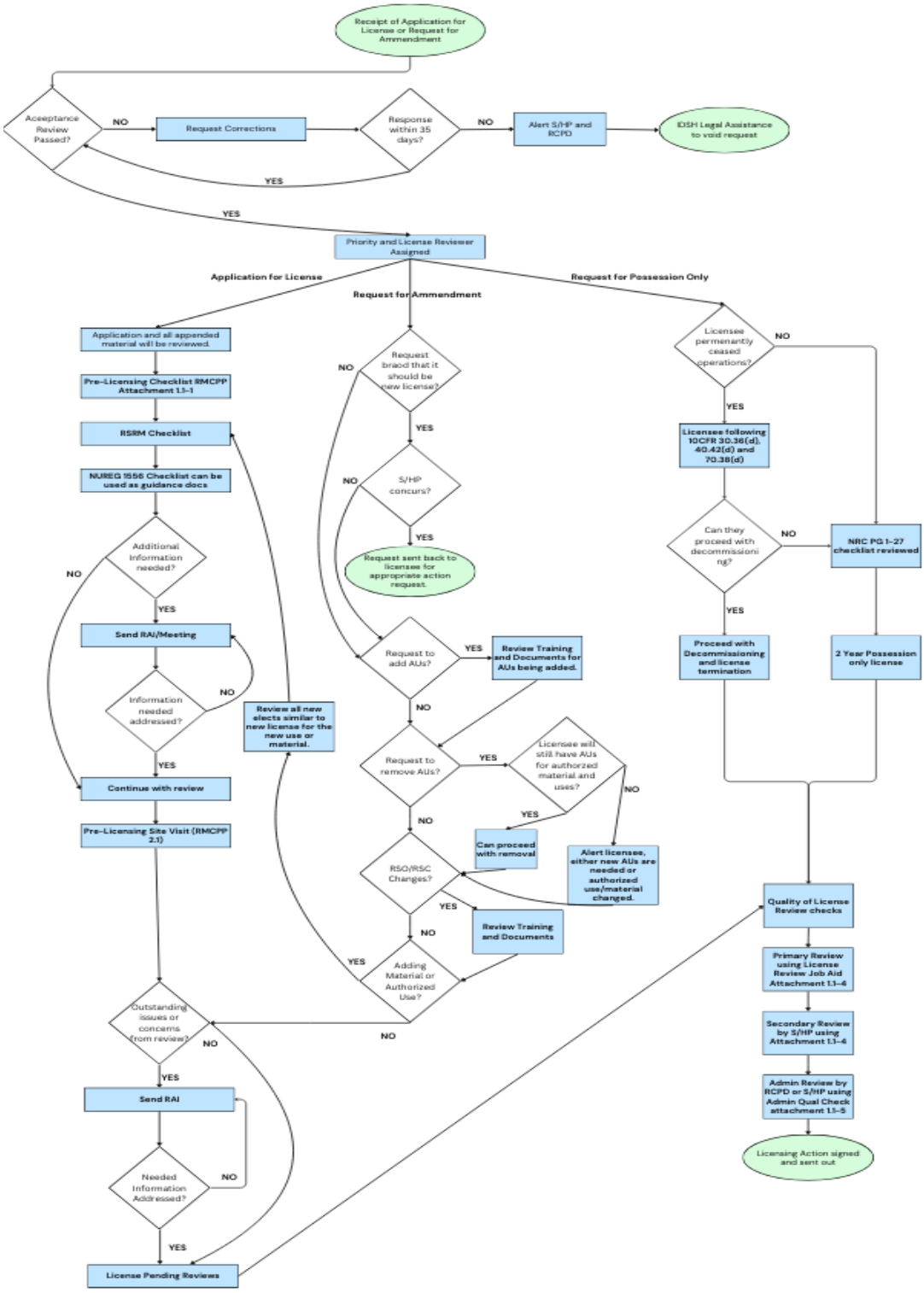
If this is an application for a NEW license, it must include remittance for the appropriate annual fee.

Department Form 313 can be found at: www.dhs.in.gov

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 1.1-8 to RMCPP 1.1, Revision 0: REVIEW OF INITIAL APPLICATION AND REQUEST FOR AMENDMENT FLOW CHART

REVIEW OF INITIAL APPLICATION AND REQUEST FOR AMENDMENT FLOW CHART



Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 1.1-9
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 the steps taken to transfer all licensed material in your possession. Your report on Department 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 and complete department Form 314.

Send your response to the following address:

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 1.1-10
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 Department 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 actions should help keep your license as complete and up-to-date as possible. If you do not wish to renew, you must complete Department Form 314 Certificate of Disposition of Radioactive Materials. It is available on our website:

www.dhs.in.gov

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/doc-collections/nuregs/staff/sr1556/index.html

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 1.1-11
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 1.2, Revision 0
License Termination/Revocation

Effective Date:

Revision	Date	Description of Changes
0		

Table of Contents

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 290 IAC 3-2-2 (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 Department 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 290 IAC 3-2-2 [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 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 the Department, 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 Department requirements.

1.4.8 **Confirmatory Survey:** A survey conducted by the Department, 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 290 IAC 3-2-2 (10 CFR 20, Subpart E). 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 the Department's regulations and termination of the license, and to demonstrate that the facility meets the Department'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 290 IAC 3-4-2 [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 IAC 290 3-2-2 (10 CFR 20.1003).

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 290 IAC 3-2-2 [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). Adopted by reference in 290 IAC 3-2-2.

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.

1.4.40 **License Review:** The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.

1.4.41 **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.

1.4.42 **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, 290 IAC 3-4-2 (10 CFR 30.61), 290 IAC 3-13-2 (10 CFR 40.71), and 290 IAC 3-15-2 (10 CFR 70.81).

1.4.43 **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.

1.4.44 **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.

1.4.45 **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.

1.4.46 **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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.47 **mrem/y (millirem per year):** One one-thousandth (0.001) of a rem per year. (See also sievert.)

1.4.48 **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.

1.4.49 **Non-impacted Areas:** The areas with no reasonable potential for residual radioactivity in excess of natural background or fallout levels.

1.4.50 **Pathway:** See exposure pathway.

1.4.51 **Performance-Based Approach:** Regulatory decision-making 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.

1.4.52 **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.

1.4.53 **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.

1.4.54 **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.

1.4.55 **Prescribed Amount of Financial Assurance:** An amount of financial assurance based on the authorized possession limits of the RMCP license, as specified in 290 IAC 3-4-2 (10 CFR 30.35(d)), 290 IAC 3-13-2 (40.36(b)).

1.4.56 **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 290 IAC 3-4-2 [10 CFR 30.4]).

1.4.57 **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.

1.4.58 **Reasonable Alternatives:** Those alternatives that are practical or feasible from a technical and economic standpoint.

1.4.59 **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.

1.4.60 **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 290 IAC 3-2-2 [10 CFR 20.1004]).

1.4.61 **Remedial Action:** See decontamination.

1.4.62 **Remediation:** See decontamination.

1.4.63 **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 290 IAC 3-2-2 (10 CFR 20.2001).

1.4.64 **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.

1.4.65 **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.

1.4.66 **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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.67 **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.

1.4.68 **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.)

1.4.69 **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.

1.4.70 **Risk Insight:** Results and findings that come from risk assessments.

1.4.71 **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 (IAC 3-2-2 [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.

1.4.72 **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.

1.4.73 **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.

1.4.74 **Screening Approach/Methodology/Process:** The use of (1) predetermined building surface concentration and surface soil concentration values, or (2) a predetermined 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.

1.4.75 **Sealed Source:** Any special nuclear material or byproduct material encased in a capsule designed to prevent leakage or escape of the material.

1.4.76 **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 290 IAC 3-2-2 [10 CFR 20.1004]).

1.4.77 **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.

1.4.78 **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.

1.4.79 **Site Characterization Survey:** See characterization survey.

1.4.80 **Site-Specific Dose Analysis:** Any dose analysis that is done other than by using the default screening tools.

1.4.81 **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 cm^2), followed by a quantification of the activity on the medium. Also known as a swipe.

1.4.82 **Source Material:** Uranium or thorium, or any combination of uranium and thorium, in any physical or chemical form, or ores that contain by weight one-twentieth 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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.83 **Source Term:** A conceptual representation of the residual radioactivity at a site or facility.

1.4.84 **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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.85 **Specific Licenses:** Licenses issued to a named person who has filed an application for the license under the provisions of Rules 4, 6 through 10, and 12 through 15. Examples of specific licenses are industrial radiography, medical use, irradiators, and well logging.

1.4.86 **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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.87 **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.

1.4.88 **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.

1.4.89 **Timeliness:** Specific time periods stated in Department regulations for decommissioning unused portions of operating nuclear materials facilities and for decommissioning the entire site upon termination of operations.

1.4.90 **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 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.91 **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.

1.4.92 **Unrestricted Area:** An area, access to which is neither limited nor controlled by the licensee (see 290 IAC 3-2-2 [10 CFR 20.1003]).

1.4.93 **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.

1.4.94 **Vadose Zone:** See unsaturated zone.

1.4.95 **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 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 290 IAC 3-4-2 (10 CFR 30.36), 290 IAC 3-13-2 (10 CFR 40.42), and 290 IAC 3-15-2 (10 CFR 70.38).

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 working 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 notice to cease licensed activities shall be recorded and transmitted to the licensee by registered mail, return receipt requested (RMCPP 1.1 attachment 1.1-9 *Sample Letter for Expired License*). This notification to the licensee transmits the requirements for the proper disposition of radioactive materials with a Department Form 314 (Attachment 1.2-1) 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 IC 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 IC 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.

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 290 IAC 3-4-2 (10 CFR 30.35, 30.36, and 30.51); 290 IAC 3-13-2 (10 CFR 40.36, 40.42, and 40.610; 290 IAC 3-15-2 (10 CFR 70.25, 70.38, and 70.510), as appropriate, or affirm that they are not required to retain or transfer the records.

4.1.4 License Termination Letter.

4.1.5 Department 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 1.2

Attachment 1.2-1 Department Form 314 Certificate of Disposition of Materials

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 1.2-1
Department Form 314 Certificate of Disposition of Materials

Attachment 1.2-1 Department Form 314 Certificate of Disposition of Materials

Department Form 314 can be found at:

Indiana Department of Homeland Security

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 1.3, Revision 0
NRC Licenses Affected by Agreement State

Effective Date:

Revision	Date	Description of Changes
0		

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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:

1.4.3.1 An application for a license to receive, possess, and use licensed radioactive material;

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 users, RSO, quantity of material, add isotopes, facilities, etc.; and/or

1.4.3.4 A request for termination of a license(s).

2.0 RESPONSIBILITIES

2.1 Radioactive Materials Control Program Staff

2.1.1 Maintains the records, letters, forms, and report files and updates the files and WBL, as necessary.

2.1.2 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, an Amendment Request, or Renewal*.

3.2.2 In the event of a request for a termination of one of the licenses acquired from a file transferred by the NRC, RMCPP 1.2, *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 1.3

None

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 1.4, Revision 0
Renewal Notices, Receipt and Tracking of Licensing Actions

Effective Date:

Revision	Date	Description of Changes
0		

Table of Contents

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 deny the request.

1.2 References

1.2.1 290 IAC 3.

1.2.2 Department 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 Radiation Support Specialist

2.1.1 Receives, logs, and acknowledges the receipt of an application, including application fee, for a new license in the licensee/applicant file.

2.1.2 Prepares the renewal letter to notify the licensee that the license will expire in 90 days.

2.1.3 Sends out acknowledgment letters for receipt of termination requests in a timely fashion (if possible, within 15 working days).

2.1.4 Prepares a list for the Senior Health Physicist that shows the status of each licensing action.

2.2 Health Physicist (HP)

2.2.1 Responds to requests for license applications and uses the schedule in RMCPP 1.1 *Review of Initial Application for License, Amendment Request, or Renewal* for prioritization of license reviews.

2.2.2 Records dates as provided for receipt and tracking of all licensing actions, including transmittal of timely filed letters for renewals.

2.2.3 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.

2.2.4 Performs secondary review of licenses prepared by other Department licensing staff members.

2.3 Senior Health Physicist (S/HP)

2.3.1 Responds to requests for license applications and uses RMCPP 1.1 for prioritization of license reviews.

2.3.2 Conducts license review or secondary reviews as assigned by the Radiation Control Program Director.

2.3.3 Conducts completeness review for renewals and signs deemed timely filed letter for renewals as assigned by the Radiation Control Program Director.

2.3.4 Assigns licensing actions and completeness reviews to Health Physicists for secondary review of license applications.

2.4 Radiation Control Program Director (RCPD)

2.4.1 Provides guidance to S/HP on Prioritizing and reviewing licensing actions.

2.4.2 Assigns and adds milestones in WBL.

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

3.2.1 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 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 Request for Additional Information

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 Writing the License: 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 Secondary Review: The primary reviewer shall forward the licensing action file with the draft license to the S/HP or designee to perform a secondary review. The secondary reviewer will discuss any issues of concern with the primary license reviewer and make the necessary corrections following the License Review Job Aid (Attachment 1.1-4).

3.6.3 Supervisory Review: Before a licensing action is signed and approved by the RCPD, the S/HP or RCPD in their absence must make a supervisory review as documented on the Administrative Qualitative Checklist (Attachment 1.1-5).

3.6.4 Documentation: 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 Signing Approval of the Licensing Action: The license can be signed by the RCPD or by the SHP in their absence after the secondary review and the supervisory review.

3.7.2 File Documentation: 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 (Department Form 313) – filed in Indiana license file.

4.1.2 Request for Additional Information – filed in Indiana license 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 1.4

None