State of Ohio

Department of Health

BUREAU OF RADIATION PROTECTION

APPLICATION FOR AGREEMENT STATE STATUS

Submitted by
The Ohio Department of Health
State of Ohio
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EXHIBIT 12

SEALED SOURCE AND DEVICE

REVIEW AND EVALUATION PROGRAM

AND

SUPPORTING DOCUMENTS

STATE OF OHIO
DEPARTMENT OF HEALTH
BUREAU OF RADIATION PROTECTION

SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

REVISION 1
EFFECTIVE DATE: 27 FEBRUARY 1998

Final 2/19/98
Rev. 1 - 2/27/98

This program prescribes the methodology used by the state of Ohio, Department of Health professional, technical staff in the review, evaluation, registration and updating of sealed sources and devices containing radioactive material as requested by licensees and license applicants within the state boundaries. The authority for this activity is granted to the state of Ohio Department of Health by Agreement with the United States Nuclear Regulatory Commission under the Agreement State provisions of the Atomic Energy Act of 1954, as amended.

This procedure is applicable to all persons in the state of Ohio and to those facilities that do business in the state of Ohio where the use and possession of radioactive material is under the jurisdiction of the state as provided for under the auspices of chapter 3748. of the Ohio Revised Code.

This program is initially applicable to the review, evaluation, registration and updating of sealed sources and devices containing naturally-occurring and accelerator-produced radioactive material and upon acceptance as an Agreement State by the United States Nuclear Regulatory Commission will be applicable to the licensing of byproduct material, source material, and Special Nuclear Material in quantities that does not form a critical mass.

STATE OF OHIO
DEPARTMENT OF HEALTH
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SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

Ohio Department of Health
Bureau of Radiation Protection

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NMS-SSD-001	Licensing Guide - Program Specific Guidance about Portable Gauge Licenses
NMS-SSD-002	Licensing guide - Program Specific Guidance about Radiography Licenses
NMS-SSD-003	Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Radioactive Material
NMS-SSD-004	Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Radioactive Material
NMS-SSD-005	Licensing Guide - Program Specific Guidance for the Preparation of License Applications for the Use of Sealed Sources and Devices for

[1] Not all implementing procedures are attached to this program. NMS-SSD-003 - NMS-SSD-011 are available for review at IMPEP or Readiness Review.

	Performing Industrial Radiography
NMS-SSD-006	Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in X-Ray Fluorescence Analyzers
NMS-SSD-007	Licensing Guide - Guide for the Preparation of applications for Licenses for the use of Sealed Sources in Non-Portable Gauging Devices
NMS-SSD-008	Licensing Guide - Guide for the Preparation of applications for Licenses for the use of Sealed Sources in Non-portable (Fixed Location) Gauges
NMS-SSD-009	Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in Portable Gauges

SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

Ohio Department of Health
Bureau of Radiation Protection

POLICY STATEMENT

Radioactive material as used in sealed sources or devices takes many forms, from the small, limited quantity sources used for daily calibration of radiological instrumentation used at a facility for measuring and accounting for dose rates, loose or fixed surface contamination or airborne radioactivity to very large, high quantity sources used for industrial radiography or medical applications such as teletherapy.

This program provides a description of the reasons for a sealed source and device evaluation program and the reasons for a registration program, as considered separate from the licensing of radioactive material within the state. The program is initially effective for sealed source and device evaluation for naturally-occurring and accelerator-produced radioactive material (NARM) and after acceptance by the United States Nuclear Regulatory Commission (NRC) as an Agreement State will apply to those sealed sources and devices that contain byproduct material, source material, and Special Nuclear Material in quantities not sufficient to form a critical mass as defined in the agreement.

Under the auspices of the Atomic Energy Act of 1954 as amended (AEA) (42 USC 2021), the NRC and the Conference of Radiation Control Program Directors, Inc. (CRCPD) have developed an elaborate methodology for the review and evaluation of sealed sources and devices containing radioactive material and under this program, the Department of Health has adopted these methodologies for the same purposes.

The General Assembly of the state of Ohio has designated the Department of Health as the agency

responsible for administering the state's radiation protection program for the safety and health of the general public and the protection of the environment by the licensing and inspection of facilities that handle or use radioactive material on a day-by-day basis. In this evolution, the authority to register by evaluation and safety review sealed sources and devices containing radioactive material is assumed by the Department of Health by this program and its several implementing procedures.

SCOPE

Initially, this program prescribes the methodology used by the Department of Health technical staff in the review, evaluation, and registration of sealed sources and devices containing radioactive material. This program is applicable to all persons within the state of Ohio who use or possess radioactive material and are licensed in accordance with the criteria of chapter 3748. of the Ohio Revised Code and the rules promulgated thereunder.

It has been determined within the state of Ohio that a program for the review, evaluation and registration of sealed sources or devices containing radioactive material is necessary to protect public health and safety by preventing inadequate sealed sources and devices from being distributed and used. The registry for sealed sources and devices is maintained by the NRC and is a shared responsibility between the NRC, who have accepted responsibility for product review and the Agreement States and NARM Licensing States performing product review. The registry will assist a member of the professional staff in the review of a license application in identifying sealed sources and devices and in assisting to identify lost or abandoned sealed sources or devices. Background files for each sealed source and device placed in the registry is the responsibility of the licensing authority

for that radioactive material, either the NRC, the Agreement State, or the NARM Licensing State.

OVERVIEW

The NRC has the authority to perform all reviews of sealed sources and devices containing radioactive material if the applicant is located outside of the state of Ohio and is not located in another Agreement State who has accepted and is maintaining authority for product review, NARM licensing state with approval for product review, or if the applicant is a Federal facility, or is requesting an evaluation of an exempt product containing byproduct material, provided the applicant is not the United States Department of Energy (DOE) or the sealed source or device contains solely NARM.

Ohio is responsible to review and evaluate any sealed source or device if the sealed source or device contains NARM solely and the applicant is located in the state of Ohio. Following approval by the NRC as an Agreement State, the state of Ohio will assume the responsibility to perform all reviews of sealed sources or devices containing radioactive material that is under the auspices of the Agreement provided the applicant is not the DOE, a Federal facility such as the United State military, the Department of Transportation, etc., or the sealed source or device contains an exempt amount of radioactive material under the auspices of the Agreement.

The applicant must identify the source or device if it is registered by the NRC if the applicant is applying for a state of Ohio license for radioactive material. In the event a licensee requests a review of a sealed source or device, that licensee is responsible to provide all information needed by the

state of Ohio for the review process. If a distributor of a sealed source or device intends to prevent that sealed source or device from being reviewed by each customer, then that distributor is responsible for providing this information. In the event an applicant for a License for Radioactive Material in the State of Ohio requests licensing of a sealed source or device which, upon review, is found to not have been reviewed by the U.S. NRC, an Agreement State which has accepted and is maintaining product review status, or by the State of Ohio, then the licensee shall request a full review by the State of Ohio.

PROVISIONS OF THE REVIEW AND EVALUATION PROCESS

The criteria for filing a request for a sealed source or device containing radioactive material is governed by rule 3701 -39-021 of the Ohio Administrative Code (OAC). As provided in the OAC, the applicant must provide information on the source as described in the Implementing Procedures to this program to the Department of Health, Bureau of Radiation Protection. In the event that an applicant considers a part or all of the application confidential or proprietary, the applicant is responsible to mark the application in red with the words, "TRADE SECRET". The reviewer, upon receipt of such a marked document will determine with the assistance of the Program Administrator of Nuclear Materials Safety section if the information is necessary to perform a safety evaluation of the product. Regardless of this decision, the document so indicated will be maintained separately from the application and marked "Not Subject to Public Disclosure per section 1333.61, 'The Uniform Trade Secrets Act' of the Ohio Revised Code. Following review and approval the applicant is responsible to manufacture and distribute the approved sealed source or device in accordance with the statements and representations, including the manufacturer's quality control program, contained

in the application and as included in the provisions of the registration certificate.

A request for a review of a sealed source or device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about the installation, service and maintenance, operating and safety instructions, potential hazards and environmental conditions to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect the health and safety of the general public and to minimize danger to life and property. The technical reviewer is responsible to perform a technical and safety review and prepare the registration certificate. The technical reviewer shall assign a specific registry number to the certificate, submit the registration certificate to the NRC for distribution and review and provide for the maintenance and upkeep of a registry certificate.

The state of Ohio is prepared to provide the following types of reviews:

- Specifically Licensed Products;
- Generally licensed products;
- Custom products; and
- Amendments and changes to any of the above.

The technical reviewer shall follow the guidance provided in the implementing procedures to this program which include:

- Licensing guide - Program Specific Guidance about Radiography Licenses;
- Licensing Guide - Applications for sealed source and device evaluation and Registration;
- Licensing Guide - Program Specific Guidance about Portable Gauge Licenses;
- Licensing Guide - Standard Review Plan for Applications for Sealed Sources and Devices Evaluations and Registrations;
- Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Radioactive Material ;
- Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Radioactive Material ;
- Licensing Guide - Program Specific Guidance for the Preparation of License Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography;
- Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in X-Ray Fluorescence Analyzers;
- Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in Non-Portable Gauging Devices;
- Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in Non-portable (Fixed Location) Gauges;
- Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in Portable Gauges; and
- BRP Procedure BRP-LICENSE-O11, *Use of Sealed sources in Portable Gauging Device Licenses.*

Additional guidance is provided in state of Ohio Licensing Guides for *Establishing Quality*

Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Radioactive Material. The technical review shall also consider the As Low as is Reasonably Achievable (ALARA) policy in the review of any sealed source or device containing radioactive material. The sealed source or device must meet the applicable portions of state rules concerning labeling of the radioactive material, manufacturing requirements, and registration requirements as provided in rule 3701-39-021 of the Administrative Code. Additionally, the sealed source or device depending on its planned use, must also meet any and all requirements as specified in specifically developed guidance documents for radiography devices, medical sources, irradiator sealed sources and well logging sealed sources.

Technical staff shall remain qualified for sealed source or device review and evaluation by training and refresher training. Staff personnel have attended the NRC Sealed Source and Device Workshop and a specialized training segment for sealed source and device review and registration has been developed and is a part of the training regimen for Nuclear Materials Safety section staff and other Bureau of Radiation Protection staff who might be assigned a part in or a portion of a review of a sealed source or device. Included in the qualifications for a staff member to perform a review of a sealed source or device are the following:

- Blueprint reading - mechanical, P&ID, electrical, etc.;
- Knowledge of welding techniques and practices, including tig welding, stick welding, brazing, etc.;
- General Engineering Principles, including prototype testing, engineering analysis, tensile, compressive and shear forces, stress, strain and strength analysis, use of ductility and

hardness measurement scales and the interpretation of results of ductility and hardness testing, temperature variances on metals, lubricants, plastics, and other man-made materials including melting points, thermal expansion and contraction, angle of moment, torsion and torque values and the interpretation of tension and torque testing, shape of components as they apply to fatigue, slenderness, and rupture;

- The effects of corrosion, clearances, lubricants and applications of lubricants, and friction.

Additional criteria are provided in the Licensing Guide - *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations.*

Technical Professional staff performing review and evaluations will receive training on the aspects of quality assurance and quality control as defined in Title 10 Code of Federal Regulations Part 50 (10CFR50) Appendix B, and ASME/ANS NQA-1. This will include the use of audits and surveillances at a facility where sealed sources or devices are manufactured to ensure the criteria of the quality assurance and quality control programs are maintained.

In addition, in the event a request for a review is received that is considered beyond the scope of the technical staff at Department of Health the Licensing Supervisor, Program Administrator and the Bureau Chief have the authority to seek assistance in areas of expertise that may be lacking in the Bureau from other state agencies or through a contract, such as Civil Engineers, Structural and Mechanical Engineers, Electrical Engineers, and other engineering disciplines as needed.

The Bureau of Radiation Protection section maintains a complete library reference section devoted

to

handbooks, training guides, manuals and other instructional aides to be used by technical staff during the review of requests for registration. These books include but are not limited to the following:

- *Marks Standard Handbook for Mechanical Engineering;*
- *Handbook of corrosion Resistant Piping;*
- *Corrosion Volume I, Metal/Environmental Reactions;*
- *Mechanical Engineering Design*; and
- Various Industry and Consensus Standards.

The following areas are included in a review of a sealed source or device containing radioactive material by the technical reviewer. The overall process of review is described in Licensing Guide *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations*. Appendix A of this guide contains a detailed descriptive checklist for this review.

- Compatibility of materials;
- Ruggedness of the sealed source or device;
- Tamper resistance of the sealed source or device;
- Systems included in the device, such as pneumatic, hydraulic, electrical, etc;
- Method of fastening the source of radioactive material to the device;
- Sealed source design including voids, tolerances, dispersibility, solubility;
- Safety mechanisms; and
- Construction methodologies and techniques including uses of radiation resistant glues and lubricants, welding methods and techniques.

REGISTRATION CERTIFICATES AND THE REGISTRY

Licensing Guide - *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations* contains specific guidance for the completion of a Registration Certificate. In addition, details on the registry of the sealed source or device with the NRC Registry is also contained in this guide. The following information will be contained in each Registration Certificate:

- Header - includes the title of the document, the registration number, date of issue, pages, and the sealed source or device type;
- First Page Information - includes the name and address of the manufacturer and distributor, the serial number of the sealed source or device, the manufacturer and model number of any incorporated sealed source within the device, radionuclides, maximum allowable activity quantities, leak test frequency, principal uses and an indication if the sealed source or device is for custom use;
- Description - provides a narrative description of the construction of the product, safety features of the product and ON/OFF and safety indicators. The description will also contain other features of the sealed source or device such as materials of construction, fabrication techniques, encapsulation methods and other information;
- Labeling - describes how labeling requirements are fulfilled and lists the information to be found on the label. This section also describes the construction of the label, where it is to be attached and any exemptions from the labeling requirements;
- Diagrams - provides a bibliographic listing of all diagrams, drawings, sketches, or pictures

of the product that are a part of the certificate;

- Conditions of Normal Use;
- Prototype testing - describes the tests performed on the prototypes of the product;
- External Radiation Levels - maximum radiation levels when loaded with the maximum quantity of radioactive material allowed;
- Quality Assurance and Quality Control - defines the procedures to be followed by the manufacturer;
- Limitations and Other Considerations of Use;
- Safety Analysis Summary as performed by the reviewer;
- References; and
- The Issuing Agency.

AMENDMENTS

The applicant may, with submittal of a revised or amended application or request for review and evaluation amend and make changes to the registered product that affects the commitments made in the information provided in the certificate of registration. These requests must address the changes to the product, and specifically how these changes affect the original safety evaluation of the product. In the event the registrant requests an amendment to the certificate, the certificate will be amended in its entirety if the amendment requires an additional safety evaluation, review and evaluation or other major modification. In this event, the Registration Certificate will be changed to indicate that this is an Amendment in Entirety. The specifics for amending the certificate are included in the Licensing Guide - *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations.*

Applying for an inactive status for a sealed source or device is also included in this Licensing Guide.

INCIDENTS

The state of Ohio is prepared to implement the Incident Response Program in the event of any incident at a facility where a sealed source or device containing radioactive material is involved. This Incident Response Program is part of the overall Agreement State Program for Radioactive Material developed and maintained by the Nuclear Materials Safety section of the Department of Health.

SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

Ohio Department of Health
Bureau of Radiation Protection

IMPLEMENTING PROCEDURES

(NOTE: The following list of Implement Procedures supplement this program. These procedures may or may not be attached to this program. Procedures not attached to this program are available for review and use at the Ohio Department of Health, Bureau of Radiation Protection.)

SRP-03001-001	Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations
Consolidated Guidance	Consolidated Guidance -- Applications for Sealed Source and Device Evaluation and Registration
NMS-DDS-003	Licensing Guide - Program Specific Guidance about Portable Gauge Licenses - this procedure is not attached to this program
NMS-DDS-004	Licensing guide - Program Specific Guidance about Radiography Licenses - this procedure is not attached to this program
NMS-DDS-005	Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Radioactive Material - this procedure is not attached to this program
NMS-DDS-006	Licensing Guide - Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Radioactive Material - this procedure is not attached to this program
NMS-DDS-007	Licensing Guide - Program Specific Guidance for the Preparation of License Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography - this procedure is not attached to this program
NMS-DDS-008	Licensing Guide - Guide for the Preparation of Applications for

	Licenses for the use of Sealed Sources in X-Ray Fluorescence Analyzers - this procedure is not attached to this program
NMS-DDS-009	Licensing Guide - Guide for the Preparation of applications for Licenses for the use of Sealed Sources in Non-Portable Gauging Devices - this procedure is not attached to this program
NMS-DDS-010	Licensing Guide - Guide for the Preparation of applications for Licenses for the use of Sealed Sources in Non-portable (Fixed Location) Gauges - this procedure is not attached to this program
NMS-DDS-011	Licensing Guide - Guide for the Preparation of Applications for Licenses for the use of Sealed Sources in Portable Gauges - this procedure is not attached to this program

ATTACHMENT 1

IMPLEMENTING PROCEDURES FOR THE SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

STATE OF OHIO
DEPARTMENT OF HEALTH

Consolidated Guidance

APPLICATIONS FOR SEALED SOURCE AND DEVICE EVALUATION AND REGISTRATION

Rev. 1

Effective Date: 27 July 1998

This consolidated guidance along with the state of Ohio *Sealed Source and Device Review and Registration Program* and the state of Ohio *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations* provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

STATE OF OHIO
DEPARTMENT OF HEALTH

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Consolidated Guidance About Materials Licenses

This document combines the guidance previously found in NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and the Office of Nuclear Material Safety and Safeguards Policy and Guidance Directives 84-22, "What Source and Device Designs Require an Evaluation," and 84-5, "Source and Device Evaluation Technical Assistance Request."

"Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides applicants requesting a sealed source or device safety evaluation, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

ALARA	As Low As is Reasonably Achievable
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DCD	Document Control Desk
FDA	United States Food and Drug Administration
GPO	Government Printing Office
IMNS	Division of Industrial and Medical Nuclear Safety
ISO	International Organization of Standardization
MOU	Memorandum of Understanding
NARM	Naturally occurring or Accelerator-produced Radioactive Material
NRC	United States Nuclear Regulatory Commission
OC	Office of the Controller
OGC	Office of the General Counsel
OSP	Office of State Programs
QA	Quality Assurance
QC	Quality Control

Purpose

This consolidated guidance provides assistance to applicants on submitting requests to the NRC for radiation safety evaluation and registration of sealed sources and devices containing byproduct material. In addition, it is designed to provide the reviewer of such requests for sealed source and device safety evaluations with guidance, information, and materials necessary to make a

determination that the product is acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Radiation safety programs for the use of byproduct material as a sealed source or device are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment, or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used. The regulations provided in chapter 3748 of the Ohio Revised Code and the rules promulgated thereunder which require an applicant for a license to use a sealed source or device to identify the sealed source or device as registered with NRC in accordance with 10 CFR 32.210 as delineated in rule 3701-39-021 of the Ohio Administrative Code or to provide the information contained in 10 CFR 32.210 as delineated in rule 3701-39-021 of the Ohio Administrative Code. rule 3701-39-021 of the Ohio Administrative Code provides for the "registration" of a product and provides a means for having a single safety evaluation of the product performed. This process allows applicants and license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action. The State of Ohio has applied for and received the regulatory authority for the review and evaluation of sealed sources and devices for the NRC and for entering these sealed sources and devices in the U.S. NRC Registry for Sealed Sources and Devices data base.

The NRC maintains a registry of radiation safety information on sealed sources and devices containing byproduct material. The state of Ohio and other agreement states also provide information on their radiation safety evaluations to the NRC for the registry. The NRC, the state of Ohio, the Agreement States, and NARM Licensing States use the information in the registry. Thus

a vendor needs to provide detailed information about its sealed source or device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the United States.

Any information collection activities mentioned in this document are contained as requirements in rule 3701-39-021 of the Ohio Administrative Code which details by reference Title 10 CFR Parts 19, 20, 21, 30, 31, 32, 34, 35, 36, 39, 40, 70, and 71, which provide the regulatory basis for this document.

Agreement States

The state of Ohio will enter into an Agreement with the NRC to allow for the discontinuance of certain regulatory authorities of the NRC within the state of Ohio and the assumption of those authorities by the state. This process makes Ohio an Agreement State and gives Ohio and other states that are Agreement States the authority and responsibility to perform certain activities, including performing safety evaluations and registration of byproduct, source, or special nuclear materials used, possessed, or distributed by persons within their borders. Any applicant, other than a Federal agency or distributor of a product to persons exempt from licensing, that is located in the state of Ohio or any other Agreement State that wishes to apply for safety evaluation and registration of a sealed source or device needs to contact the Bureau of Radiation Protection for guidance on preparing an application; file these applications with the Bureau of Radiation Protection, not with the NRC.

When the Bureau of Radiation Protection or any other Agreement State issues a registration certificate, a copy of the registration certificate is forwarded to the Division of Industrial and Medical Nuclear Safety (IMNS) of the NRC by the State. IMNS performs an administrative review of each certificate that includes looking for gross errors or omissions and ensures the inclusion of all necessary information on the first page of the certificate. The certificate is incorporated into the national registry and copies are distributed to the NRC regions, all Agreement States, and

appropriate Federal and international agencies. If any administrative problems or errors are identified with the state of Ohio or any other Agreement State registration certificate, they are resolved directly with the Bureau of Radiation Protection or the Administration responsible in the Agreement State.

The state of Ohio's regulations may vary from NRC regulations. As such, sealed sources or devices registered by an Agreement State may not have met the regulations required of an NRC licensee. However, any registration issued by the state of Ohio will ensure the applicant has met the requirements for a license for radioactive material issued by the Bureau of Radiation Protection in the state of Ohio. In addition to the state of Ohio registration requirements, the NRC may identify significant safety concerns about a sealed source or device that has been evaluated by the state of Ohio or an Agreement State. In these cases, IMNS will continue to incorporate the registration certificate into the national registry. A cover letter indicating why the sealed source or device is not approved for use by NRC licensees is attached to the registration certificate. IMNS will raise the safety issues with the State that issued the registration certificate and with the vendor through OSP. In addition, the NRC will attempt to obtain a listing of any NRC licensees that may have acquired the device and will take appropriate action. Corrective actions to resolve the registration issues, if any, will be the responsibility of the Agreement State.[1]

The above process is necessary to: (1) ensure that NRC license reviewers are aware of particular NRC concerns with the registration certificate and (2) provide other Agreement States with the information necessary to determine whether a license to use the sealed source or device should be approved. If the registration certificates and cover letters are not included, an NRC or Agreement State license reviewer may receive a copy of the registration certificate directly from the registration certificate holder or an Agreement State and may inadvertently assume that products listed in the registration certificate are acceptable for licensing.

Table 2.1 Who Evaluates Sealed Sources and Devices?

Applicant and Its Location	Regulatory Agency
Distributor of products to persons exempt from licensing regardless of location	NRC
Federal agency regardless of location	NRC
Non-Federal entity in non-Agreement State, US territory or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site NOT subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Management Responsibility

The state of Ohio recognizes that effective applicant/registration certificate holder management is vital to achieving safety and complying with regulatory requirements. The state of Ohio also believes that consistent compliance with its regulations provides reasonable assurance that regulated activities within the state of Ohio will be conducted accordingly. Based on results of routine and special inspections of licensed activities, the state of Ohio has determined that ineffective management is frequently the underlying cause of compliance problems. Management refers to a senior-level manager who has responsibility for overseeing regulated activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

Table 2.1 Who Evaluates Sealed Sources and Devices?

Applicant and Its Location	Regulatory Agency
Distributor of products to persons exempt from licensing regardless of location	NRC
Federal agency regardless of location	NRC
Non-Federal entity in non-Agreement State, US territory or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site NOT subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Management Responsibility

The state of Ohio recognizes that effective applicant/registration certificate holder management is vital to achieving safety and complying with regulatory requirements. The state of Ohio also believes that consistent compliance with its regulations provides reasonable assurance that regulated activities within the state of Ohio will be conducted accordingly. Based on results of routine and special inspections of licensed activities, the state of Ohio has determined that ineffective management is frequently the underlying cause of compliance problems. Management refers to a senior-level manager who has responsibility for overseeing regulated activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Completeness and accuracy of records and all information provided to the Bureau of Radiation Protection as specified in rule 3701-39-021 of the Administrative Code and Chapter 3748 of the Ohio Revised Code;
- Knowledge about the contents of the application;
- Applying for a registration certificate amendment if the information provided in the application or contained in the certificate is modified or changed. Registration certificate holders must comply with the information in the registration certificate until the certificate is amended; and,
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to ensure that the registration certificate holder meets its regulatory requirements. The registration certificate holder is required to manufacture or distribute the product in accordance with: (1) the statements and representations contained in the application for safety review and registration; (2) the provisions of the registration certificate; and, (3) state of Ohio statutes and regulations.

Applicants and registration certificate holders may be subject to enforcement actions due to noncompliance with regulatory requirements. For information on the state of Ohio enforcement program, see "General Statement of Policy Enforcement Actions," which is available from the Ohio Department of Health upon request.

Applicable Regulations

It is the applicant's or registration certificate holder's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation. The following state of Ohio statutes and rules contain regulations applicable to sealed source and device evaluations:

- Chapter 3748 of the Ohio Revised Code;
- rule 3701-38-021 of the Ohio Administrative Code; and
- rule 3701-39-021 of the Ohio Administrative Code.

The regulations embodied in rule 3701-39-021 of the Ohio Administrative Code delineating Title 10 CFR 30.32(g) and 32.210 codify the methodology whereby vendors of sealed sources of radioactive material and devices containing sealed sources submit radiation safety information necessary to perform an independent, technical safety evaluation, and to obtain registration of radiation safety information on certain sealed sources and devices.

The specific provisions in rule 3701-39-021 of the Administrative Code delineating Title 10 CFR 30.32(g) require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. This requirement is repeated in the State of Ohio Licensing Program for Radioactive Materials.

The state of Ohio has a also has two stand alone documents that delineate and outline the safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the state of Ohio evaluates and registers radiation safety information. These documents are the Sealed Source and Device Review and Registration Program and Standard Review Plan 03001-001, Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations. Copies of these documents or copies of the Licensing Program for Radioactive Materials may be obtained from the Department of Health on request.

Current state of Ohio statutes and rules only require that products used under a specific license issued in accordance with chapter 3748 of the Revised Code and the rules promulgated thereunder be registered with the state of Ohio and the NRC. However, if registration of a product design is deemed necessary by state of Ohio, the applicant needs to provide the information contained in the documents referenced above and the application will be evaluated in the same manner as all registration applications.

(NOTE: the documents used by the state of Ohio, including the Sealed Source and Device Review

and Registration Program and Standard Review Plan 03001-001, Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations delineated and outline the requirements stated in Title 10 CFR 32.210.)

The products listed in Sections 4.1 through 4.5 are used by persons exempt from licensing requirements or used in accordance with a general license and NRC has determined that registration of the product design is necessary. However, in addition to the general registration criteria in 10 CFR 32.210, the regulations require that the products meet certain specific requirements. These specific requirements are listed in the appropriate section (Sections A through E) and need to be addressed during the product evaluation. The NRC has retained the right and authority to perform these design reviews and the applicant is reminded to submit the application for these products directly to the NRC.

Some specific-licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration criteria provided in the Sealed Source and Device Review and Registration Program and Standard Review Plan 03001-001, Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations. The specific requirements for these products are listed in Sections F through I and need to be addressed during the product evaluation.

A. Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147 for Use by Persons Exempt from Licensing Requirements

Under Chapter 3748 of the Revised Code and rules promulgated thereunder which includes the criteria of Title 10 CFR 30.19, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rules promulgated thereunder which includes the criteria of Title 10 CFR 32.22. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements,

imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable Rules
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.19(a) & (c), 32.22(a)
Maximum Radiation Levels	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.22(a)(2)(vi)
Maximum Dose Commitments	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.22(a)(2)(xiii)&(xiv)
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.25(b)[2]

B. Gas and Aerosol Detectors Containing Byproduct Material for Use by Persons Exempt from Licensing Requirements

Under Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.20, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.26. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.20(a), 32.26[3]
Maximum Radiation Levels	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.26(b)(6)
Maximum Dose Commitments	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.26(b)(13)&(14)
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.29(b)[4]

C. Devices Used under the General License in Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.5

Under Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.5, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.51. The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.5(a), 32.51(a)(2)(I)
Maximum Dose Commitments	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.51(a)(2)(ii)&(iii)
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.51(a)(3)
Leak Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.51(b)
Testing and Servicing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.51(b) & (c)

D. Luminous Safety Devices Used in Aircraft under Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.7

Under Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.7, persons may use luminous safety devices containing tritium or promethium-147 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.53. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation, are listed below:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.53(c)&(d)
Prototype Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.53(d)(4), 32.101
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.54
Quality Control	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.55, 32.110

E. Ice Detection Devices Containing Strontium-90

Under Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 31.10, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.61. Therefore, the requirements for product evaluation are imposed on the person licensed to transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.61(c)&(e)
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.61(d)
Prototype Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.61(e)(4), 32.103
Quality Control	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.61(e)(5), 32.62, 32.110

F. Radiography Equipment

Persons specific licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR Part 34. The vendor or custom user of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below must be addressed:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 34.20(a), 34.22
Leak Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 34.27
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 34.20
Prototype Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 34.20
Maximum Radiation Levels	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 34.20, 34.21

G. Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR Part 39, Subpart C. One such requirement is that the licensed material be as insoluble and nondispersible as practicable. The vendor or custom user of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below must be addressed:

Area to be Addressed	Applicable Regulations
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 39.31(a)
Leak Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 39.35
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 39.41(a)(1) & (2)
Prototype Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 39.41(a)(3)

H. Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator. The vendor or custom user of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below must be addressed:

Area to be Addressed	Applicable Regulations
Design	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 36.21(a)(2), (3), & (4)
Leak Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 36.59
Prototype Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 36.21(a)(5)

I. Sealed Sources and Devices for Medical Use

In accordance with Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 35.49, only sealed sources and devices that are manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 10 CFR 32.74 may be used for medical uses. The vendor of the sealed sources may demonstrate that the sealed source meets the requirements as part of the evaluation and registration of the sealed source or device. Therefore, during an evaluation of medical sealed sources or devices, the items listed below must be addressed:

Area to be Addressed	Applicable Regulations
Labeling	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.74(a)(2)(viii) & (a)(3)
Leak Testing	Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.74(b)

One exception to the above requirement is teletherapy sources. Specifically, teletherapy sources do not need to meet the requirements of Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.74. However, Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 35.49(b) indicates that they do need to be manufactured and distributed in accordance with a license issued pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR Part 30.

General Policies and Procedures

Sealed Source and Device Designs That Do Not Require Evaluation by the state of Ohio

Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.32(g) applies to all sealed sources and devices used by state of Ohio or NRC specific licensees and requires evaluation of the product by the state of Ohio as an agreement state or the NRC. However, the possession and use of certain products does not require the evaluation and registration of the product by state of Ohio. Specifically, evaluation and licensing of the following products should be handled as indicated below by the license reviewer:

Calibration and Reference Standards

Calibration and reference sources may be licensed without evaluation review by the state of Ohio if the sources do not exceed the following:

- For beta and/or gamma emitting material - 3.7 MBq (100 microcuries) or ten times the quantity specified in Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.71, Schedule B, whichever is greater.
- For alpha emitting material - 0.37 MBq (10 microcuries).

The above values were chosen because they represent minimal hazard to public health and safety. To license these sources, license reviewers need to identify the isotope in the license application, use the statement "calibration or reference sources", and state the maximum quantity for each source. Both possession and distribution to specific licensees may be authorized.

Products Used in Research and Development or by Broad Scope Licensees

Sealed sources or devices containing sealed sources that are intended only for use under research and development or broad scope licenses need not be evaluated by state of Ohio if the licensing reviewer has made a determination that:

- For unregistered sources, or registered sealed sources not possessed and used in accordance with the registration, - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.
- For registered sealed sources contained in unregistered devices - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

If a research and development or broad scope licensee wishes to transfer a sealed source or device to another specific licensee, then the recipient must meet the criteria listed above or the sealed source or device must be "registered" in accordance with Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 32.210 prior to transfer.

License reviewers should utilize the following standard license condition for those recipients of the registered sealed source contained in unregistered devices:

- "The licensee shall use only sealed sources for which a sealed source registration certificate has been issued by the state of Ohio pursuant to Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code or the U. S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210(e), another Agreement State or NARM Licensing State for product review. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate."

Custom Sealed Sources or Devices

Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) need not be sent to the state of Ohio for evaluation if:

(a) they contain less than 7.4 GBq (200 millicuries) of radioactive material or less than 740 GBq (20 curies) of tritium, and

(b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

Thus, the applicant would not have to rely on the intrinsic safety of the sealed source or device to demonstrate compliance with Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 30.33. Custom sealed source and devices which contain an activity greater than that listed above must be submitted to the state of Ohio for evaluation and registration.

To license these custom sealed sources and/or devices, license reviewers need to identify the isotope in the license application, use the statement "custom source" (for unregistered sources) or "sealed source" (for registered sealed sources) including a unique identifier (e.g., drawing or model number), if possible, and state the maximum quantity of radionuclide per source or device. License reviewers

need to describe, as clearly as possible, the actual use of the custom source or device.

Examples: "For use in a Model A analyzer custom built for the licensee by ABC Company in Notown" or "Custom source for use in XYZ Model 100 gauge."

The authorization to use sources or devices described above, that have not been evaluated and registered by the state of Ohio or the NRC, apply to only to the custom user of the product.

Custom Users

A user of a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant is considered a custom user. Custom users are specifically identified on the first page of registration certificates. The request for the safety evaluation and registration of the product may be made by the custom user or vendor. Regardless of the applicant, the custom user is required to meet all commitments made in the application and registration certificate. Typically, no more than two different state of Ohio, NRC, or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

As Low As Is Reasonably Achievable

The state of Ohio's requirements to establish programs, procedures, and engineering controls for achieving doses that are as-low-as-is-reasonably-achievable (ALARA) are included in Chapter 3748 of the Revised Code and rule 3701-39-021 of the Administrative Code which delineates Title 10 CFR 20.1101.

State of Ohio guidance document entitled, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," (see also U.S. NRC Regulatory Guide

8.10 of the same title) explains the state of Ohio's position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ALARA philosophy when designing and constructing sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair, and use of the sealed source or device. This guide may be useful to applicants for establishing and following an ALARA philosophy during the design of a sealed source or device.

Naturally Occurring or Accelerator-Produced Radioactive Material

The state of Ohio and other Agreement and Non-Agreement States issue registration certificates for sealed sources or devices containing Naturally occurring or Accelerator-produced Radioactive Material (NARM). Copies of these registration certificates are provided to IMNS by the States. IMNS does not perform a review of these certificates, but does incorporate these certificates into the national registry. Copies are forwarded to the NRC regions, all Agreement States, and appropriate Federal and international agencies as a service to the States. This practice replaces the United States Food and Drug Administration (FDA) "Radioactive Materials Reference Manual." Questions concerning NARM certificates should be directed to the Manager, Technical Services, Bureau of Radiation Protection, Ohio Department of Health.

As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of sealed sources or devices that contain NARM. Exceptions to this general rule include sealed sources or devices that contain material that can be reactor or accelerator produced (e.g., cadmium-109), or sealed sources or devices that contain NARM commingled with byproduct material, in either the same or separate encapsulations (e.g., moisture density gauges containing radium-226 and cesium-137).

Foreign Vendors

Foreign vendors present a unique situation for the state of Ohio and the NRC in that the state of Ohio nor the NRC has jurisdiction over foreign entities. The NRC has historically followed the regulation of 10 CFR Part 110 since a foreign vendor is required to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission. If the vendor establishes an address within the state of Ohio, then the regulatory authority for that vendor will reside in the state. In addition, the NRC inspects the United States distributor of the product and may occasionally audit foreign vendors to determine if the products distributed are in accordance with the statements made in support of the registration certificates. The state of Ohio inspects the state of Ohio distributor of the product and may inspect foreign vendors, with an address within the boundaries of the State of Ohio, to determine if the products distributed are in accordance with the statements made in support of the registration certificates.

Use of International or Foreign Standards

In some cases, an applicant may wish to test a product in accordance with an international or foreign standard. The NRC shall maintain this authority in accordance with established NRC documentation on Sealed Source and Device Evaluations and Registrations.

FDA-NRC Memorandum of Understanding

(NOTE: This section is not applicable for State of Ohio needs, and is placed in this document for clarification and explanation only.)

The FDA and the NRC signed a Memorandum of Understanding (MOU)[5] to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make

use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Federal Food and Drug and Cosmetic Act, as amended by the Safe Medical Devices Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the MOU, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of any potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For IMNS, this includes information used by the NRC for product evaluations and approvals, and any incidents involving product failures. The FDA must be notified in writing when the NRC begins an evaluation of a medical product, whether it is for a new product or for an amendment to an existing product. The notification should include the company, product model number, and the scope of the request. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a pre-marketing approval (510k) issued by FDA. If the pre-marketing approval is not submitted with the application, the applicant will be instructed to contact the FDA and obtain the appropriate approval.

Applicants needing information on FDA requirements may contact:

Food and Drug Administration
Office of Compliance, HFZ-300
2098 Gaither Road
Rockville, MD 20850
(301) 594-4692

Computer Software

State of Ohio safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators. Software applications that deal with process controls are not part of the product evaluation. The reviewer will determine that if such systems fail (e.g., a power failure), the sealed source or shielding would return to, or remain in, the fully shielded position. Medical applications involving computer software and patient planning systems are, in general, within FDA jurisdiction and FDA is responsible for any necessary review of the software.

Applicants should note that some computer systems and software programs, including embedded microprocessors,currently in use, and some systems and programs being distributed, may experience problems as a result of the turn of the new century. Applicants should evaluate the effects of the problems on the normal operation and the operation of the safety features of their equipment.

Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by the state of Ohio may pose an undue hazard when used in accordance with the conditions of the registration certificate and corrective actions cannot be implemented or agreed upon between the registration certificate holder and the

NRC, the NRC may modify or remove the registration certificate from the national registry and may issue orders modifying licenses to all persons licensed by the state of Ohio and the NRC to use the sealed source or device. IMNS will also notify OSP so that the other Agreement States are made aware of the state of Ohio or NRC actions concerning the sealed source or device.

Incidents

Incidents involving products evaluated and registered by the state of Ohio are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its integrity and adequacy, taking into account the causes of the incident. If it is determined that a generic product fault exists, the registration certificate holder will be notified and appropriate actions, affecting both products currently in use and newly manufactured products, will be taken. In addition, the state of Ohio will re-evaluate similar products to ensure they are not susceptible to the same type of faults.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product.

Some information concerning incidents involving products evaluated by the State of Ohio shall be forwarded to and may be kept on file by IMNS for use in performing future evaluations of the products involved and products similar to those involved. However, for the state of Ohio, the Bureau of Radiation Protection and for the NRC the Office of Analysis and Evaluation of Operational Data is the office responsible for compiling, tracking, and analyzing incidents and reports.

Trade Secrets (Proprietary Information)

Registration certificates and information contained in the background files for the registration

certificates, such as applications, may be made available to the public. Persons may request access to this information in accordance with Chapter 149 of the Revised Code.

Trade secrets also known as proprietary information (i.e., information not to be disclosed to the public) should not be included in an application unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information marked as "TRADE SECRET" ("proprietary," "confidential," "restricted," or "is the express property of Company X," may be considered by the Bureau as synonymous), the reviewer needs to determine whether the information is necessary to perform the safety evaluation. 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, in accordance with Chapter 149 of the Ohio Revised Code, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements in Chapter 149 of the Ohio Revised Code. If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with the provisions of Chapter 149 of the Ohio Revised Code and the applicant should be notified in writing that the State of Ohio plans to honor the request. However, the notification needs to inform the applicant that the State of Ohio may have cause to review the determination in the future, for example, if the scope of a Freedom of Information request includes the information. In all review situations, if the State of Ohio needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

Transportation

This document does not cover detailed requirements for the transportation of devices and sealed sources. The State of Ohio's transportation requirements are contained in rule 3701-39-021 of the Ohio Administrative Code which delineates and reflects the criteria of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." This rule establishes:

(1) requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material and

(2) procedures and standards for State of Ohio approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding A_1 or A_2 as defined in 10 CFR 71.4).

Transportation of radioactive materials both inter- and intra-state shall be completed in accordance with the criteria expressed in Title 49 Code of Federal Regulations, Parts 100 - 199, but exclusively in Part 173, Subpart I.

Although an application for radiation safety evaluation of a sealed source or device as discussed in this document is not expected to include a detailed description of packaging and transportation procedures to demonstrate compliance with rule 3701-39-021 of the Ohio Administrative Code, the applicant is expected to be familiar with the way those requirements apply to the sealed source or device and the action needed to ensure that transportation of the device is performed in accordance with applicable requirements.

Any vendor who has questions about the requirements for transportation may contact the State of Ohio Department of Transportation or State of Ohio Department of Health, Bureau of Radiation Protection to obtain assistance.

Although the state of Ohio does not evaluate packaging or transportation requirements during sealed

source or device evaluations, the State of Ohio does evaluate the effects the packaging or transportation has on normal use and operation of the product as part of the evaluation. Specifically, the state of Ohio evaluates the effects of normal conditions experienced during transport (e.g., extreme temperatures, vibration) on the sealed source or device. Applicants should consider these effects during the design of the products and packaging for transport.

How to File

Any applicant desiring a review and evaluation of a sealed source or device should request that the Department provide a copy of the *Sealed Source and Device Review and Registration Program* and this document. The Bureau of Radiation Protection does not require a special application, however, the applicant should ensure that the following information is contained in the information provided for review and evaluation:

General/Format:

- Be sure to review the applicable regulations and use the most recent guidance, including this document, in preparing an application.
- Submit all documents, including all drawings if practicable, printed, on standard 8-1/2 inch x 11 inch paper. If submission of larger documents is necessary, they should be folded to 8-1/2 inch x 11 inch.
- All pages in an application should be numbered consecutively. If revisions are necessary after an application has been submitted, revised or replacement pages should be submitted and should show the date of revision or revision number. Supplemental pages submitted for insertion should be indicated alphanumerically (e.g., 12a, 12b, etc.).
- Submit an original, signed application and one additional copy. Retain a copy of the registration application for future reference.

- Applicants may include a copy of their submittal on 3.5 inch disk in WordPerfect format.

Content:

- Complete the "Summary Data" section of Appendix A, "Application and Review Checklist." found in the state of Ohio *Standard Review Plan for Application for Sealed Source and Device Evaluations and Registrations*
- Attach the balance of the application to the "Summary Data" information. The order of the information in the application should correspond to th section of the Consolidated Guidance entitled, *Contents of the Application and Review Process.*
- Complete the "Checklist" included in Appendix A found in the state of Ohio *Standard Review Plan for Application for Sealed Source and Device Evaluations and Registrations* as a guide to determine whether all necessary information has been provided.
- The application should also include a drawing(s), no larger than about 4 inch x 6 inch, that may be included in the registration certificate, and that provide an overall representation of the product and its safety features.
- When drawings, operating manuals, descriptive sales literature, or similar documents are submitted as part of an application, they should be identified clearly as being part of the application. This might be done by marking the materials individually and listing them on a cover sheet for the application or listing them as enclosures to the letter that transmits the application.
- Avoid submitting trade secret (proprietary) information unless it is absolutely necessary.
- The application should include a clear, concise presentation of the information necessary for the evaluation, avoiding ambiguous and conflicting statements and wordy descriptions that do not contribute to a technical review.
- Terms included in the application should be used as they are defined in State of Ohio rules and national consensus standards, as applicable. All abbreviations and acronyms should be defined.

Engineering Drawings:

- All drawings should have a drawing number, revision number, company name, title, scale, and date. References to parts or other drawings should be clearly indicated.
- If drawings have been reduced or enlarged, this should be clearly indicated.
- All drawings should include one or several isometric projection diagrams showing components pertinent to radiation safety such as shielding material, shielding thickness, on-off mechanism, on-off indicator, label location, assembly methods, source mounting and security, and dimensions, tolerances, and materials of construction.
- Engineering drawings must be in English. To facilitate preparing an application on a product manufactured outside the United States, the applicant may elect to write or otherwise affix the English translation directly on an engineering drawing.

It may be advantageous to submit a prototype product (without radioactive material) or a part of a product with an application. For example, a vendor of radiography equipment may elect to submit a "pigtail" connector (used to join the source assembly to the drive cable) as a means of clarifying the related engineering drawings and operating instructions. Large pieces of equipment should not be submitted because of handling and storage limitations at the State of Ohio offices. The state of Ohio will not return any prototype or part of a product, however, applicants may, after the device or sealed source is included on the register of the NRC pick up the prototype at the Department's offices at 246 North High Street, Columbus, OH.

All license applications will be available for review by the general public at the Department of Health, State of Ohio.

Where to File

Applicants wishing to register a sealed source or device may file an application with the State of Ohio by submitting the application to:

The Ohio Department of Health
Bureau of Radiation Protection
Technical Services Section
P. O. Box 118
Columbus, OH 43266-0118

Registration Fees

For applicants for sealed source and device evaluations, the appropriate fee shall be "full cost" as described in paragraph (P) of rule 3701-38-021 of the Administrative Code. Full cost fees are invoiced on a quarterly basis. Once the technical review process has begun, no fees will be refunded; application fees will be charged regardless of the State of Ohio's disposition of an application or the withdrawal of an application.

Direct all questions about State of Ohio's fees to the Manager, Technical Services or Bureau Chief, Ohio Department of Health, Bureau of Radiation Protection at 614/644-2727.

Document Flow

Application Receipt and Assignment to a Reviewer

Requests for safety evaluations of sealed sources or devices usually are submitted by the applicant directly to the Bureau of Radiation Protection. However, applications submitted to State of Ohio Department of Health sections (e.g., as part of a licensing action) are forwarded to the Bureau as a

technical assistance request.

When the Bureau of Radiation Protection receives an application, an acceptance review is performed to determine whether there is sufficient information to initiate a review. If there is sufficient information to initiate a review, the applicant is sent a letter acknowledging receipt of the application; if not, the entire package is returned to the applicant for resubmission of a complete application.

Applications are logged into the sealed source and device action tracking system where they are assigned to a reviewer. Each action is assigned a unique tracking number. Assignment to a reviewer is determined on a first-in basis. An application may be assigned a higher priority based on the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. Requests for higher priority should include adequate justification.

Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and regulations, corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by two persons having signature authority. In addition, the reviewer needs to identify any complex policy issues and bring them to management's attention.

In some cases, the adequacy of an element of the product design may not be readily evident. As a result, it may be necessary for the reviewer to exercise professional judgment regarding the adequacy

and safety of the product design. Such judgment should be discussed with the applicant and included in a note from the reviewer to the registration file. A copy of the note to the registration file should be provided to the applicant.

Once the evaluation and registration are complete, the registration certificate, including cover letter to the applicant and technical assistance request response, if applicable, and all information used in support of the evaluation, are forwarded to the registration assistant for distribution and filing.

Distribution of Completed Certificates

Registration certificates are distributed in accordance with the State of Ohio *Sealed Source and Device Review and Registration Program.*

Inclusion in the Sealed Source and Device Computerized Registration System

Once the state has issued a registration, a copy of the registration is forwarded to the NRC for inclusion in the national registry and the computerized registration system in accordance with the criteria delineated in the State of Ohio *Sealed Source and Device Review and Registration Program.* The NRC then adds the registration certificate to the sealed source and device computerized registration system. The information included on the first page of the registration certificate is included in the system and certificate information can be located by searching on any item that is included in the first page of the certificate.

Contents of the Application and the Review Process

Applicants requesting safety evaluations and persons who evaluate the adequacy of products must address the following items to verify sufficient information is submitted and determine whether the design of the product is adequate for its proposed uses.

Applicants are encouraged to follow the instructions in the State of Ohio *Sealed Source and Device Review and Registration Program* when submitting applications. Applicants should complete the "Summary Data" section of Appendix A found in the state of Ohio *Standard Review Plan for Application for Sealed Source and Device Evaluations and Registrations* and use the "Checklist" to ensure that they have addressed all items listed in this section. The balance of the application should be attached to the copy of the appendix. Reviewers should use the checklist to verify the applicant has addressed all items listed in this section. In addition, the Ohio Department of Health technical staff shall use the State of Ohio *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations* as guidance for application review.

It should be noted that certain regulations include specific requirements applicable to evaluation and registration of products. These regulations are referenced in this document. The regulatory requirements take precedence over the general guidance provided in this section. Applicants must ensure, and reviewers verify, that all regulatory requirements are met.

The checklist is not considered an all inclusive review document. It is designed to highlight important aspects of the application. Further detail and review of specific areas of the applications may be necessary.

Summary Information

Manufacturer and Distributor

Applications must include the complete names and addresses of both the manufacturer and distributor of the product. The same person may be both the manufacturer and distributor. However, if different, the distributor should be the person applying for the evaluation. The distributor will be responsible for meeting the requirements associated with the registration, whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

Custom User

Applications must indicate whether the product is intended for use by a custom user. The customer user needs to be identified by name and complete address. A product specifically designed and constructed to the order of a single licensee may be considered a custom product. Since there is a single user of the product, the State of Ohio can appropriately consider specific departures from accepted standards from the point of view of compensating qualifications or conditions of use for the particular licensee. Usually, these departures occur in the areas of prototype testing and quality control (QC) procedures.

Other Companies Involved

The application must include the name, complete mailing address, and function of all other companies involved in the manufacture and distribution of the product.

Model Number, Sealed Source or Device Type, and Principal Use Code

The application must clearly state the model number designation for the product. This model number will be listed on the registration certificate for the product and may be listed on licenses of persons applying to use the product. The model number is used by the State of Ohio, the NRC and Agreement States to uniquely identify the product.

An applicant may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the products. Applicants should provide detailed engineering drawings of each basic source or device series containing overall dimensions, maximum and minimum dimensions, tolerances, materials of construction, and differences between models in the series.

The application needs to identify the sealed source or device type as used by the industry (e.g., level gauge, radiography device, self-shielded irradiator, teletherapy unit, etc.) and the principal use code that most accurately describes the product. A listing of principal use codes is included in Appendix B. This information assists applicants and reviewers in determining the applicable regulations, codes, and standards that affect registration of the product.

The application also needs to identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or by persons exempt from licensing requirements. If applicable, the applicant and reviewer need to determine which general license or exemption applies for possession and use of the product. Information needed to make this determination must be provided by the applicant. This is discussed further under the section entitled Conditions of Use of this document, which discusses the conditions of use of the product.

Radionuclides Used in the Product

The applicant must identify all radionuclides that will be used in the product and include the maximum requested activity for each, including loading tolerance. The application must also include the form of the radioactive material, including contaminates or impurities, if applicable. It is not necessary for applicants to provide information on contaminates or impurities that have little effect on the radiation levels from the sealed source or on how the sealed source will react under extreme environmental conditions.

For evaluations of devices, the applicant must identify whether the associated sealed source is currently registered. If so, the model number designation and the manufacturer or distributor of the sealed source, as listed on the registration certificate for the sealed source, must be identified.

If the sealed source is not currently registered, the sealed source must be registered separately or as part of the device. In either case, the applicant must submit sufficient information to register the

sealed source and the reviewer must perform a complete evaluation of the sealed source. If the sealed source is registered as part of the device, the registration certificate for the device should note that the sealed source is not registered separately, is registered as part of the device, and is only approved for use in the device.

Leak Test Frequency

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products are required to be leak tested at intervals not to exceed 6 months. Leak test procedures must be capable of detecting the presence of 185 Bq (0.005 microcurie) of removable contamination.

Products containing only krypton-85, hydrogen-3 (tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries) with the exception of radium, are exempt from periodic leak testing requirements. However, prior to initial distribution of the product, a leak test should be performed.

Devices may be approved with leak test intervals greater than 6 months if sufficient information is submitted to justify such a request. Current policy requires, for specific- or general-licensed products, the applicant to supply the information listed in Title 10 CFR 32.51(b) or 32.74(b)(1) as referenced in Chapter 3701-390-021 of the Administrative Code for evaluation if a longer leak test interval is requested.

The following regulations should be referenced for additional information concerning leak testing:

Regulations	Applicability

10 CFR 32.51(b) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.5 general license.
10 CFR 34.27 as referenced by Chapter 3701-39-021 of the Administrative Code	Sources and devices designed for use in radiography operations.
10 CFR 39.35 as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in well logging operations.
10 CFR 36.59 as referenced by Chapter 3701-39-021 of the Administrative Code	Irradiator operations.
10 CFR 32.74(b)as referenced by Chapter 3701-39-021 of the Administrative Code	Sources or devices for medical use.

Certification and Signature of a Management Representative

Individuals acting in a private capacity are required to date and sign the application. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in the section entitled Management Responsibility, signing the application acknowledges management's commitment and responsibilities for the regulatory requirements. The State of Ohio will return all unsigned applications for proper signature.

It is a criminal offense to make a willful false statement or representation on applications or correspondence.

When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Conditions of Use

The applicant must identify, and the reviewer evaluate, the intended use and users of the product and which standards, policies, and regulations are applicable. Applicable standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, QC and quality assurance (QA), or leak testing requirements.

The intended use of the product should include descriptions of the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the possibility that the device may be used as a component in other products.

The applicant and reviewer must also evaluate the likely environments to which the product will be subjected during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). The applicant and reviewer need to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

The applicant should provide the estimated working life of the product. The reviewer should evaluate the product's estimated working life to determine whether it is justified based on the information submitted. Inclusion of the working life of the product is important since registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or re-evaluation of a product integrity may be necessary.

Construction of the Product

Applicants need to describe construction aspects of the product including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. This should include a brief written description and summary of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets.

The brief written description and summary of the construction aspects should include the overall operation of the product, identification of primary components and safety features, type of installation including method of attachment to its mounting if installed in a fixed location and means of relocation if portable, the primary construction materials used for the product's structure and integrity and for its safety features, accessibility of the radiation beam during use, the means of providing containment, security, and shielding of the radiation source including shutters or other movable shielding, location and operation of on/off or shielded/exposed indicators, and identification of other design features that protect the product from abuse or tampering. In addition, the identification of the components of the product and safety features should include a description of each's purpose, function, and operation. An overall drawing of the product identifying primary components and safety features and indicating overall dimensions is useful as a complement to the written description of the product and for providing an understanding of the operation of the product. Detailed design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the product's safety and integrity. This should include complete annotated engineering design and/or construction drawings of all safety critical components, specification sheets, materials lists, and/or detailed written descriptions. In particular, mounting and integrity of the radioactive material or sealed source in the product must be described in detail. Drawings of safety critical parts and components should be fully dimensioned with tolerances, include identification of the safety critical parts, indicate the materials of construction or refer to a materials specification sheet or list, indicate fabrication and assembly methods, and include a drawing number and revision date or number. Parts critical to safety include those parts or components that provide primary containment, safety, and

shielding of the radioactive material or sealed source. In addition, drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the product should be provided. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

All special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source need to be adequately described. In addition, accessibility of the radiation beam during use, including the size of openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use need to be addressed.

The reviewer must evaluate how the product is constructed and evaluate its integrity. The reviewer should be able to determine the construction of the product from the drawings and written description provided with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

- The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g.,

corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).

- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation or expected conditions of use.

- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

- The fixed shielding will not move nor easily become dislodged from the device.

- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.

- All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source.

- The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition, if applicable.

- The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red

should be used for the open condition where exposure could occur and green should be used for the closed condition where the source is "safe" in the shielded position.

- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).

- If pneumatic or hydraulic systems are used, there are appropriate filtration, relief valves, and operating pressures.

- The operation is designed to be fail-safe, that is, loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.

- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing.

- If applicable, the device is hermetically sealed from foreign materials or moisture.

- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, if applicable. In addition, void spacing should allow for any thermal expansion of the materials.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure the radioactive material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Appendix B found in the state of Ohio *Standard Review Plan for Application for Sealed Source and Device Evaluations and Registrations* includes a listing of references that may be useful in determining the adequacy and integrity of the product design.

The following regulations should be referenced for additional information concerning product designs:

Regulations	Applicability
10 CFR 30.19(a)&(c); 10 CFR 32.22(a) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.19 exemption.
10 CFR 30.20(a),); 10 CFR 32.26) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.20 exemption.
10 CFR 31.5(a); 10 CFR 32.51(a)(2) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.53(c)&(d) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(c)&(e) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20 & 34.22 as referenced by Chapter 3701-39-021 of the Administrative Code	Sources and devices designed for use in radiography operations.
10 CFR 39.41(a)(1)&(2) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in well logging operations.
10 CFR 36.21(a)(2)(3)&(4) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in irradiator operations.

Labeling

Applicants must provide a description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached. The

labeling should be sufficiently durable to remain legible for the useful life of the product and, for devices, should be in a readily visible location. It is recommended that applicants provide samples or copies of the labels as part of the application.

The reviewer must verify that the application includes sufficient information concerning the labeling of the product. In addition to applicable regulatory requirements, applicants and reviewers should follow the guidelines outlined below for labeling of products:

- For Devices: Model Number, Serial Number, Isotope, Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words "CAUTION - RADIOACTIVE MATERIAL."[6] If applicable, the label should include a statement that it contains depleted uranium as shielding and include the total weight of the uranium. The label should also include limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions, if applicable.

- For Sealed Sources: Should contain the same information as included on a device. However, because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification for which information will be included. Final approval of the information is left to the discretion of the reviewer. Below is a listing, in no particular order, of the information, with a description of why the information may be important:

    - Trefoil Symbol and/or the Words "CAUTION - RADIOACTIVE MATERIAL" - This information is important if a source is found by a member of the public since it alerts the person finding the source that it contains radioactive material. The trefoil system is fairly well recognized. Therefore, for small sources where all the information may not fit, it is probably more important than the words "CAUTION

- RADIOACTIVE MATERIAL."

- Serial Number - The serial number can usually be traced back to determine the original activity, isotope, date of assay, and the last known user of the source. The current activity can be calculated, given this information. However, to trace back to this information, either the vendor or the last person possessing the source must be known and be in business. The serial number may be important for sources that would be stored in large quantities. This would assist the licensee in maintaining accountability of each source.
- Distributor's Name or Logo - This may be important in trying to locate additional information concerning the source. However, if the serial number is not known or the distributor is no longer in business, this information may not be of much value.
- Model Number - The State of Ohio includes the sealed source model numbers in its sealed source and device computerized registration system. Therefore, the State of Ohio could identify the distributor, possible isotopes, and maximum allowable activities, given the model number.
- Isotope, Activity, Date of Assay - This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other information included on the source, as indicated above, or by analysis and from surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will remain legible under normal use conditions through the working life of the product.

The preferred method of labeling sealed sources is engraving or laser etching the information. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable depending on the likely environments in which the product will be used.

Labels must be placed so that they are easily visible to the users of a device and will remain attached to the part of the device that contains the radioactive material, that is, they are not attached to the detector housing or to a barrier or guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations. For example, devices distributed to specific licensees must not include statements concerning use of the device under a general license.

The following regulations should be reviewed for additional information concerning product labeling:

Regulations	Applicability
10 CFR 32.25(b) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.19 exemption.
10 CFR 32.29(b) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(3) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.54 as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(d) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20 as referenced by Chapter 3701-39-021 of the Administrative Code	Source and devices designed for use in radiography operations.
10 CFR 39.31(a) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in well logging operations.
10 CFR 32.74(a)(2)(viii) & (a)(3) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources and devices for medical use.

Prototype Testing

An applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered).

Applicants need to determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. This may include:

- Testing a prototype of the product. A prototype product must be a complete representation of the final product that includes all safety features, shielding, safety markings (if appropriate), and any accessory features or mounting that may have a detrimental effect to the safety and integrity of the product when subjected to normal or likely accident conditions. Prototypes must be constructed from the same materials and to the same dimensions and tolerances as the final product, but may be a scale representation of the final product. Any variations of the prototype product from the final product must be analyzed for the effect to the test results the change would be expected to cause (see engineering analysis below).

- Performing an engineering analysis. An engineering analysis consists of a detailed, systematic analysis of the design and materials of construction of the product and the processes used in the manufacturing of the product to determine the product's ability to maintain its integrity when subjected to normal and likely accident conditions. The analysis may consist of calculations, modeling, sample testing, and evaluation. In addition, when evaluating products for which an industry standard is applicable, an engineering analysis may be used to demonstrate that the item would successfully pass the standard tests, if it were subjected to the tests. The conclusions of an engineering analysis should be fully

justified with supporting documentation describing the analysis and including calculations or other applicable reference material.

- Operational history of the product. Operational history includes identical devices (excluding accessory equipment that has no effect on the safety or integrity of the product) used in equivalent or more severe conditions of normal use. This typically includes products used in the United States as a custom product or in another country. Operational history should include the environmental and operating conditions, numbers of cycles per year, the results of any known accident conditions, the results and root causes of any known product failures, and the years of use of the product. Operational history must be sufficient to demonstrate that the product would be expected to operate safely and maintain its integrity during the product's intended normal conditions of use. In addition, if operational history is sufficiently comprehensive, it may also be used to demonstrate product integrity for likely accident conditions. However, a product's operational history would not be sufficient to demonstrate its ability to operate safely or maintain its integrity if it has never been subjected to the extremes of expected normal use or likely accident conditions.

- Comparison to a similar or equivalent model previously reviewed and registered. Information concerning a similar or equivalent product may be used to demonstrate safety or integrity of the requested product, if the design of the similar or equivalent product and its intended normal and likely accident conditions of use are identical or similar to the requested product or can be related (through engineering analysis) to the requested product's conditions of use. In addition, prototype testing of the similar product may also be submitted if it can be related to the requested product. The comparison should contain the information on the similar or equivalent product including prototype testing, applicable engineering analyses, or operational history and a detailed discussion and analysis of how this information relates to the requested product. In addition, the comparison must demonstrate that the requested product's ability to operate safely and maintain its integrity is equivalent

to or more robust than the previously-approved product, or that the differences between the products are such that the integrity and safety would not be affected.

Regardless of which approach the applicant chooses to pursue, the reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions, and whether the information adequately addresses all concerns about the source or device's integrity when used in a way the applicant has defined as the normal conditions of use.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product which may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

Sources

Typically, for sealed sources, the State of Ohio will only accept actual testing of a prototype unit to demonstrate integrity. This is because the sealed source is the primary containment of the radioactive material. The sealed sources should normally be tested in accordance with ANSI N542, "Sealed Radioactive Sources, Classification," or International Organization of Standardization (ISO) 2919, "Sealed Radioactive Sources, Classification." When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ANSI or ISO standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a bend test and applicants may need to verify a

source design will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin walled sources, the prototype source should include all engraved or etched labeling information prior to testing.

Devices

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N542 or ISO 2919 classification for its intended use and be authorized for the activity to be loaded. The registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. A listing of applicable standards is included in the state of Ohio *Sealed Source and Device Review and Registration Program.*

If there is no applicable standard for a product, the applicant and reviewer, using professional judgement, need to ensure that the testing performed sufficiently simulates the conditions that may be expected during use, handling, storage, and transport of the product. The applicant and reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the applicant and reviewer need to consider other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate they will maintain their containment integrity and that the necessary safety features remain operable after being subjected to any conditions they are likely to experience. The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure the

radioactive material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Occasionally, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratory standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity.

The following regulations should be referenced for additional information concerning prototype testing:

Regulations	Applicability
10 CFR 32.53(d)(4); 10 CFR 32.101 as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(4); 10 CFR 32.103 as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20 as referenced by Chapter 3701-39-021 of the Administrative Code	Source and devices designed for use in radiography operations.
10 CFR 39.41(a)(3) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in well logging operations.
10 CFR 36.21(a)(5) as referenced by Chapter 3701-39-021 of the Administrative Code	Sources used in irradiator operations.

Radiation Profiles

The applicant should provide the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides. The applicant should include the maximum radiation levels on the surface of the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and levels in the radiation beam (if the beam is accessible). If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported. The reviewer must verify that the applicant has provided the maximum radiation levels.

Measured radiation levels are preferable, but calculated levels also are acceptable. If the measured radiation levels are submitted, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used -- including type, window thickness, and sensitivity -- are acceptable for the nuclide and quantity included in the product. If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.

If the applicant is taking credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at, and at distances from, each barrier or guard need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters should be consistent with the inverse-square law and levels for non-gamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50 Sv/hr (5 mrem/hr) at 30.5 cm (12 in.) is an industry goal that has been used for many

years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, it is the responsibility of the user to ensure the product is used in accordance with chapters 3701-38-021 and 3701-39-021 of the Administrative Code which references Title 10 CFR Part 20, (e.g., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limits or limits for members of the public and that occupational exposures are AJ ARA).

If a device is intended for use on a patient, the dose to the patient for a typical application should be provided. This will serve as a reference point in approving and licensing the product.

The following regulations should be referenced for additional information concerning radiation profiles and maximum dose commitments:

Regulations	Applicability
10 CFR 32.22(a)(2)(vi), (xiii), and (xiv) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.19 exemption.
10 CFR 32.26(b)(6), (13), and (14) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(2)(ii) &(iii) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.5 general license.
10 CFR 34.20 & 34.21(a) as referenced by Chapter 3701-39-021 of the Administrative Code	Source and devices designed for use in radiography operations.

Quality Control and Quality Assurance

The applicant must provide details of the QC program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the registration certificate for the product. At a minimum, the QC program needs to ensure that:

(1) the materials of construction and the final assembly meet the design specifications;
(2) the final product is leak tested;
(3) a final radiation profile is performed;
(4) a test that verifies the product operates as intended, including all safety functions, is performed; and,
(5) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed.

Some of these inspections may be performed on a sample basis. The reviewer must verify that the applicant has provided adequate information concerning the QC program.

Current state of Ohio practice allows acceptance of the submission of a QA program in lieu of a QC program. The QA program provides control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices. This puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through refurbishment. Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing radioactive Material," provides applicants with information necessary to establish and implement a QA program that encompasses all of the QA and QC requirements necessary for the manufacture and distribution of sealed sources and devices. The guide contains sample documentation and a checklist for assessing completeness and implementation of the program. QA programs submitted by applicants are evaluated against Regulatory Guide 6.9. It should be noted that Regulatory Guide 6.9 discusses acceptance of programs meeting the

requirements of other established QA standards. The state of Ohio has adopted Regulatory Guide 6.9 until such time as a guide is developed that follows the criteria of Regulatory Guide 6.9 for use by the state of Ohio.

If the product is registered for use by a custom user, submission of a complete QC program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Since the purpose of a QC program is to ensure all devices are manufactured to the same specifications, development and submission of a complete program may not be feasible. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

The following regulations should be referenced for additional information concerning quality assurance and control:

Regulations	Applicability
10 CFR 32.55 & 32.110 as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(5), 32.62, & 32.110 as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.10 general license.

Installation, Servicing, and Instructions to Users

The applicant should provide any special procedures that need to be followed when the product is installed at the user's facility. These include verifying the integrity of the mounting, the installation of interlocks, guards or barriers, and determining whether the installation needs to be performed by a specific licensee. General licensees may be permitted to perform installation depending on the

design of the product.

In addition, the applicant needs to indicate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary training for users, changing of sources, and final disposal of the radioactive material. The applicant needs to indicate whether the applicant, or the manufacturer or distributor, will provide the necessary services or identify an entity that will provide such services. If the applicant cannot identify an entity that will provide the necessary services, the registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant cannot identify an entity that will provide services that cannot be performed by the general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. The State of Ohio is typically notified when a vendor decides to no longer provide services.

Registration certificate holders requesting to transfer a registration certificate to inactive status should identify whether they plan to continue to provide services for the registered products or whether they are aware of an entity that will provide services. The reviewer needs to verify that procedures for servicing the product are adequate, can be performed by the persons indicated by the applicant (e.g., by a general licensee), and do not interfere with, or compromise, the integrity of the product.

The reviewer must verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor should also provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of regulations governing use and transportation of the product and a listing of regulatory authorities

who license possession and use of the product.

To assist the reviewer in determining whether certain activities may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or lead the user into violating any applicable regulations.

The following regulations should be referenced for additional information concerning servicing:

Regulations	Applicability
10 CFR 32.51(b) & (c) as referenced by Chapter 3701-39-021 of the Administrative Code	Devices used under the 10 CFR 31.5 general license.

Final Evaluation and Concurrence

Once the reviewer has evaluated all necessary information and has determined that the product is acceptable for licensing purposes, the information will be passed to a second reviewer to perform an independent technical evaluation. The second reviewer must independently arrive at the same finding as the initial reviewer. Any discrepancies between reviewers must be resolved before the registration certificate can be issued. Once both reviewers concur in the findings in the document, they will sign the certificate.

Typically, the initial reviewer will generate a draft registration certificate for evaluation by the second reviewer. The second reviewer will evaluate both the application and the draft registration certificate to ensure accuracy and completeness.

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, requesting a meeting with applicant, notifying the applicant of the need for information via telephone or electronic mail, or obtaining the information directly from the applicant during a telephone conversation or via electronic mail.

Because of the need to complete the application reviews in a timely manner, the reviewer should do the following when addressing deficiencies in applications:

Sending Deficiency Letters to Applicants

Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter should request that the response be provided in duplicate. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days is typically 30 to 60 days but depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product).

If a written response[7] to the deficiency letter is received within 5 working days after the date requested in the deficiency letter, the reviewer will proceed with review of the response.

If a written response to the deficiency letter is not received within 5 working days after the date requested in the deficiency letter, the reviewer should send a second letter to applicant. The second letter should notify the applicant that unless a response to the first letter is received within 30 calendar days from the date of the second letter, the Bureau of Radiation Protection will consider

the application as "abandoned"[8] for failure to provide the requested information "without prejudice" to the resubmission of a complete application. An application that is abandoned may not be reopened and the applicant must submit a new application and pay the appropriate fees to apply for the sealed source or device review.

Meetings with Applicants

State of Ohio or applicants may request meetings to discuss sealed source and device applications. The meetings may be prior to submission of an application or to discuss items included in a deficiency letter. Meetings between State of Ohio and applicants may be at an State of Ohio office, or at the applicant's facility if it is determined that it would enhance State of Ohio's understanding of the product.

Use of the Telephone or Electronic Mail to Obtain Additional Information

There is no prohibition on using the telephone or electronic mail for obtaining clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process.

Use of the telephone or electronic mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include a model number for a sealed source, need for a applicant commitment to perform a procedure, or clarification of a material type or a dimension.

If the deficiency is a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, either via telephone or electronic mail, must be documented, in writing, and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented, in writing, by the person initiating the telephone call. If the applicant does not respond within 15 calendar days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly specify the deficiencies and be handled as a typical deficiency letter with the exception that it includes a statement that the information needs to be received within a specified time frame or the application will be voided.

Response Time Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions must be approved by the Bureau of Radiation Protection and must be documented, in writing, in a conversation record.

Contents of the Certificate

This information is delineated in the state of Ohio *Sealed Source and Device Review and Registration Program.*

Modifications to Existing Registration Certificates

It is the obligation of the registration certificate holder to keep the registration certificate current. If a registration certificate holder plans to make a change to the registered product that affects the commitments made in the information provided in support of the application or the conditions included in the registration certificate, the registration certificate holder must file for an amendment or correction to the registration certificate. Until the amendment request is approved and the amended certificate is issued, the registration certificate holder is obliged to comply with the

information in the certificate. Registration certificate holders are encouraged to anticipate the need for certificate amendments as far in advance as possible.

An application to amend a certificate should be prepared in triplicate. The registration certificate holder should retain one copy for their records and submit the original and one additional copy to the address specified above. The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the product. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

An application to amend a certificate should be accompanied by the appropriate fee and, for medical products, the registration certificate holder needs to notify FDA about the proposed changes to the product.

The request for an amendment or correction needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

Amendments

If the registration certificate holder requests an amendment to the certificate (i.e., it requires a safety evaluation to be performed), the certificate should be amended in its entirety. The certificate header

should include, under the title, the following:

AMENDED IN ITS ENTIRETY

The certificate should be assigned a new issue date and the certificate should be re-issued in its entirety. When possible, the reviewer should use bold type face to highlight the changes that have been made to the certificate.

Corrections

If the change only involves corrections to the certificate (i.e, does not require a safety evaluation to be performed such as change in address or error identified in the certificate), then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face to make the corrections. Each affected page should include, in the header, under the title, the words

CORRECTED PAGES,

the number of each page affected, and the date of the correction. An example of this format is shown below:

CORRECTED PAGES 1, 2, & 4 - JULY 3, 1998

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registration certificate holder in the reference section of the certificate. If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registration certificate holder requests an amendment, requiring a safety evaluation, to the certificate.

Combining Registration Certificates

Registration certificate holders may request that State of Ohio combine two or more certificates into a single certificate. However, it is state of Ohio policy, based on NRC policies, that only products which are essentially identical in design, function, construction, and which vary only in a dimensional capacity, in the sources used or in their application, may be grouped together on a single registration certificate.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets state of Ohio policy and can administratively combine the registration certificates.

Transfers to Inactive Status

If a registration certificate holder requests that a registration certificate be transferred to inactive status[9], the registration certificate holder should provide:

(1) the total number of the products sold; the number of products still in use[10];
(2) the services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services;
(3) a commitment that the registration certificate holder will no longer commercially distribute the product; and,
(4) verification that no changes were made to the product since its initial registration or last amendment.

The reviewer must verify that the above information is included and that the background file for the product evaluation is complete and accurate. Because some registrations were issued many years

ago, the files may not include all the information that is now required. Therefore, the reviewer should request that the registration certificate holder submit any and all additional information that would be needed to make a determination that the product is acceptable for licensing purposes. The reviewer needs to write an updated registration certificate, including the new registration number (see Appendix D found in the state of Ohio *Standard Review Plan for Application for Sealed Source and Device Evaluations and Registrations* for issuance of inactive registration certificate numbers) and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. The registration certificate will replace the old registration certificate and will be used as the basis for continued licensing of the product.

Re-Activating Inactive Registration Certificates

Vendors may submit requests to re-activate inactive registration certificates. Requests to re-activate inactive registration certificates are handled in one of the two methods:

- If the background information on file with the State of Ohio for the inactive registration certificate is complete, up-to-date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to the State of Ohio requesting re-activation of the registration certificate. The letter must include commitments that the information on file with the State of Ohio is complete and accurate and that the vendor commits to abide by all information on file with the State of Ohio. The reviewer must verify the information is complete prior to assigning a new registration certificate number and re-issuing the certificate.
- If the background information on file with the State of Ohio for the inactive registration certificate is incomplete, not up-to-date, or the vendor requests changes to the information (e.g., changes in the design of the product or manufacturing or distribution procedures), the vendor must submit a complete application for evaluation and registration in accordance with

this document. The reviewer must review and evaluate the application in the same manner as a new application.

Identifying and Reporting Defects and Noncompliance as Required by 10 CFR Part 21 as referenced by Chapter 3701-39-021 of the Administrative Code

Registration certificate holders are required to adopt appropriate procedures to evaluate deviations in product designs or failures to comply with registration requirements to identify defects or failures to comply that are associated with a substantial safety hazard. A substantial safety hazard is defined in Part 21 as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Title 10 CFR parts 30, 40, 50, 60, 61, 70, 71, or 72 as referenced by Chapter 3701-39-021 of the Administrative Code. Further, it provides the following for determining moderate exposure or release of licensed material:

Guidelines for determining moderate exposure:

- Greater than 250 mSv (25 rem) exposure (whole body or its equivalent to other body parts) to occupationally exposed workers in a period of a year or less.

- Greater than 5 mSv (0.5 rem) exposure (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of a year or less.

Guidelines for determining potential for release of licensed material:

- Release of materials in amounts reportable under the provisions of 10 CFR 20.2202(b)(2) as referenced by Chapter 3701-39-021 of the Administrative Code.

All defects or failures to comply that are associated with, or could lead to, a substantial safety hazard

must be reported to the State of Ohio pursuant to 10 CFR 21.21 as referenced by Chapter 3701-39-021 of the Administrative Code. In addition, registration certificate holders are required to meet the posting requirements specified in 10 CFR 21.6 as referenced by Chapter 3701-39-021 of the Administrative Code.

Applicants are not required to submit copies of the procedures that are necessary to meet the requirements of 10 CFR Part 21 as referenced by Chapter 3701-39-021 of the Administrative Code. However, applicants need to be aware of the need for such procedures and the State of Ohio will evaluate the procedures during inspections.

Glossary

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for the State of Ohio, the NRC and other Agreement States to issue licenses.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Agreement State means a State that has entered into an agreement with the NRC allowing the State to regulate the use of radioactive material within the State. A complete listing of the current Agreement States, including addresses and points of contacts, can be obtained from OSP.

Agreement State Registration Certificate means a registration certificate, issued and maintained by an Agreement State, for a sealed source or device evaluated by the Agreement State.

Applicant means a vendor or custom user of a product that applies for a certificate of registration with the State of Ohio, the NRC or an Agreement State. The applicant is responsible for ensuring the information provided in the application is complete and accurate.

Associated Equipment is equipment that is used in conjunction with a device and directly effects the safe use of the device or ensures the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with

the source). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of a device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as a device evaluation and a separate registration certificate should be issued for the equipment.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different State of Ohio or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but no longer may be authorized for initial distribution. Unless otherwise stated in the registration certificate, the sealed source or device included on an inactive registration certificate still may be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may be authorized to provide service and replacement parts for the sealed source or device and may be authorized to receive the sealed source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device cannot be changed.

The State of Ohio, the NRC and the Agreement States may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive serves to alert the license reviewer that the user may not be able to find a firm to service the device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support, and services are still applicable.

Inactive Vendor means a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may be authorized to provide services for the sealed source or device.

NARM stands for Naturally occurring or Accelerator-produced Radioactive Material. This material is subject to licensing and regulation by the State of Ohio. FDA Center for Devices and Radiological

Health assists States in their review and regulatory approval for distribution of devices containing NARM.

Product means any sealed source, device, or associated equipment registered with the State of Ohio, the NRC or an Agreement State.

Registration Certificate Holder means a vendor or custom user of a product that holds a certificate of registration with the State of Ohio, the NRC or an Agreement State. The registration certificate holder is responsible for ensuring the information in the registration certificate is current and correct and for ensuring products manufactured or distributed conform with the conditions of the certificate.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working Life means the time period when the product is expected to maintain its integrity. The working life should is based on the radiotoxicity, total activity, product construction, normal operating environments, likely abnormal conditions, fatigue, and wear.

APPENDIX A

MEMORANDA BETWEEN C. PAPERILLO AND S. TREBY REGARDING LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

APPENDIX B

PRINCIPAL USE CODES AND DEFINITIONS

Appendix B - Principal Use Code and Definitions

CODE

A **Industrial Radiography** - The examination of the structure of material by nondestructive methods that use sealed sources of radioactive material.

B **Medical Radiography** - The process of producing x-rays or gamma ray images to assist in medical diagnosis.

C **Medical Teletherapy** - The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient.

D **Gamma Gauges** - The use of gamma radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.

E **Beta Gauges** - The use of beta radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.

F **Well Logging** - The lowering and raising of measuring devices or tools that may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well or adjacent formation.

G **Portable Moisture Density Gauges** - Portable gauges that use a sealed source to determine or measure the content or density of material. Includes hand-held and dolly-transported devices with sources.

H **General Neutron Source Applications** - All applications, except reactor startup and well logging that use a neutron source.

I **Calibration Sources (activities greater than 30 mCi)** - Sources of a known purity and activity that are used to determine the variation in accuracy of a measuring instrument and to ascertain correction factors.

J **Gamma Irradiator, Category I** - An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volumes undergoing irradiation is not physically possible because of the design of the irradiator.

K **Gamma Irradiator, Category II** - A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry controlled system.

L **Gamma Irradiator, Category III** - An irradiator in which the sealed source is contained

in a storage pool, usually containing water, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

M **Gamma Irradiator, Category IV** - A controlled human access irradiator in which the sealed source is contained in a storage pool usually containing water, is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry controlled system.

N **Ion Generators, Chromatography** - The use of an ion-generating source and a device to determine the chemical composition of material.

O **Ion Generators, Static Eliminators** - The use of an ion-generating source and a device to eliminate static electricity on a surface or a surrounding area.

P **Ion Generators, Static Eliminators** - The use of an ion-generating source and a device to detect gases and particles created by combustion.

Q **Thermal Generator** - The use of an radionuclide and a device to produce heat to produce energy.

R **Gas Sources** - Sealed sources containing radioactive gases such as krypton-85 or hydrogen-3.

S **Foil Sources** - Sources that are constructed using thin metal foil. The radioactive material may be secured to the foil in a number of ways, for example, plating, laminating, or cold welding.

T **Other** - All uses not covered in other categories

U **X-Ray Fluorescence** - Sources and devices that use radioactive material to excite the atoms of samples that in turn emit characteristic x-rays and thereby provide a means for sample analysis.

V **General Medical Use** - Includes diagnostic sources and devices such as bone mineral analyzers and therapeutic devices and sources such as interstitial needles, therapeutic seeds, and ophthalmic devices.

W **Self-luminous Light Source** - A source consisting of a radioactive nuclide or nuclides incorporated into solid inactive materials or sealed in a protective envelope and incorporating a phosphor to emit light.

X **Medical Reference Sources** - Includes flood sources, instrument check sources, and spot markers.

Y **Calibrators** - Devices containing calibration sources that are used to determine the variation in accuracy of a measuring instrument and to determine necessary correction factors.

ENDNOTES - this procedure is not attached to this program

1. This policy is described in the memorandum to Office of the General Counsel (OGC) dated September 30, 1993, and OGC's response dated December 23, 1993

2. The regulation requires identification of the person licensed under 10 CFR 32.22. Identification can be the full name of the licensee, their registered trademark, or their **NRC** exempt distribution license number.

3. This regulation is applicable to devices designed to protect life or property from fires and airborne hazards. It has been determined that gas and aerosol detectors designed to detect explosives or chemical agents may be licensed for distribution in accordance with this regulation.

4. The regulation requires identification of the person licensed under 10 CFR 32.26. Identification can be the full name of the licensee, their registered trademark, or their **NRC** exempt distribution license number.

5. The MOU was published in the Federal Register (**58 FR 47300**) on September 8, 1993.

6. The word danger may be used in lieu of the word caution.

7. A written response may be either a letter or a fax from the applicant.

8. "Abandoned" is not meant to have legal connotations. It means simply that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment. "Without prejudice" is not meant to be understood in a legal sense. This means that the applicant can resurrect its application within some reasonable time without having to pay another fee, having its application redocketed, etc. "Void" should not be thought of in its legal sense. It means here that the application is, in practical effect, nullified.

9. State of Ohio also will transfer a registration certificate to inactive status if it knows the registration certificate holder is out of business.

10. The actual number of products sold and still in use may not be known by the registration certificate holder. However, the registration certificate holder should still provide a best estimate.

STATE OF OHIO
OHIO DEPARTMENT OF HEALTH
Bureau of Radiation Protection

STANDARD REVIEW PLAN FOR APPLICATIONS FOR SEALED SOURCE AND DEVICE EVALUATIONS AND REGISTRATIONS

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Revision 1

Final 2/19/98 - rrg
Rev. 1 - 2/27/98

The purpose of this document is to provide the reviewer of a request for a sealed source or device safety evaluation with the information and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the reviewer with a listing of the applicable rules delineated in the Ohio Administrative Code and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, and information on how to perform the evaluation and write the registration certificate.

This Standard Review Plan follows the criteria of NUREG 1550, Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations. This guide is prepared for the guidance of the technical staff of the Bureau responsible for the review of a sealed source or device application. Standard review plans are not substitutes for rules of the Administrative Code and thereafter compliance with these standard review plans is a matter of policy.

STATE OF OHIO
OHIO DEPARTMENT OF HEALTH
Bureau of Radiation Protection

STANDARD REVIEW PLAN FOR APPLICATIONS FOR SEALED SOURCE AND DEVICE EVALUATIONS AND REGISTRATIONS

Effective Date: 27 July 1998
Revision 1

Final 2/19/98 - rrg
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Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations

INTRODUCTION

Purpose

The purpose of this document is to provide the reviewer of a request for a sealed source or device safety evaluation with the information and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the reviewer with a listing of the applicable rules of the Ohio Administrative Code and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, and information on how to perform the evaluation and write the registration certificate.

Applicable Rules of the Ohio Administrative Code

The state of Ohio has incorporated rules pertaining to the use, possession, transfer, and disposal of radioactive materials in rules 3701-38-021 and 3701-39-021 of the Ohio Administrative Code (OAC). The authority for the licensing of radioactive material is provided in Chapter 3748 of the Ohio Revised Code (ORC).

The regulations embodied in rules 3701-38-021 and 3701-39-021 of the Administrative Code codify the current and long-standing practice whereby vendors of sealed sources of radioactive material and devices containing sealed sources file with the state of Ohio and subsequently with the US NRC (see 10CFR30.32(g), 30.33(a)(2) and 32.210 for US NRC regulations), radiation safety information necessary to perform an independent, technical evaluation and to obtain registrations of radiation safety information on certain sealed sources and devices.

Specifically, rule 3701-39-021 of the Administrative Code, by reference to the Code of Federal Regulations, 10CFR30 et seq. state that the user's equipment and facilities must be adequate to protect health and minimize danger to life or property. The specific provisions of rule 3701-39-021 by inference to Title 10 Code of Federal Regulations require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. Rule 3701-39-021 of the Administrative Code outlines the NRC safety evaluation and registration certificate and clarifies the regulatory responsibility of registrants of products for which the state of Ohio evaluates and registers radiation safety information.

Requirements for the manufacture, distribution, and use of certain sealed sources and devices are set forth in Chapters 3701-38 and 3701-39 of the OAC. Details of how these requirements apply are included in section 4, Regulations that Address Specific Registration Requirements of this

document.

Purpose of Registration

Radiation safety programs for the use of radioactive material as a sealed source or device are structured on the presumption that the radioactive material will not breach its containment and contaminate the environment, or unnecessarily expose individuals to radiation. This presumption depends largely on the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are used.

Registration of a product provides a means for having a single safety evaluation of the product performed and allows license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action.

The Bureau of Radiation Protection, Ohio Department of Health has the responsibility and the authority to conduct safety evaluations of sealed sources and devices. In support of this, the bureau,

- conducts safety evaluations for applicants under state of Ohio jurisdiction;
- maintains a state sealed source and device registry and forwards all information on sealed sources and devices to be distributed outside of the state to the US NRC for incorporation into the national sealed source and device registry;
- conducts generic studies related to the use of sealed sources or devices as necessary to ensure health and safety;
- develops and implements technical and policy guidance related to sealed sources and devices for the state of Ohio;
- responds to technical assistance requests from vendors located in the state of Ohio; and
- provides technical support for incidents and emergency response.

Definitions

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for the state of Ohio to issue a license for radioactive materials.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Associated Equipment means equipment used in conjunction with a device and directly affects the safe use of the device or ensures the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with the source). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of the device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as for a device evaluation and a separate registration certificate should be issued for the equipment.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time, but no longer may be authorized for initial distribution. Unless otherwise stated in the registration certificate, the sealed source or device included on an inactive registration certificate may still be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may continue to provide service and replacement parts for the sealed source or device and may receive the sealed source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device can not be changed.

The state of Ohio may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive serves to alert the license reviewer that the user may not be able to find a firm to service the device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support and services are still applicable.

Inactive Vendor means a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may provide services for the sealed source or device.

Product means any sealed source, device or associated equipment registered with the state of Ohio, the US NRC, another agreement state, or NARM Licensing state approved for product review.

Registrant means a vendor or custom user of a product that holds a registration certificate with the state of Ohio or the US NRC, another agreement state or NARM Licensing state approved for

product review.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working life means the time period when the product is expected to maintain its integrity. The working life should be based on the radiotoxicity, total activity, product construction, normal operating environment, like abnormal conditions, fatigue and wear.

GENERAL POLICIES AND PROCEDURES

Rule Implementing Guides

State of Ohio Rule Implementing Guide (RIG) Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices containing Radioactive Material and Rule Implementing Guide, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Sealed Sources containing Radioactive Material may be used by applicants who wish to submit a sealed source or device design for safety evaluation and registration. This safety evaluation is required before the sealed source or device may be approved for distribution and use. The two documents provide guidance in the following areas:

- Applicable rules;
- How to file an application, including where to file, how to determine the fees associated with the evaluation, how to handle proprietary information, other agencies that may be involved in the review process, and applicable transportation regulations;
- Information included in the application and suggestions on the form in which the information should be arranged;
- making amendments to current registration certificates; and
- the responsibility of the registrant once the safety evaluation has been performed and the registration certificate has been issued.

Each of these two rule implementing guides also contain a checklist that can be used by applicants to ensure their submission is complete.

Rule Implementing Guide Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Source and Devices Containing Radioactive Material provides applicants with information necessary to establish and implement a Quality Assurance program that encompasses all of the Quality Assurance and Quality Control requirements necessary for the manufacture and distribution of sealed sources and devices. The RIG contains sample documentation and a checklist

for assessing completeness and implementation of the program.

Implementing Directives

Implementing Directives (IDs) are intended to assist license reviewers in determining if sufficient information is provided by a license applicant. The following ID's are designed for review of applications involving the distribution and use of a sealed source or device.

ID SSDE-01, What Source and Device Designs Require an Evaluation gives guidance for license reviewers on what sealed source and device designs require a radiation safety evaluation. The directive specifically addresses whether the following products require a source or device evaluation:

1. Calibration and reference standards below certain activity levels;
2. Sealed sources and devices used in research and development or by broad scope licensees if the applicant is qualified to use the radioactive material in unsealed form (for sealed sources) or unshielded form (for devices containing registered sealed sources); and
3. Custom sealed sources or devices below certain activity levels if the applicant is qualified to use the radioactive material in unsealed form. Any other sealed source or device containing a sealed source would require a safety evaluation unless specifically granted an exemption by the department.

ID SSDE-02, Source and Device Evaluation Technical Assistance Program gives guidance for license reviewers on how to file a technical assistance request for the evaluation of a sealed source or device. The request is submitted directly to the Technical Services section of the department and the Manager, Technical Services forwards the assistance request to a specified license review specialist who deals directly with the applicant to complete the evaluation.

Other ID's designed for use by license reviewers in approving the use of sealed sources and devices may be applicable to the evaluation and registration of a sealed source or device. The reviewer should consult the index of Implementing Directives to determine which ID's may be applicable.

As Low As is Reasonably Achievable (ALARA)

The requirements for the implementation of the department's ALARA policy in included in rule 3701-39-021 of the OAC. The department ALARA Policy explains the Department of Health position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ALARA philosophy when designing and constructing sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair and use

of the sealed source or device. The department ALARA Policy may be useful to applicants for establishing and following an ALARA policy during the design of a sealed source or device.

Certificates Generated in Ohio and other Agreement States

The state of Ohio, other Agreement States and NARM Licensing States approved for product review. perform evaluations of products that are distributed to persons located in states under NRC jurisdiction, other Agreement States, and NARM Licensing States or custom products used by persons located in states under NRC jurisdiction and other Agreement States. Exceptions to this are products that are distributed to persons exempt from licensing and Federal facilities that distribute products or are custom users. The US NRC has reserved regulatory jurisdiction over these activities and will perform any necessary evaluations.

Registration certificates generated by the state of Ohio are forwarded to the US NRC in accordance with NUREG-1550, Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations. The US NRC will resolve any disagreements directly with the state of Ohio.

NARM Material Registration Certificates by the State of Ohio

The state of Ohio issues registration certificates for sealed sources or devices containing radioactive material that is categorized as Naturally Occurring or Accelerator Produced Radioactive Material. Following acceptance by the US NRC as an Agreement State, the state of Ohio shall also issue registration certificates for sealed sources and devices containing byproduct material, source material, or special nuclear materials of less than a critical mass. Copies of all generated registration certificates by the state of Ohio are forwarded to the Sealed Source Safety Section of the Division of Industrial and Medical Nuclear Materials Safety, US NRC to be routed to all NRC regions, all other agreement states, and appropriate Federal and international agencies. This practice is delineated in NUREG 1550 - Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations, and replaces the Federal Food and Drug Administrations Center for Device and Radiological Health "Radioactive Material Reference Manual."
The NRC will accept applications for radiation safety evaluations and registrations of sealed sources and devices containing radioactive material that can be produced either from a reactor or from an accelerator (e.g., cadmium-109), or sealed sources or devices that contain NARM commingled with byproduct material, in either the same or separate encapsulations.

Use of International or Foreign Standards

In some cases, an applicant may indicate that a product has been tested in accordance with and meets the requirements of an international or foreign standard. However, in order for the reviewer to find this acceptable, the reviewer must first ensure that the standard referenced meets or exceeds any specific regulatory requirements (e.g., compliance with ANSI N432-1980 for radiography equipment). The reviewer must then review the requirements and acceptance criteria of the standard based on the normal and likely accident conditions associated with use, handling, storage, and transport of the product to determine if the standard is acceptable. The reviewer may compare a foreign or international standard with an applicable US standard in determining the acceptance criteria of the standard. This may include professional judgement on the part of the reviewer.

Computer Software

State of Ohio safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source position, and the functionality of indicator lights. Software applications that deal with process controls are not part of the product evaluation. The reviewer needs to determine that if such systems fail (e.g., a power failure) the source would return to, or remain in, the shielded position. Medical applications involving computer software and patient planning systems are within FDA jurisdiction and FDA is responsible for any necessary review of the software.

Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by the state of Ohio is no longer safe for use and corrective actions can not be agreed upon between the registrant and the department, the department will remove the registration certificate from the state registry, notify the US NRC to remove the registration certificate from the national registry, and may issue orders modifying licenses to all persons licensed to use the sealed source or device. The department will also notify U. S. NRC Office of State Programs (OSP) so that all other agreement states are made aware of the department's actions concerning the sealed source or device.

Incidents

Incidents involving products evaluated and registered by the state of Ohio are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its adequacy and integrity, taking into account the causes of the incident. If it is determined that a generic product fault exists, the registrant needs to be notified and appropriate actions, affecting both products currently in use and new products in design, need to be taken. In addition, the department will re-evaluate similar products to ensure they are not

susceptible to the same type of problems.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product.

Some information concerning incidents involving products evaluated by the department is kept on file by the department for use in performing future evaluations of the products involved and products similar to those involved. In all cases, the Technical Services section is the bureau office responsible for tracking and analyzing the reports.

Proprietary Information

Proprietary information, or information that is not to be disclosed to the public, should not be included in an application unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information that the licensee or person requesting the safety evaluation considers proprietary, the application should be marked, in red, on all copies, the words, "Trade Secret". The reviewer, upon receipt of such a marked document will make a determination with the assistance of the Program Administrator of Nuclear Materials Safety if the information is necessary to perform a safety evaluation for the product. If the information is not necessary, the application part containing the proprietary information will be returned to the applicant. If it is a necessary part of the review, the document that is so indicated will be maintained separately from the application, and marked "Not Subject to Public Disclosure per section 1333.61, 'The Uniform Trade Secrets Act' of the Ohio Revised Code."

If the information is necessary, the reviewer shall ensure that the applicant has submitted a formal request, in accordance with chapter 3748 of the ORC and rules promulgated thereunder. The reviewer needs to evaluate the applicant's request for withholding. If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing, that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with bureau procedures for sensitive unclassified information and the applicant should be notified in writing that the state plans to honor the withholding request. If it is a necessary part of the review, the document that is so indicated will be maintained separately from the application, and marked "Not Subject to Public Disclosure per section 1333.61, 'The Uniform Trade Secrets Act' of the Ohio Revised Code." However, the

notification needs to inform the applicant that the state may have cause to review the determination at a later date, for example, if the scope of a Freedom of Information Act request includes the information. In all review situations, if the department needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

Application and Fees

The person, facility, or licensee that is requesting a safety evaluation of sealed sources and devices, products or sealed sources for radioactive material either for commercial distribution or manufactured in accordance with the unique specification of a single applicant shall submit this request on a form similar to attachment A of this Standard Review Plan, Request for Safety Evaluation, Amendment to a registration certificate for sealed sources and devices. This form is provided by the department and should be requested from the department.

For applicants for sealed source and device evaluations, the appropriate fee shall be based on full cost of the review as specified in paragraph (P) of rule 3701-38-021. The registration certificate or amendment may not be issued until payment of the full fee has been received.

Once a registration certificate is issued, any changes to the registration certificate involving a review by technical staff personnel shall be subject to amendment fees as specified in Appendix A of rule 3701-38-021 to be billed at "full cost" as specified in paragraph (P) of rule 3701-38-021.

DOCUMENT FLOW

Application Receipt and Assignment to a Reviewer

Requests for safety evaluations of sealed sources or devices are submitted directly to the department by the applicant on a form similar to Attachment A of this Standard Review Plan. When the department receives an application, an initial review is performed to determine whether there is sufficient information to start a review. If not, the entire package is returned to the applicant for re-submission of a complete application. If there is sufficient information to start a review, the applicant is sent a letter acknowledging receipt of the application. The Acknowledgment Letter should be similar to that included as Attachment B of this Standard Review Plan.

Applications are logged into the sealed source and device application tracking system and assigned to a technical reviewer. Assignment to a technical reviewer is determined by the proposed use of the sealed source or device, and work-load of available professional staff. An application may be

assigned a higher priority based on the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed.

While an application is in the review process, support staff shall ensure that appropriate fees have been paid by review of documentation from accounts receivable. Although Technical Services section may proceed with review of the sealed source or device, final approval of the product will not be issued until all application fees are paid in full.

After the package, including a copy of the registration certificate as signed by the director, is completed by the Technical Services section, the original application is filed in the Technical Services section document files under the assigned docket number with the registration certificate number/amendment number cross-referenced in the filing database. All additional correspondence generated between the state of Ohio and the applicant/licensee shall have the docket number affixed and shall be filed in the original files.

Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards, rules, regulations, and orders corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by the director. In addition, the reviewer needs to identify any complex policy issues and bring them to the Bureau of Radiation Protection management attention.

In some cases, the adequacy of an element of the product design may not be readily evident. It may be necessary for the reviewer to use professional judgment. Such judgment should be discussed with the applicant and included in a note from the reviewer to the docket file. A copy of the note to the docket file should be provided to the applicant.

Once the evaluation and registration are complete, the registration certificate, including the cover letter to the applicant and technical assistance request response, and all information used in support of the evaluation needs to be forwarded to Technical Services section support staff for filing and distribution.

Distribution of Completed Certificates

The support staff for the Technical Services section handles distribution of all registration certificates

issued by the department. The support staff ensures that the original department registration certificates are maintained in the docket folder and that a master set of copies of the certificates are maintained and easily accessible in the Technical Services section files.

Inclusion in the Sealed Source And Device Registration System

Once issued, the registration certificate is included in the sealed sources and devices registration system. The information included on the first page of the registration certificate is included in the system and the certificate information can be located by searching on any item that is included in the first page of the certificate. A later section of this document describes the information that is included on the first page of a registration certificate.

RULES IN THE OAC THAT ADDRESS SPECIFIC REGISTRATION REQUIREMENTS

Current rules only require that products used under specific license issued in accordance with rules 3701-38-021 and 3701-39-021 of the OAC be registered in accordance with the OAC. However, if evaluation and registration of a product intended to be distributed to general licensees or persons exempt from licensing is deemed necessary by the department, evaluation criteria used will be equivalent to the guidelines expressed in rule 3701-39-021 of the OAC as this rule reflects the criteria of 10CFR30, et seq. and this Standard Review Plan. These guidelines will be used to determine the adequacy of the product. The products listed below are intended for use by persons exempt from licensing requirements or use in accordance with a general license.

The state of Ohio, other Agreement States and NARM Licensing States approved for product review perform evaluations of products that are distributed to persons located in states under NRC jurisdiction and other Agreement States or custom products used by persons located in states under NRC jurisdiction and other Agreement States. Exceptions to this are products that are distributed to persons exempt from licensing and Federal facilities that distribute products or are custom users. The US NRC has reserved regulatory jurisdiction over these activities and will perform any necessary evaluations.

The rules require applicants for licenses to distribute products to provide the safety evaluation information similar to that required by rule 3701-39-021 of the OAC and the department has determined that evaluation and registration of these products is necessary. In addition to the general safety evaluation information listed in the rules, the rules require that the products meet certain specific requirements. These specific requirements are listed in the appropriate sections below and

shall be addressed during the product evaluation.

Some specifically licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration requirements of rule 3701-39-021. The specific requirements for these products are listed in sections below and need to be addressed during the product evaluation.

Self-luminous products - exempt from Licensing Requirements

Under rule 3701-39-021 of the OAC, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to rule 3701-38-021. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR30
Maximum Radiation Levels	3701-39-021 as reference 10CFR31, 32
Maximum Dose Commitments	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR31, 32
Quality Control	US NRC Regulatory Guide 6.9, Appendix C

Gas and Aerosol Detectors - exempt from Licensing Requirements

Under rule 3701-39-021 of the OAC, persons are exempt from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to rule 3701-38-021 of the OAC. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR31, 32
Maximum Radiation Levels	3701-39-021 as reference 10CFR31, 32
Maximum Dose Commitments	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR31, 32
Quality Control	US NRC Regulatory Guide 6.9, Appendix C

Devices used under General Licenses

Under rule 3701-38-021 of the OAC, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to this chapter. The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR31, 32
Operation	3701-39-021 as reference 10CFR31, 32
Maximum Dose Commitments	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR31, 32
Periodic Testing	3701-39-021 as reference 10CFR31, 32
Servicing	3701-39-021 as reference 10CFR31, 32

Luminous Safety Devices Used in Aircraft

Under rule 3701-39, persons may use luminous safety devices containing tritium or promethium-147 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to rule 3701-39-021. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR31, 32
Prototype Testing	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR31, 32
Quality Control	3701-39-021 as reference 10CFR31, 32

Ice Detection Devices Containing Strontium-90

Under rule 3701-39, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to rule 3701-39-021. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR31, 32
Prototype Testing	3701-39-021 as reference 10CFR31, 32
Quality Control	3701-39-021 as reference 10CFR31, 32

Radiography Equipment

Persons specifically licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of rule 3701-39-021 of the OAC. The manufacturer or distributor of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and device registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below needs to be addressed:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR34, 39
Prototype Testing	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR34, 39
Maximum Radiation Levels	3701-39-021 as reference 10CFR34, 39

Well-logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of rule 3701-39-021 of the OAC. The manufacturer or distributor of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and device registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below needs to be addressed:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR34, 39
Prototype Testing	3701-39-021 as reference 10CFR31, 32
Labeling	3701-39-021 as reference 10CFR34, 39
Leak Testing	3701-39-021 as reference 10CFR34, 39

Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use equipment that meets the requirements of rule 3701-39-021 of the OAC. One such requirements is that the licensed material be as insoluble and nondispersible as practicable is used in a wet-source-storage or wet-source-change irradiator. The manufacturer or distributor of sealed sources may demonstrate that the sealed sources meet these requirements as part of the evaluation and device registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below needs to be addressed:

Area to be Addressed	Applicable OAC Rule
Design	3701-39-021 as reference 10CFR36
Prototype Testing	3701-39-021 as reference 10CFR36

Sealed Sources and Devices for Medical Use

In accordance with rule 3701-39-021 of the OAC, only sealed sources and devices, except for teletherapy sources, that are manufactured, labeled, packaged and distributed in accordance with a license issued pursuant to rule 3701-39-021 may be used for medical uses. The manufacturer or distributor of the sealed source may demonstrate that the source meets the requirements as part of the evaluation and device registration of the sealed source or device. Therefore, during an evaluation of medical sealed sources or devices, the items listed below need to be addressed:

Area to be Addressed	Applicable OAC Rule
Labeling	3701-39-021 as reference 10CFR31, 32
Leak Testing	3701-39-021 as reference 10CFR31, 32

REVIEW PROCESS

The person evaluating the adequacy of a product needs to review the following items to determine whether sufficient information has been supplied and whether the design of the product is adequate for its proposed uses and users. A checklist is provided in Appendix A, Review Checklist to assist the reviewer in performing an evaluation.

As already noted in the section above, certain products are required to meet specific criteria outlined in the rules delineated in the OAC. The requirements listed in the section above are in addition to the general device registration requirements in rule 3701-38-021 and 3701-39-021. Products intended for use by general licensees or persons exempt from licensing requirements must meet these specific requirements to be registered. Products intended for use by specific licensees that do not meet the specific criteria identified in the section above may still be registered by the department. However, the device registration for the product must clearly indicate that the product is not approved by state of Ohio licensees unless a specific exemption is granted during the license review process.

Manufacturer and Distributor

The reviewer must ensure that the application includes the complete name and address of the manufacturer and distributor of the product. The same person may be both the manufacturer and distributor. However, if different, the distributor should be the person applying for the evaluation. The distributor will be responsible for meeting the requirements associated with the device registration, whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

Model Number, Sealed Source or Device Type, and Licensing Requirements for Users of the Product

The application must clearly state the model number designation for the product. This model number will be listed on the device registration certificate for the product and may be listed on licenses of persons applying to use the product. The model number is used by the state of Ohio, the U.S. NRC, NARM Licensing States and other agreement states to identify the product.

The sealed source or device type needs to be determined in accordance with the 25 categories listed in the principal use code section of US NRC Regulatory Guides 10.10 and 10.11. This assists the reviewer in determining the applicable rules, regulations, codes, and standards that affect device registration of the product.

The application also needs to identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or whether the user will be exempt from licensing requirements. For products used by specific licensees, the reviewer needs to determine whether, in addition to the rules delineated in rules 3701-38-021 and 3701-39-021 of the OAC, other rules or regulations apply to the possession and use of the product, such as those indicated in the section above. If applicable, the reviewer needs to determine which general license or exemption applies for possession and use of the product. Information needed to make this determination must be provided by the applicant. This is discussed further in a later part of this section which discusses the conditions of use of the product.

Radionuclides Used in the Product

The applicant needs to identify ALL radionuclides that will be used in the product and include the maximum allowable activity for each, including loading tolerance. The application must also include the form of the radioactive material, including contaminants or impurities, if applicable. It is not necessary for applicants to provide information on contaminants or impurities that have little effect on the radiation levels from the source or on how the source will react under extreme environmental conditions.

For evaluation of devices, the reviewer needs to determine if the sealed source is currently registered. If so, the model number designation of the sealed source, as listed on the device registration certificate for the sealed source, needs to be identified by the applicant.

If the sealed source is not currently registered and is to be registered as part of the device, the reviewer must perform a complete evaluation of the sealed source and indicate on the device registration certificate for the device that the sealed source is not registered separately, is registered as part of the device, and is only approved for use in the device.

Leak Test Frequency

The reviewer must evaluate the maximum time interval between leak tests performed on the product. Typically, products are required to be leak tested at intervals not to exceed six months and the test must be capable of detecting the presence of 185 becquerels (0.05 microcuries) of removable contamination.

Products containing only krypton-85 (Kr^{85}), hydrogen-3 (H^3 - tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 megabecquerels (100 microcuries) are exempt from periodic leak testing requirements. However, prior to initial

distribution of the product, a leak test should be performed and documented.

Devices may be approved with leak test intervals greater than 6 months, but not more than 3 years, if sufficient information is submitted to justify such a request. Current policy requires the applicant to supply the information listed in the Administrative Code for evaluation if a longer leak test interval is required.

Conditions of Use

The reviewer needs to evaluate the intended use and users of the product and determine which standards, rules, policies, and regulations are applicable. Applicable rules, standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, Quality Control and Quality Assurance, maximum number of exempt quantity sealed sources allowed, or leak testing requirements.

The previous section of this Standard Review Plan includes the specific regulations that apply to the licensing of certain types of products used under specific and general licenses and products used by persons exempt from licensing. The reviewer needs to determine if any of these regulations apply and if so, evaluate whether the products meet these regulations.

The reviewer must also evaluate the likely environments to which the product will be subjected during normal use and during likely accident conditions. The conditions of normal use and likely accident conditions should include those conditions experienced during use, handling, storage and transportation (extremes experienced during accident conditions during transportation need not be considered). The reviewer needs to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature, (i.e., thermal cycling), and cycling of the on/off mechanism.

In addition, the reviewer must evaluate whether the product's estimated working life, that the applicant has provided, is justified based on the information submitted. Inclusion of the working life of the product is important since device registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or re-evaluation of product integrity may be necessary.

Construction of the Product

The reviewer needs to evaluate the drawings of the product submitted by the applicant. The

drawings should include complete specifications, including dimensions, tolerances, and materials of construction, for all parts critical to safety. Parts critical to safety include those parts that provide primary containment and shielding for the radioactive material and the sealed source. For non-critical parts that contribute to the safety of the product, the applicant should include drawings that show the part's overall configuration. The applicant may include a range of dimensions and materials of construction for non-critical parts.

The reviewer needs to evaluate how the product is constructed and evaluate its integrity. The reviewer should be able to determine the construction of the product from the drawings and written description provide with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

- The assembly methods (e.g., welds, bolts, screws) including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling) and cycling of the on/off mechanism;
- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact;
- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation;
- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).
- The fixed shielding will not move nor easily become dislodged from the device;
- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users;
- All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source;
- The device can be locked in the closed condition (source fully shielded) and can not be locked in the open condition;

- The device contains indicators that clearly identify whether the source shielding is in the open or closed condition. If colors are used to identify the open or closed condition, red shall be used for the open condition and green shall be used for the closed condition;
- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the rules (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers);
- If pneumatic or hydraulic systems are used, there are appropriate filtration and relief valves;
- The operation is designed to be fail-safe, that is, on loss of power or a failure in the system the shutter would return to, or remain in the fully shielded position, or the sealed source would be withdrawn to the fully shielded position;
- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing;
- If applicable, the device is hermetically sealed from foreign materials or moisture;
- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, and expansion, if necessary, of the material.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure the radioactive material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation greater than 20% constitutes a compromise of the shielding integrity.

Appendix B, Standard Reference Materials includes a listing of references that may be useful in determining the adequacy and integrity of product design.

Labeling

The reviewer needs to verify that the application includes sufficient information concerning the labeling of the product and needs to ensure that the labeling of the product includes the information listed below:

For devices: Model Number, Serial Number, Radioisotope, Maximum Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL[1]". If applicable, the label must include a statement that it contains depleted

[1] The word DANGER may be used in lieu of the word CAUTION

uranium as shielding and include the total weight of the uranium. The label may also need to contain limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions.

For Sealed Sources: Should contain the same information as included on a device. However, because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification of which information will be included. Final approval of the information is left to the discretion of the reviewer. Below is a listing, in no particular order, of information, with a description of why the information may be important:

- Trefoil Symbol and/or the Words "CAUTION - RADIOACTIVE MATERIAL" - This information is important if a source is found by a non-licensee since it alerts the person finding the source that it contains radioactive material. The trefoil symbol is fairly well recognized. Therefore, for small sources where all the information may not fit, it (the trefoil) is probably more important that the words, "CAUTION - RADIOACTIVE MATERIAL".
- Serial Number - The serial number can usually be traced back to determine the original activity, radioisotope, date of assay, and the last know user of the source. The current activity can be calculated, given this information. However, to trace back to this information, either the vendor or the last person possessing the source must be known and be in business. The serial number would be important for sources that would be stored in large quantities. This would assist the licensee in tracking each source.
- Distributor's Name or Logo - This may be important in trying to locate additional information concerning the source. However, if the serial number is not known or the distributor is no longer in business, this information may not be of much value.
- Model Number - the department and the US NRC track source model numbers through the sealed sources and devices device registration system. Therefore, the department or the NRC could identify the distributor, possible radioisotopes, and maximum allowable activities, given the model number.
- Radioisotope, Maximum Activity, Date of Assay - This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other information included on the source, as indicated above, or by analysis and from surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will

remain legible. The preferred method of labeling sealed sources is engraving or laser etching the information. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable depending on the likely environments in which the product will be used.

Placement of labels must be such that they are easily visible to the users of the product and will remain attached to the part of the device that contains the radioactive material, that is, they are not attached to the detector housing or to a barrier or a guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable statute, rule or regulation. For example, devices distributed to specific licensees should not include statements concerning the use of the device under a general license.

There are specific labeling requirements for devices designed for use by general licensees and person exempt from licensing. A listing of the regulations that include these requirements are included in the previous section.

Prototype Testing

The reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions. The conditions of normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (only normal conditions during transportation need to be considered). The applicant may demonstrate the device's integrity by:

- testing a prototype of the product;
- providing operational history of the product or a similarly designed product (usually information concerning when the product was used in another country or used in the United States as a custom product); or
- providing an engineering analysis.

If the operational history is provided in lieu of testing, it should include the years of use of the product that adequately reflects the expected actual use. The engineering analysis should be based on comparison with a product that has passed the appropriate prototype tests or has demonstrated its integrity through adequate operational history.

Typically, for sealed sources the department will accept testing of prototype sealed sources to demonstrate integrity. This is because the sealed source is the primary containment of the

radioactive material. The sealed sources should normally be tested in accordance with ANSI N542, Sealed Radioactive Sources, Classification or ISO 2919, Sealed Radioactive Sources, Classification. When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ANSI or ISO standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a "Bend Test" and applicants may need to verify a source design that will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin walled sources, the prototype source should include all engraved or etched information prior to testing.

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N542 or ISO 2919 classification for its intended use and be authorized for the activity to be loaded. The device registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. A listing of applicable standards is included in Appendix c of this Standard Review Plan. If there is no applicable standard for a product, the reviewer, using professional judgment, needs to evaluate if the testing performed by the applicant sufficiently simulates conditions that may be expected during use, handling, storage, and transport of the product. The reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the reviewer needs to evaluate whether the applicant gave further consideration to other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate they will maintain their containment integrity and that the necessary safety feature remain operable after being subjected to any conditions they are likely to experience.

The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure the radioactive material is not dispersed, the source capsule remains with the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

If an applicant demonstrates a device's integrity by providing the operational history of the device, the operational history of a similar device, or by performing an engineering analysis, the reviewer needs to evaluate whether the information adequately addresses all concerns about the device's integrity when used in a way the applicant has defined as the normal conditions of use.

From time to time, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratory standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product which may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

Radiation Profiles

The reviewer needs to verify that the applicant has provided the maximum radiation levels around the product when it contains the maximum quantity of each nuclide, or combination of nuclides. The applicant should include the maximum radiation levels on the surface at of the product at 5 (2.0 inches), 30 (11.8 inches), and 100 (39.4 inches) centimeters from the product and levels in the radiation beam, if the beam is accessible. If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported. Measured radiation levels are preferable, but calculated levels may be acceptable. If the measured radiation levels are submitted, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used – including type, window thickness (density), and sensitivity – are acceptable for the nuclide and quantity included in the product. If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.

If the applicant is taking credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at and from each barrier to guard need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters

should be consistent with the inverse-square law and levels for non-gamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50 μSv/hr (5 mR/hr) at 30.5 cm (12 inches) is an industry goal that has been used for many years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, it is the responsibility of the user to ensure the product is used in accordance with rule 3701-39-021 of the OAC (i.e., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limit or limits for members of the public). However, as already discussed, certain regulations limit the maximum allowable radiation levels and/or the maximum dose commitments for certain classes of products used by general licensees or persons exempt from licensing.

If a device is used on a patient, the dose to the patient for a typical application must be provided. This will serve as a reference point in approving and licensing the product.

Quality Control and Quality Assurance

The reviewer needs to ensure the applicant will implement a Quality Control program that will ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the device registration certificate for the product. At a minimum, the Quality Control program needs to ensure that:

- the materials of construction and the final assembly meet the design specifications;
- the final product is leak tested;
- a final radiation profile is performed; and
- a test that verifies the product operates as intended, including all safety functions, is performed.

In addition, a visual and mechanical inspection of components that are considered critical to safety or are known or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Some of these inspections may be performed on a sample basis.

Current practice allows acceptance of the submission of a Quality Assurance program in lieu of a Quality Control program. The Quality Assurance program provide control over all activities, applicable to the design, fabrication, inspection, testing, maintenance, repair, modification and distribution of the sealed sources or devices that contain radioactive material. This puts more emphasis on the overall management structure and on the program that covers construction of the

device from the time of initial design through refurbishment. The Quality Assurance program is evaluated against US NRC Regulatory Guide 6.9 (RG 6.9). It should be noted that RG 6.9 discusses acceptance of programs meeting the requirements of other established Quality Assurance standards.

If the product is registered for use by a custom user, submission of a complete Quality Control program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Since the purpose of a Quality Control program is to ensure that all devices are manufactured to the same specifications, development and submission of a complete program may not be feasible. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

Installation, Servicing and Instructions to Users

The reviewer needs to evaluate whether any special procedures need to be followed when the product is installed at the user's facility. These include the integrity of the mounting, installation of interlocks, guards or barriers, and whether the installation needs to be performed by a specific licensee. General licensees may be permitted to perform installation depending on the design of the product.

In addition, the reviewer needs to evaluate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary training for users, changing of sources, and final disposal of the radioactive material. The reviewer needs to determine whether the registrant, or the manufacturer or distributor, will provide the necessary services or can identify an entity that will provide such services. If the registrant cannot identify an entity that will provide the necessary services, the device registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant can not identify an entity that will provide services that cannot be performed by the general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. The department is typically notified when a vendor decides to no longer provide services.

The reviewer needs to verify that any procedures for servicing the product do not interfere with, or compromise, the integrity of the product.

The reviewer needs to verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions for operation,

maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor should also provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of rules and regulations governing use and transportation of the product and a listing of regulatory authorities who license possession and use of the product.

To assist the reviewer in determining activities that may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the product does not misinterpret, misrepresent, or lead the user into violating any applicable statues, rules, regulations or orders of the state of Ohio or the US NRC.

Evaluating and Final Determination

Once the reviewer has evaluated all necessary information and has determined that the product is acceptable for licensing purposes, the information must be passed to a second reviewer. The second reviewer must arrive at the same finding as the initial reviewer. Any discrepancies between reviewers must be resolved before the device registration certificate can be issued.

Typically, the initial reviewer will generate a draft device registration certificate for evaluation by the second reviewer. The second reviewer will evaluate both the application and the draft device registration certificate to ensure accuracy and completeness.

DEFICIENCIES IN THE APPLICATION

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, notifying the applicant of the need for information via telephone or electronic mail, or obtaining the information directly from the licensee during a telephone conversation or via electronic mail. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application.

Because of the need to complete the application reviews in a timely manner, the following procedures need to be followed when addressing deficiencies in applications:

Sending Deficiency Letters to Applicants

- Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter should request that the response be provided in triplicate. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days should not exceed 60 days but depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product).
- If a written response[2] to the deficiency letter is received within 5 working days after the date requested in the deficiency letter, proceed with the review of the response;
- If a written response to the deficiency letter is not received within 5 working days after the date requested in the deficiency letter, the reviewer should send a second letter to the applicant. The second letter should notify the applicant that unless a response to the first letter is received within 21 working days from the date of the second letter, the reviewer will consider the application as "abandoned"[3] for failure to provide the requested information "without prejudice"[4] to the resubmission of a complete application. Prompt action (5 working days) should be taken to "void"[5] the application after the application has been considered as "abandoned".
- If a response to the deficiency letter is received after the application has been voided and the response is received not more than 1 year from the date of the letter and payment for review time is current, the application should be assigned a new docket number and review should proceed. No additional fee may be necessary if it is a continuation of the evaluation. If in the opinion of the initial reviewer an amendment has occurred in the sealed source or device design, construction, or other feature that renders the original application null and void, then an additional review cost may be assessed.

Use of the Telephone or Electronic Mail to Obtain Additional Information

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[2] A written response may be either a letter, by electronic mail (e-mail) or a facsimile (fax) from the applicant.

[3] "Abandoned" is not meant to have legal connotations. It means simply that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment.

[4] "Without prejudice" is not meant to be understood in a legal sense. It means here that the applicant can resurrect its application within some reasonable time without having to incur the cost of another review of the same material that has been completed and paid for at the time the review was abandoned.

[5] "Void' should not be though of in its legal sense. It means here that the application is, in practical effect, nullified.

There is no prohibition on using the telephone or electronic mail (e-mail) for obtaining clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application.

Use of the telephone or e-mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include model number for a sealed source, need for a licensee commitment to perform a procedures, or clarification of a material type or dimension. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application.

If the deficiency is a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, either via telephone or e-mail, must be documented and included as part of the application. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application.

In all cases, the telephone conversation or e-mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call or e-mail transmission. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application. If the applicant does not respond within 10 working days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly state the deficiencies and be handled as a typical deficiency letter with the exception that it includes a statement that the information needs to be received within a specified time frame or the application with be voided.

Response Time Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone or by e-mail transmission. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions and the reviewer's responses, must be documented in writing. In any case where electronic or telephone methods are used, a hard-copy, i.e., paper copy, of the request for information shall be created and filed with the application.

WRITING THE CERTIFICATE

To thoroughly use the device registration system, the device registration certificate issued for each product needs to be in a standard format. This allows the license reviewers and inspectors to quickly retrieve information necessary to perform a license review, perform a site inspection, or respond to incidents involving lost, damaged, and/or abandoned sealed sources or devices.

The device registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix D, Standard device registration Certificate Formats, of this Standard Review Plan includes standard formats for device registration certificates for a device and for a sealed source. Further clarification of the information that needs to be included in an device registration certificate is listed below.

Header

The header needs to include the title of the document, the device registration number, date of issue, page numbering, and the sealed source or device type. If the certificate is an amendment or a correction, this needs to be indicated in the title; the page number of each affected page needs to be listed. The device registration number is assigned by the reviewer, in accordance with the number procedures in Appendix E, Assigning device registration Certificate Numbers of this Standard Review Plan. The issue date is the date the certificate has received both reviewer and concurrence signatures.

First Page Information

The first page of each certificate includes the name and complete address of the manufacturer and distributor, the model number of the sealed source or device, the manufacturer and model number for the sealed source incorporated in the device, isotopes, maximum allowable activity levels, leak test frequency, principal uses (including code and description) and an indication of whether the registered product is designed for custom use. If registered for custom use, the name and address of the custom user is included. This information is entered into the department maintained registry of sealed sources and devices.

Starting on the second page of the certificate, the following subsections are included in the order listed below:

Description

This section provides a narrative description of the construction of the product, safety features of the product, and ON/OFF and safety indicators. The description should include the materials of

construction and fabrication techniques for critical safety components of the product. These typically include source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device security features, such as tamper resistant fasteners, locks, etc. Overall dimensions of the sealed source and device are also included.

Certificates for sealed sources should include the chemical and physical forms of the source material. Certificates for devices should describe how the sealed source is secured within the device and how the product is protected from its intended environment (e.g., hermetically sealed, fire-proof, corrosion-resistant, etc.).

Labeling

This section describes how the labeling requirements are fulfilled. It lists the information that can be found on the label, construction of the label, and how and where the labeling is attached to the product. Any exemptions from labeling requirements or omissions of information typically included on the labels should be noted.

Diagrams

This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate. These are typically included as attachments to the certificate and should include overall dimensions of the product, the location of the sealed source within the device, and the safety related features of the product. A person using the certificate, such as an inspector or license reviewer, should be able to identify a device given the diagrams and the description from the certificate.

Conditions of Normal Use

This section lists the environmental conditions the product is designed to withstand. The normal intended uses of the product and any limitations that define these uses are included in this section. The working life is also included.

Prototype Testing

This section describes tests performed on prototypes of the product to demonstrate it will maintain its integrity. If the product was tested in accordance with an applicable industry or consensus standard, the corresponding classification, as defined in the standard, should be stated in this section. If the product was tested in accordance with an application rule, regulation or order, this section specifies whether the product satisfactorily met the requirements of the rule, regulation or order.

If, in lieu of prototype testing a product, an applicant submitted operational history of the product or a similar product, or provided an engineering analysis that demonstrates that the product is adequately designed, this section should provide the details of the operational history or analysis and the basis for determining the design to be adequate.

External Radiation Levels

This section states the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or combination of nuclides. If the manufacturer is unable to provide measured external radiation levels for the product, a conservatively calculated maximum radiation profile is listed. If applicable, the radiation profiles are listed for shutter-on and shutter-off conditions. The stated levels are the maximum radiation levels expected from the product and take into consideration factors affecting the levels, such as whether product is present in the measuring area or whether certain areas around the device are restricted from access. Any significant contaminants that would change the expected radiation levels are stated. Ideally, the radiation levels listed in this section would include the levels on contact with the product at 5, 30 and 100 cm. from the product, and in the beam

Should there be a device containing a number of isotopes and designed with a range of dimensions, a distributor may commit to ensuring that the radiation levels do not exceed a specified level. If this is the situation, the certificate needs to include the maximum allowable radiation level and include limitations concerning the installation of the device.

Quality Assurance and Quality Control

This section should include a summary of the Quality Control procedures that will be followed to ensure that product meets all applicable specifications. If the Quality Control procedures meet a national or industry standard or regulation, it is specified in this section. In lieu of submitting Quality Control procedures, an applicant may commit to following a Quality Assurance program. Again, if the Quality Assurance program meets a national or industry standard or regulation, it is specified in this section. If the applicant commits to following a complete Quality Control or Quality Assurance program, a short summary of the program may be included and this section should also reference that details of the complete program are on file with the department. The section would also contain a statement reflecting that the Quality Control or Quality Assurance program has been assessed and deemed acceptable to the department.

Limitations and Other Considerations of Use

This section establishes the limiting conditions imposed on the sealed source or device. These include leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools and specific licensing conditions that may be performed by the license reviewer. This section needs to clearly indicate the service that may be performed by general-licensed users of the products, state that sources or devices should not subject to environments that exceed their ANSI or ISO classifications, and state that if subjected to such environments, the licensee must discontinue use of the source or device until a demonstration that no affects to the source or device integrity has occurred as a result of operation outside the specified range. It also includes a limitation that states that the device registration certificate and the information contained within the references shall not be changed without the written authorization of the state of Ohio.

Limitations on sealed sources and devices can be divided into 2 categories, the first being limitations placed on the manufacturer or distributor of the sealed source or device and the second being limitations placed on the user of the sealed source or device. Limitations of the first category are derived from rules contained in rule 3701-39-021 of the OAC. In addition to rules contained in the OAC, the second category of limitations is also derived from conditions imposed by the manufacturer, by particular conditions of use that would reduce the radiation safety of the device, and by circumstances unique to the sealed source or device, which require that the sealed source or device receive a special limitation.

In addition, this section of the certificate may contain reviewer notes. The purpose of such notes is to identify to license reviewers areas of use of the product that cannot be controlled as part of the device registration. This alerts the license reviewer to verify that the licensee implements certain administrative procedures before initial use, as part of routine use, or as part of an emergency response to an incident. For example, indicating in a reviewer note that a vendor no longer offers servicing for the product alerts the license reviewer to obtain more than a statement that services will be provided by the vendor.

Safety Analysis Summary

This section summarizes the conclusion of the evaluation performed by the reviewer and states that the product is acceptable for certain licensing conditions. Also, typically listed in this section are any additional features that the device, surroundings, environment, or accessories may contribute to the integrity or safety of the product. These may include physical constraints such as barriers, fences, or guards and actual use time in terms of radiation exposure resulting from working around the product.

References

This section incorporates by reference the documents that were submitted in support of the application. These references include applications, letters, faxes, e-mails, and enclosures to such documents. The applicant is required to adhere to the information and commitments included in these references.

Issuing Agency

This section identifies the Ohio Department of Health, Bureau of Radiation Protection, the US NRC, a NARM Licensing States approved for product review, or another agreement state agency that issued the certificate and includes the date issued and the typed names and signatures of the two persons who reviewed the certificate and all applicable documentation. All certificates include two signatures as part of the Quality Control measures. All device registration certificates shall also be signed as approved by the director.

Measurements and Use of Dual Units

The department has adopted the International Units for all radiation and radioactivity m measurements and requires that documents specified to a licensee, such as a device registration certificate, include dimensions in the units employed by the licensee. Similarly, this policy can be applied to registrants. In addition to including the units employed by the registrant it is recommended that device registration certificates include dual-units as specified below:

- All measurements should be stated in the units employed by the registrant, followed by the appropriate English or international System (SI) of Units conversion in parenthesis;
- All measurements not provided by the applicant should be specified in English units, followed by the converted SI value;
- The method of stating measurements for a specified property should be consistent throughout the document. If the measurement of the property is first stated in SI, with the English conversion in parenthesis, then all other measurements should be stated in SI, with the English conversion in parenthesis;
- If a value is being restated (i.e., the measurement was included in a table, was already stated in the same section of the document, or was included on the first page of the document (such as the maximum activity), the restated measurement need not have the conversion following it since the conversion has already been included in the document.

MODIFICATION TO EXISTING device registration CERTIFICATES

If a registrant plans to make a change, to the registered product that affects the commitments made in the information provided in support of the application, the registrant needs to file for an amendment or correction to the device registration certificate. The request needs to address the changes to the product, and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have a detrimental effect on how the device would react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

Amendments

If the registrant requests an amendment to the certificate, that is, it requires a safety evaluation to be performed, the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

AMENDED IN ITS ENTIRETY

The certificate should be assigned a new issue date and the certificate should be reissued in its entirety. When possible, the reviewer should use bold face type to highlight the changes that have been made to the certificate.

Corrections

If the change only involves corrections to the certificate, that is, it does not require a safety evaluation to be performed, then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold face type to make the corrections and indicate the areas that are corrected by a "rev. bar" (a straight line running down the right hand margin of the area affected). Each affected page should include, in the header, under the title, the words: CORRECTED PAGES, the number of each page affected and the date of correction. An example of this format is shown below:

CORRECTED PAGES 1, 2, & 4 - AUGUST 16, 1997

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registrant in the reference section of the certificate.

If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registrant requests an amendment, requiring a safety evaluation, to the certificate.

Transfers to Inactive Status

If a registrant requests that a device registration certificate be transferred to inactive status, the reviewer needs to ensure that the registrant provides the total number of the products sold, the number of products still in use, [6], the services the registrant will still provide to users of the product, a commitment that the registrant will no longer distribute the product, and verification that no changes were made to the product since its initial device registration or last amendment. In addition, the reviewer needs to verify that the background file for the product evaluation is complete and accurate. The reviewer needs to write an updated device registration certificate, including the new device registration number and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. This device registration will replace the old device registration and will be used as the basis for continuing to license the product.

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[6] The actual number of products sold and still in use may not be known by the registrant. However, the registrant should still provide a "best estimate".

APPENDIX A

REVIEW CHECKLIST

Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations

Appendix A - Review Checklist

Manufacturer/Distributor: device registration No:

Model No: References:

DESCRIPTION	SAT/DEF	COMMENTS
FIRST PAGE		
Registrant's Name and Address		
Manufacturer & Distributor Name and Address		
Custom User's Name and Address		
Model Number		
Type (from RG 10.10 or 10.11)		
User's Authority to Possess (general, specific, both, exempt)		
Radionuclides, Activity (Max w/% error), form, manufacturer, model, registered (note on device registration certificate if source is registered as part of the device).		
Leak Test Frequency No periodic leak test for: Kr^{85}, H^3, radioactive gas, isotopes with $T_{1/2} \leq 30$ days, beta/gamma emitting material of <3.7 MBq (100μCi) or Alpha emitting material <370 kBq (10 μCi) Greater than 6 month frequency: Use criteria in Rule 3701-39-021		
DESCRIPTION/CONSTRUCTION		

Appendix A - Review Checklist

If registrant is requesting to register more than one source/device on a certificate, are designs similar enough to allow?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screws, welds, etc.)		
Source mounting (size and integrity) and security		

Appendix A - Review Checklist

DESCRIPTION	SAT/DEF	COMMENTS
Is source ANSI classification sufficient: Radiography - Unprotected ..... 43515 Radiography - In device ..... 43313 Medical - Radiography ..... 32312 Medical - γ Teletherapy ..... 53524 γ Gauges - Unprotected ..... 43333 γ Gauges - In Device ..... 43232 β Gauges, Low Energy γ Gauges, or X-Ray Fluorescence ..... 33222 Oil Well Logging ..... 56522 Portable Moisture/Density ..... 43333 Neutron Applications ..... 43323 γ Irradiators (II, III, IV) ..... 43424 γ Irradiators (I) ..... 43323 Static Eliminators ..... 22222 Smoke Detectors ..... 32222 (From ANSI N542-1977)		
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances		
On-Off indicators (description, qty., location)		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (aluminum & steel, depleted uranium & steel, etc.) See "Corrosion" information		
Shielding efficiency and integrity		
For medical devices - was a FDA 510k provided? (Provide written notification to FDA)		

Appendix A - Review Checklist

Well logging sources must be nondispersible and non-soluble.		
See ANSI and "Other Standards" list for references for particular source/device designs (e.g., radiography, Brachytherapy, etc.)		

Appendix A - Review Checklist

DESCRIPTION	SAT/DEF	COMMENTS
LABELING		
Copy of label		
Materials, dimensions, colors (note on device registration certificate if labeling is exempt from the color requirements of rule 3701-39-021 of the OAC)		
Permanent attachments and location(s) - visible to users?		
Contents: Model #, Serial #, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL", (Depleted Uranium information must be included)		
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)		
Actions to be taken when product reaches end-of-life		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage and transport)		
How the device will be used		
Meet does limits of rule 3701-39-021 for general and exempt distribution		
PROTOTYPE TESTING/HISTORICAL USE		
Test methods and conditions (for source and device)		
Test results		

Appendix A - Review Checklist

Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis		

Appendix A - Review Checklist

DESCRIPTION	SAT/DEF	COMMENTS
RADIATION PROFILES		
Survey instrument used (type, window, sensitivity, etc)		
Conditions		
Distance from source/surface (per ANSI 538-1979)		
Shutter On and Off/source shielded		
Scatter (product in beam)		
Guards and Shields in place		
Verify radiation surveys for γ radiation meets inv^2 law		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law		
QUALITY ASSURANCE		
Materials, subassemblies, services		
Assembly methods (screws, welding, etc)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
Quality Assurance Manual		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility		
Interlocks, locks, barriers		

Appendix A - Review Checklist

Beam access: size of air gap/opening to beam/verify size with new General License rule)		
Mounting Integrity		

Appendix A - Review Checklist

DESCRIPTION	SAT/DEF	COMMENTS
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION		
Leak test results and radiation survey		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For General License distribution Verify information forwarded to NRC for update of NRC source listing		
SERVICING		
Manufacturer provides or user performs: Installation Calibration Relocation Leak Test Maintenance Radiation survey Repair Training Source change/installation		

APPENDIX B

STANDARD REFERENCE MATERIALS

Appendix B - Standard References Materials

Avallone, E.A. and Baumeister, T, Marks Standard Handbook for Mechanical Engineering, Ninth edition, 1987

Balanger, R, et al. NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Americium-241", November 1979

Buckley, D.W., et al. NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material" October 1980

Linauskas, S. H., "Doses from Portable Gauges", (Research Report), August 1988

Schweitzer, P. A., Handbook of Corrosion Resistant Piping, 1969

Shirley, J. E., and Mitchell, L. D., Mechanical Engineering Design, Fourth edition, 1983

Shier, L. L., Corrosion, Volume 1, Metal/Environment Reactions, 1976

Williams, N, et al., "Strength of Materials", 1981

APPENDIX C

INDUSTRY AND CONSENSUS STANDARDS

Appendix C - Industry and Consensus Standards

Brachytherapy

ANSI N44.2 - 1973	For Leak-testing Radioactive Brachytherapy Sources
ANSI N44.1 - 1973	Integrity and Test Specifications for selected Brachytherapy Sources

Gauges

ISO 7205-1986(E)	Radioactive Gauges - Gauges designed for permanent installation
ANSI N538-1979	Classification of Industrial Ionizing Radiation Gauging Devices

Irradiators

ANSI N433.1 - 1977	Safe Design and Use of Self-contained Dry Source Storage Gamma Irradiators (Category I)
ANSI N43.10 - 1984	Safe Design and Use of Panoramic, Wet-source Storage Gamma Irradiators (Category IV)

Light Sources

ANSI N43.4 - 1975	Classification of Radioactive Self-luminous Light Sources

Power Generators

IAEA No. 33	Guide to the safe Design, Construction, and Use of Radioisotopic Power Generators for certain Land and Sea Applications

Radiography

ANSI N43.9 - 1991	For gamma radiography - Specifications for Design and Testing of Apparatus
ANSI N432-1980	Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography
ISO 3999 - 1977 (E)	Apparatus for Gamma Radiography - Specification

Smoke Detectors

Nuclear Energy Agency	Recommendation for Ionization Chamber Smoke Detectors

Appendix C - Industry and Consensus Standards

in Implementations of Radiation Protection Standards - 1977

Sources (General)

ISO 2919-1980 (E)	Sealed Radiation Sources, Classification
ANSI N542-1977	Sealed Radiation Sources, Classification - (Revision of ANSI N5.10-1968)
ANSI N5.10 - 1968	Sealed Radiation Sources, Classification

Teletherapy

ANSI N449.1 - 1978	Procedures for Periodic Inspection of Cobalt 60 and Cesium-137 Teletherapy Equipment

X-ray Fluorescence

ANSI N43.2 - 1977	Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment
ANSI N537 - 1976	Radiological Safety Standard for the Design of Radiographic and Fluoroscopic Industrial X-ray Equipment

Miscellaneous

ANSI N43.3 - 1993	Installations using non-medical X-ray and Sealed Gamma Ray sources, energies up to 10 MeV
NCRP Report #49	Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of energies up to 10 MeV

APPENDIX D

STANDARD device registration CERTIFICATE FORMATS

Appendix D - Standard device registration Certificate Format

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO: DATE: Page 1 of 5

SOURCE TYPE: short description of the source type
MODEL: ABC

MANUFACTURER / DISTRIBUTOR: Name
Street
City, State, zip
(If the manufacturer and distributor are the same, keep subheading as shown. If different, delete the word MANUFACTURER from the subheading)

MANUFACTURER: : Name
Street
City, State, zip
(This subheading and information is not necessary if manufacturer and distributor are same)

ISOTOPE: MAXIMUM ACTIVITY:

List isotopes Xx millicuries (xx GBQ) – Units should be such that the amount is in the 1 to 999 range

LEAK TEST FREQUENCY: Not Required
6 Months

PRINCIPAL USE: (A) Industrial Radiography – from listing in RG 10.11

CUSTOM SOURCE: YES NO
CUSTOM USER: Name
Street
City, State, Zip
(Delete in entirety if not applicable)

Appendix D - Standard device registration Certificate Format

SOURCE TYPE: short description of the source type

DESCRIPTION:

Provide the complete description of the source

LABELING:

The source is engraved with the trefoil, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION - RADIOACTIVE MATERIAL". The text is X" (X mm) high and is on the end/side of the source capsule

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring...
The source may be used in harsh environments but shall not be subjected to environments that exceed its ANSI N542 - 1977 classification, 77C 00000

PROTOTYPE TESTING:

A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N542-1977/ISO 2919 and achieved a classification of 77C 00000

Appendix D - Standard device registration Certificate Format

NO: DATE: Page 3 of 5

SOURCE TYPE: short description of the source type

EXTERNAL RADIATION LEVELS:

The following dose rates were reported by the manufacturer for the Model ABC source containing 1.0 curie (37 GBq) of Am^{241}.

TABLE 1

		Maximum Radiation Level			
Distance		From Window		From Sidewall/Back	
(Inches)	(Cm)	(mR/hr)	(μSv/hr)	(mR/hr)	(μSv/hr)
1.97	5				
11.81	30				
39.37	100				

QUALITY ASSURANCE AND QUALITY CONTROL:

XXXXX maintains a Quality Assurance and Quality Control program which has been deemed acceptable for licensing purposes by the state of Ohio, department of health. A copy of the program is on file with the department.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by the state of Ohio, the US NRC or another agreement state.
- The device shall only be used by the custom user listed in this certificate, xxxxxx.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 KBq (0.005 microcuries) of removable contamination.
- This device registration sheet and the information contained within the references shall not be changed without the written consent of the department of health, state of Ohio.

Appendix D - Standard device registration Certificate Format

SOURCE TYPE: short description of the source type
SAFETY ANALYSIS SUMMARY

Based on review of the Model ABC sealed source, its ANSI classification, and the information and test data cited below, we (continue to) conclude that the source is acceptable for licensing purposes.

Furthermore, we (continue to) conclude that the source would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

- 'a application dated January 1, 0000, with enclosures thereto
- 's letters dated August 16, 1996 and December 25, 1996, with enclosures thereto
- 's facsimiles dated July 4, 0000 and May 23, 0000.

Appendix D - Standard device registration Certificate Format

NO: DATE:

SOURCE TYPE: short description of the source type

ISSUING AGENCY

State of Ohio
Department of Health

Date: Reviewer:

Name of First Reviewer

Date: Reviewer:

Name of Second Reviewer

William Ryan, Director
Ohio Department of Health

Date

Appendix D - Standard device registration Certificate Format

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: DATE: Page 1 of 8

SOURCE TYPE: short description of the source type

MODEL: ABD

MANUFACTURER / DISTRIBUTOR: Name
Street
City, State, zip
(If the manufacturer and distributor are the same, keep subheading as shown. If different, delete the word MANUFACTURER from the subheading)

MANUFACTURER: : Name
Street
City, State, zip
(This subheading and information is not necessary if manufacturer and distributor are same)

SEALED SOURCE MODEL DESIGNATION: Acme Model 123

ISOTOPE:	MAXIMUM ACTIVITY:
List isotopes	Xx millicuries (xx GBq) – Units should be such that the amount is in the 1 to 999 range

LEAK TEST FREQUENCY: Not Required
6 Months

PRINCIPAL USE: (A) Industrial Radiography – from listing in RG 10.10

Appendix D - Standard device registration Certificate Format

SOURCE TYPE: short description of the source type

CUSTOM SOURCE: YES x NO
CUSTOM USER: Name
Street
City, State, Zip
(Delete in entirety if not applicable)

DESCRIPTION:

Provide the complete description of the device and if necessary, the source(s) used in the device.

LABELING:

The device is labeled in accordance with rule 3701-39-021 of the Ohio Administrative Code. The labels contain the trefoil, isotope, activity, model number, serial number, name of the distributor, and the words "CAUTION - RADIOACTIVE MATERIAL".

When distributed to persons generally licensed, the device is additionally labeled with information delineated in Rule 3701-39-021.

The labels are made of stainless steel or aluminum, rectangular in shape, (X" x X" (X cm x X cm), and are permanently attached by rivets or screws to the device. A copy of the label is shown in attachment X.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring...

SOURCE TYPE: short description of the source type

Appendix D - Standard device registration Certificate Format

CONDITIONS OF NORMAL USE (continued):

The devices are expected to be subjected to environments typically found in laboratories occupied by humans. Since the device is portable, it may experience vibration and shock typical during normal transportation.

The device will only be used by xxxxx at their xxxxxxx, City, State facility.

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurements of properties of materials in a tank or vessel. The devices are designed for the following environments:

Temperature	-40° C to 60° C (-40° F to 140° F)
Pressure	Atmospheric
Vibration	Ranges from zero to mild
Corrosion	Ranges from zero to highly corrosive vapors
Fire	NEA Division 2 hazardous area possible
Explosion	NEA Division 2 hazardous area possible

PROTOTYPE TESTING:

A prototype of the Model ABD was constructed and subjected to the tests listed below. No malfunction occurred nor was there any loss of shielding or containment integrity.

Temperature	110° C (230° F) for a period of seven hours
Vibration	Approximately 30 cps at an amplitude of 0.03" (0.76 mm) for 90 minutes
OFF/ON Mechanism	Operated by a pneumatic cylinder for a total of 9320 OFF/ON cycles
Impact	Dropped three times from a height of 4 feet (122 cm)

NO: DATE: Page 4 of 8

SOURCE TYPE: short description of the source type

PROTOTYPE TESTING (continued):

Appendix D - Standard device registration Certificate Format

Penetration ..... Dropped a 13 pound (5.9 kg), 1¼" (3.2 cm) Diameter steel rod from a height of 40" (102 cm)

A prototype of the device has been tested in accordance with ANSI/ISO standard ... and has achieved a classification of ... . The device passed the tests in accordance with the acceptance criteria included in the standard.

The sealed source(s) used in the device has been tested by their manufacturers and has achieved the following ANSI {N542-1977 or ANSI N5.10-1968} classifications

Manufacturer	Model	ANSI Classification
Amersham Corporation	AMCL	77C64344
DuPont Merck	NER-465	C33232
Isotope Products Laboratories	PH-55	C33232

The sealed source contained in the device has achieved an ANSIN542-1977 classification of 77C00000.

The sealed source contained in the device has achieved an ANSI N5.10-1968 classification of C00000.

EXTERNAL RADIATION LEVELS

XXXXXXXX reports that the radiation levels from the device are not discernable from background.

XXXXXXX reports that the radiation levels from the device do not exceed 5 mR/hr (50 μSv/hr) at 12" (30.5 cm) from the surface of the device.

SOURCE TYPE: short description of the source type

EXTERNAL RADIATION LEVELS (continued):

The following dose rates were reported by the manufacturer for the Model ABD transmission gauge containing a 1.0 curie (37 GBq) of the AM-241 sealed source:

TABLE 1

Distance		Maximum Radiation Level			
		From Window		From Sidewall/Back	
(Inches)	(Cm)	(mR/hr)	(μSv/hr)	(mR/hr)	(μSv/hr)
1.97	5				
11.81	30				
39.37	100				

The dose rates were taken with no material present in the measuring area. XXXXX indicates this represents the highest radiation levels of any possible configuration.

QUALITY ASSURANCE AND QUALITY CONTROL:

XXXXX maintains a Quality Assurance and Quality Control program which has been deemed acceptable for licensing purposes by the state of Ohio, department of health. A copy of the program is on file with the department.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device shall be distributed to persons specifically licensed by the state of Ohio, the US NRC, any state with NARM regulations, or another agreement state.
- The device may be distributed to specific or general licensees of the state of Ohio, the US NRC, any state with NARM regulations, or another agreement state.
- The device may be distributed to persons generally licensed by the state of Ohio, the US NRC, any state with NARM regulations, or another agreement state.
- The device shall only be used by the custom user listed in this certificate, xxxxxx.

Appendix D - Standard device registration Certificate Format

NO: DATE: Page 6 of 8

SOURCE TYPE: short description of the source type

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (continued):

- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by rule 3701-39-021 of the Ohio Administrative Code or Title 10 Code of Federal Regulations Part 31.5
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 KBq (0.005 microcuries) of removable contamination.
- The Model XXXXXX sealed source is approved by the state of Ohio/US NRC for use in the Model ABD. The source is not registered on a separate certificate.
- The generally licensed user is authorized to perform certain maintenance on the device (see the device operation manual). These services include: .....
- REVIEWER NOTE: Neither the distributor nor manufacturer of the device will provide servicing for the device.
- This device registration sheet and the information contained within the references shall not be changed without the written consent of the department of health, state of Ohio.

actual form used

SAFETY ANALYSIS SUMMARY

The distributor has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions of handling, storage, and use of the device the radioactive material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent (10%) of the limits specified in rule 3701-39-021 of the Ohio Administrative Code.
- Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:

Appendix D - Standard device registration Certificate Format

SOURCE TYPE: short description of the source type

SAFETY ANALYSIS SUMMARY (continued):

PART OF THE BODY	DOSE
Whole body; head and trunk; active blood forming organs; gonads; or lens of the eye	15 Rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm^2 (0.15 in^2)	200 Rem (2.0 Sv)
Other organs	50 Rem (0.50 Sv)

Based on review of the Model ABD and the information and test data cited below, we (continue to) conclude that the source is acceptable for licensing purposes.

Furthermore, we (continue to) conclude that the device would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES

The following supporting documents for the Model ABD are hereby incorporated by reference and are made a part of this registry document.

- 'a application dated January 1, 0000, with enclosures thereto
- 's letters dated August 16, 1996 and December 25, 1996, with enclosures thereto
- 's facsimiles dated July 4, 0000 and May 23, 0000.

SOURCE TYPE: short description of the source type

Appendix D - Standard device registration Certificate Format

ISSUING AGENCY

State of Ohio
Department of Health

Date: Reviewer:

Name of First Reviewer

Date: Reviewer:

Name of Second Reviewer

Typical format for device registration

This format may be compared to

actual form used

William Ryan, Director
Ohio Department of Health

Date

Appendix D - Standard device registration Certificate Format

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: DATE: Page 1 of 2

DEVICE TYPE: Smoke Detector/Gun Sight

MODEL: ABE

MANUFACTURER / DISTRIBUTOR: Name
Street
City, State, zip
(If the manufacturer and distributor are the same, keep subheading as shown. If different, delete the word MANUFACTURER from the subheading)

MANUFACTURER: : Name
Street
City, State, zip
(This subheading and information is not necessary if manufacturer and distributor are same)

SEALED SOURCE MODEL DESIGNATION: ACME Model 321

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241 (Am^{241})	1.0 microcuries (37 kBq)
Hydrogen-3 (H^3)/(Tritium)	60 millicuries (2.2 GBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (P) Ion Generator, Smoke Detectors
(W) Self-luminous Light Sources

NO: DATE: Page 2 of 2

Appendix D - Standard device registration Certificate Format

DEVICE TYPE: Smoke Detector/Gun Sight

CUSTOM SOURCE: YES x NO

DESCRIPTION:

Provide a concise, basic description of the device and if more than one model is registered, provide the differences between models.

REFERENCES

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

- 'a application dated January 1, 0000, with enclosures thereto
- 's letters dated August 16, 1996 and December 25, 1996, with enclosures thereto
- 's facsimiles dated July 4, 0000 and May 23, 0000.

ISSUING AGENCY

State of Ohio
Department of Health

Date: Reviewer:

Name of First Reviewer

Date: Reviewer:

Name of Second Reviewer

date

William Ryan, Director
Ohio Department of Health

APPENDIX E

ASSIGNING device registration CERTIFICATE NUMBERS

Appendix E - Assigning device registration Certificate Numbers

EACH device registration CERTIFICATE HAS A UNIQUE device registration NUMBER. THE device registration NUMBER CONSISTS OF EITHER 10 OR 11 CHARACTERS AS DESCRIBED BELOW:

AA - XXXX - D - YYY - S

AA - Agency Code - A two-letter abbreviation of the State where the agency issuing the certificate is located. If assigned by the state of Ohio, this will be OH. If assigned by the US NRC, this will be NR.

XXXX - Vendor Code - Each vendor (manufacturer or distributor) is assigned a unique four digit number by the department. The vendor code used for the device registration certificate number will be the vendor code for the distributor. If the company is out of business or no longer has an active device registration certificate, the vendor code will begin with 9. Technical Services section maintains the listing of vendor codes and issues new vendor codes.

D - Source/Device Code - A one letter code which indicates whether a device registration certificate is for a sealed source (S), a device (D), or associated equipment (A).

YYY - Unit Number - A separate series of three digit numbers assigned to device registration certificates for each vendor. These numbers are assigned in sequential order starting with 101 for active device registration certificates and starting with 901 for inactive device registration certificates. A new device registration for an existing vendor is assigned the next available unit number. The issuance of unit numbers is controlled by the Technical Services section.

S - License Code - This is a one letter code which indicates how the source or device has been registered. "S" indicates it may only be used by specific licensees, "G" indicates it may only be used by General Licensees, "B" indicates it may be used by both specific and general licensees, and "E" indicates it may be used by persons exempt from licensing.