STATE OF OHIO
DEPARTMENT OF HEALTH
BUREAU OF RADIATION PROTECTION

SEALED SOURCE AND DEVICE REVIEW AND REGISTRATION PROGRAM

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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 not sufficient to form

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OAC 3701-39-021	(10CFR32.51(b)) Leak test frequency longer than 6 months

[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.

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, Ohio 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 Ohio Department of Health (ODH) in accordance with this program and its implementing procedures.

SCOPE

Initially, this program prescribes the methodology used by the ODH 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. Updating the registry is a shared responsibility between the NRC, 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 in evaluating sources that malfunction during use, 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, 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.

The applicant must identify that the source or device is registered if 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 of the license cannot provide documentation of review by the U.S. NRC, an Agreement State which has accepted and is maintaining product review status, a NARM licensing state approved for product review, or by the State of Ohio, then the licensee shall request a full review by the State of Ohio. This program is based on and supported by the NRC's NUREG 1556, Volume 3, which Ohio has adopted. Reviews in Ohio will be performed in such a way that the review will not cause undue delay in making final determination on a license or amendment application or in performing routine inspections. The Manager of Technical Services is responsible for managing the sealed source and device program, including the assurance that reviews are conducted in a timely fashion.

PROVISIONS OF THE REVIEW AND EVALUATION PROCESS

The criteria for filing a request for review 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 and/or device as described in the Implementing Procedures to this program to the Ohio 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 if the information is necessary to perform a safety evaluation of the product. If there are questions concerning whether the material is necessary, the Manager of Technical Services will make the final determination. 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.

All requests for safety evaluations of sealed sources and devices received by the department are forwarded to the Technical Services Section of the Bureau of Radiation Protection, who makes a determination that the information provided is sufficient to initiate a review. 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. If an application is complete, the applicant will be notified accordingly; otherwise, the entire application is returned. The Technical Services Section is responsible for tracking all applications, which will be logged into the sealed source and device action tracking system.

The Manager of Technical Services will assign the review to a member of the technical staff who has completed all supervisory sign offs for each of the qualifying elements of Management Directive 5.6 and has signature authority for the registration certificate. The assignment will be documented in the tracking system. The technical reviewer is responsible to perform a technical and safety review, ensuring the product meets all applicable standards and rules, provide oversight of contractors performing the engineering and materials standards portion of the review if necessary, correspond with the applicant to obtain additional information as needed, generate the registration certificate, and ensure the application is reviewed and signed by two persons having signature authority~~, and prepare the registration certificate~~. In addition, the reviewer needs to identify any complex policy issues and bring them to management's attention. 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.

An independent technical review of the application and the proposed certificate of registration is performed by a second individual, who has completed all supervisory sign off for each of the qualifying elements of Management Directive 5.6 and has signature authority for the registration certificate, and supports the finding that the product is acceptable for licensing purposes. The Manager of Technical Services will also make this assignment and document such in the sealed source and device action tracking system. The independent technical reviewer must concur with the initial review, including the report of any contractor. A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the technical review (e.g., construction of the product, labeling, and prototype testing), but the concurrence review is not the same level of detail as the initial review (i.e., It is not necessary to review every page of the applicant's submittal). The concurrence review must be focused on ensuring that the product meets all applicable rules, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices.

Both reviews will be documented in the review file. Any discrepancies between the two reviews will be reported to the Manager of Technical Services, who will assess the adequacy of documentation to make a determination, or if additional information is required. Once all discrepancies have been resolved, the evaluation is complete.

~~Until the Department has performed sufficient reviews to have individual staff members perform the independent review, we will use a team approach for the concurrence review. The team leader will be an individual who has completed the SS&D training. There will be up to two other members of the team performing portions of the review assigned by the team leader who have not fully completed qualification but who have at least attended the SS & D workshop that NRC provides. The team~~

~~leader will review reports submitted by team members and compare reports to the initial review. Any discrepancies between the two reviews will require action by the Manager of Technical Services to determine if there is adequate documentation for any determination, or if additional information is necessary in order to make a determination. There will be no registry of the source or device until both reviews are in concurrence. The final independent review report for the team and signature on the report will be that of the team leader. This team approach is an interim measure. If two qualified reviewers are available, the Bureau of Radiation Protection will employ an independent and concurrence review as described above. Regardless of the method used to perform the review,~~ a A copy of the review application and registry sheet will be placed in the facility file and the original application and registry sheet will be maintained in a separate SS&D registry file. Documentation of supervisory sign off ~~for those portions of a review performed by individuals not having supervisory sign off~~ in all areas covered by Management Directive 5.6, as well as signature authority, will be maintained in the review file. The names of the reviewers and pertinent sections reviewed will be included. Both reviewers will sign the 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:

Consolidated Guidance	Consolidated Guidance – Applications for Sealed Source and Device Evaluation and Registration
NMS-SSD-03	"Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Radioactive

Material"

OAC 3701-39-021 (10CFR32.51(b)) Leak test frequency longer than 6 months

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 specific initial training and refresher training. By the effective date of the agreement, the Bureau will have up to four individuals who have participated in the NRC sealed source and device workshop. We will also request that three individuals work with NMSS headquarters in an OJT situation so that these individuals will be familiar with the methodology NMSS uses in the reviews. This will enable them to provide better oversight of contractors used to perform any engineering and materials standards portions of the review ~~and to perform those portions of reviews not sent to contractors~~. The three individuals may include:

Karl VonAhn - Biomedical engineer

Mike Snee - U.S. Navy Engineering Laboratory Technician School, BS Applied Science and Technology/Radiation Protection Specialization

George Cicotte - B.S. Physics

the individual filling the Health Physicist 3 vacancy (PCN180201.0) in the Technical Services Section

One of these three individuals will become the primary reviewer and one of the other two will become the ~~team leader for~~ individual conducting the concurrence review. ~~This allows for the possibility of more than one review coming in during the same time period. Johnathan Fortkamp (PhD Nuclear Engineering) will be going through the training over the next year to provide additional backup for~~

~~reviews and will receive the same training as the above listed individuals.~~ The two individuals currently qualified to conduct sealed source and device reviews with signature authority are George R. Cicotte and Karl Von Ahn.

Training provided for individuals performing SS & D reviews will be in addition to that which is required for all staff. This additional training and qualifications required for these individuals are specified in the Special Areas section of the Training Program and is consistent with Management Directive 5.6. ~~The specific qualifications of staff performing SS&D reviews will be submitted to NRC for evaluation prior to receiving on-the-job training at NRC.~~ Signature authority to sign off on reviews will be granted to a reviewer once he or she has fulfilled ~~the~~ all qualifications for sealed source and device review in Management Directive 5.6 and received supervisory sign off for each of these areas ~~and completed the training required in the above-referenced section. Any individual participating in a review must be qualified pursuant to Management Directive 5.6 for each aspect of a review being perf~~ ~~A team approach will be used for the initial review, if necessary, as in the concurrence review, to ensure that all aspects of a review per Management Directive 5.6 are covered by a qualified individual.~~

~~In the event a request for a review is received that is considered beyond the scope of the technical staff at the Ohio Department of Health, the~~ The Manager of Technical Services has the authority to seek assistance ~~in areas of expertise that may be lacking in the Bureau~~ from other state agencies or through a contract with private contractors such as Civil Engineers, Structural and Mechanical Engineers, Electrical Engineers, and other engineering disciplines as needed. There is no intent to require contractors to have signature approval. The responsibility of the contractor is confined to engineering and materials compatibility determination. Contractor personnel must be qualified to conduct their part of a review pursuant to Management Directive 5.6., and provide evidence of training and experience to be qualified to conduct those areas of a review covered by Management Directive 5.6. Requests for proposals (RFP) for contracts will contain all qualification requirements per areas of expertise sought in line with Management Directive 5.6. The scope of work espoused in the RFP will delineate the areas of review to be performed and specifics of requirements for tasks

to ensure adequacy of review. Documentation of the qualifications of contractor personnel to perform each aspect of the review conducted by them will be maintained in the review file.

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 the consolidated guidance about materials licenses: Application for Sealed Source and Device Evaluation and Registration.

REGISTRATION CERTIFICATES AND THE REGISTRY

The consolidated guidance document 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 model number of the sealed source or device, the manufacturer or distributor 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, including the name and address of the custom user;

- 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 for critical safety components of the product, source encapsulation materials, source holder materials, shutter mechanisms, welding process, device security features, 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, how and 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, and should include overall dimensions of the product, location s of the sealed source within the device, and the safety related features of the product;
- Conditions of Normal Use, including environmental conditions the products is to withstand, normal intended uses of the product and any limitations that define these uses, and the working life of the product;
- Prototype testing - describes the tests performed on the prototypes of the product, including the corresponding classification of an industry or consensus standard or whether satisfactorily tested against an applicable regulation;
- 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, and any applicable regulation or standard being met;
- Limitations and Other Considerations of Use, including leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools,

and specific licensing conditions that should be addressed by the license reviewer, services that may be performed by general-licensed users of the products, not subjecting device to environments that exceed ANSI or ISO classifications or discontinuance of use, and restrictions on changes to the registration or referenced documentation without permission of the Ohio Department of Health;

- Safety Analysis Summary as performed by the reviewer, including acceptability of product for certain licensing conditions, additional features that the device, surroundings, environment, or accessories may contribute to the integrity of the product;
- References submitted in the support of the application; and
- The Issuing Agency, including date issued, signatories, and applicable documentation.

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 consolidated guidance. Applying for an inactive status for a sealed source or device is also included in the consolidated guidance.

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 ODH. Incidents involving

registered sources or devices will result in notification of the state that performed the original review or the NRC, if NRC was the reviewer.

IMPLEMENTING PROCEDURES

(NOTE: The following list of Implementing 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. The document NMS-SSD-03 is identical in content to that in Reg Guide 6.9.)

Consolidated Guidance	Consolidated Guidance – Applications for Sealed Source and Device Evaluation and Registration
NMS-SSD-03	"Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Source and Devices Containing Radioactive Material"
OAC 3701-39-021	(10CFR32.51(b)) Leak test frequency longer than 6 months

ATTACHMENT 1

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

STATE OF OHIO
DEPARTMENT OF HEALTH

Consolidated Guidance About Materials Licenses:

APPLICATIONS FOR SEALED SOURCE AND DEVICE EVALUATION AND REGISTRATION

Rev. 4

Effective Date: 7 April 1999

This consolidated guidance mimics the NRC NUREG 1556, Volume 3, and along with the state of Ohio *Sealed Source and Device Review and Registration Program* 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.

Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration

Abstract

"Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," is designed to provide guidance to applicants for requests for sealed source or device safety evaluations. It also provides reviewers of such requests with the information and materials necessary to determine 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 rules 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.

Foreword

This report describes and makes available to the public information on: methods acceptable to Department staff for implementing specific parts of OAC 3701-38-021 and OAC 3701-39-021; techniques the Department staff uses in evaluating applications, including specific problems or postulated accidents; and data the Department staff needs to review applications for source and device registration. This Consolidated Guidance is not a substitute for rules 3701-38-021 and 3701-39-021 of the Ohio Administrative Code , and compliance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different than those described in this report will be acceptable, if they provide enough information for the staff to make the determinations needed to issue, continue, or reject a license.

Abbreviations

AEA	Atomic Energy Act
ALARA	As Low As is Reasonably Achievable
ANSI	American National Standards Institute
BRP	Bureau of Radiation Protection
CFR	Code of Federal Regulations
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
OAC	Ohio Administrative Code
ODH	Ohio Department of Health
OGC	Office of the General Counsel
ORC	Ohio Revised Code
OSP	Office of State Programs
QA	Quality Assurance
QC	Quality Control

1 Purpose

This Consolidated Guidance provides assistance to applicants on submitting requests to the Department 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 rules 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 rules provided in 10 CFR Section 30.32(g) as referenced in OAC 3701-39-021, require an applicant for a specific license to use a sealed source or device to identify the sealed source or device as registered with the Department in accordance with 10 CFR 32.210 or to provide the information contained in 10 CFR 32.210 as referenced in OAC 3701-39-021. 10 CFR 32.210 as referenced in OAC 3701-39-021, 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 NRC maintains a registry of radiation safety information on sealed sources and devices containing byproduct material they have evaluated. Agreement States also provide information on their radiation safety evaluations to the NRC for addition to the registry. Both the NRC and the Agreement 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.

2 Agreement States

Certain states, called Agreement States, have entered into agreements with the NRC that give them the authority for certain activities, including performing safety evaluations and registration of byproduct, source, or special nuclear materials used, possessed, or distributed by persons within their borders. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon

request from the NRC's Office of State Programs (OSP). Any applicant, other than a Federal agency or distributor of a product to persons exempt from licensing, that is located in an Agreement State and wishes to apply for safety evaluation and registration of a sealed source or device needs to contact the responsible officials in that State for guidance on preparing an application; file these applications with State officials, not with the NRC. In the State of Ohio, this consolidated guidance is used as guidance in the preparation of, filing, and evaluation of sealed sources and devices used by licensees within Ohio. This guidance is applicable only to NARM sources and devices until the effective date of an agreement between NRC and the State of Ohio. After the effective date, this guidance will also cover applicable source, byproduct, and special nuclear material. When an Agreement State issues a registration certificate, a copy of the registration certificate is forwarded to the Division of Industrial and Medical Nuclear Safety (IMNS) 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 an Agreement State registration certificate, they are resolved directly with the Agreement State.

Table 2.1 Who Evaluates Sealed Sources and Devices?

Applicant and its Location	Regulatory Agency
Distributor of products to persons containing source, byproduct and special nuclear material exempt from licensing regardless of location	NRC
Federal agency regardless of location	NRC
Non-Federal entity in non-Agreement State, US territory or possession for source, byproduct and special nuclear material	NRC
Non-Federal entity in an Agreement State at non-Federally controlled site for the use of NARM	Agreement State
Non-Federal entity in Agreement State at non-Federally controlled site for source, byproduct and special nuclear material	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site NOT subject to exclusive Federal jurisdiction for source, byproduct and special nuclear material	Agreement State

Applicant and its Location	Regulatory Agency
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

3 Management Responsibility

The Department recognizes that effective applicant/registration certificate holder management is vital to achieving safety and complying with regulatory requirements. The Department also believes that consistent compliance with its rules provides reasonable assurance that regulated activities will be conducted accordingly. Based on results of routine and special inspections of licensed activities, the Department has determined that ineffective licensee 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 Department (10 CFR 30.9 as referenced in OAC 3701-39-021,);
- 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:
    - the statements and representations contained in the application for safety review and registration;
    - the provisions of the registration certificate; and,
    - State of Ohio rules.

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 the Enforcement Program for the Bureau of Radiation Protection.

4 Applicable Rules

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 applicable rules in the State of Ohio for sealed sources and devices include

- Ohio Revised Code Chapter 3748,
- Ohio Administrative Code 3701-38-021, and
- Ohio Administrative Code 3701-39-021.

The following Parts of 10 CFR Chapter I as referenced in OAC 3701-39-021, contain specific rules applicable to sealed source and device evaluations:

- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigation
- 10 CFR Part 20, "Standards for Protection against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"
- 10 CFR 150 "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274" of the Atomic Energy Act.

The rules embodied in 10 CFR 30.32(g) as referenced in OAC 3701-39-021,and 32.210 codify the current and long-standing practice 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 practice has been used by the United States Atomic Energy Agency/NRC since the 1950's and by the Agreement States starting in 1962.

The specific provisions in 10 CFR 30.32(g) as referenced in OAC 3701-39-021,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. 10 CFR Section 32.210 as referenced in OAC 3701-39-021, outlines the safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the Department evaluates and registers radiation safety information.

Current rules only require that products used under a specific license issued in accordance with 10 CFR Part 30 as referenced in OAC 3701-39-021,be registered with the Department. However, if registration of a product design is deemed necessary by the Department, the applicant needs to provide the information contained in 10 CFR 32.210 as referenced in OAC 3701-39-021, and the application will be evaluated in the same manner as all registration applications.

The products listed in Sections 4.2 through 4.5 are used by persons exempt from licensing requirements or used in accordance with a general license. NRC has determined that registration of the product design is necessary for Atomic Energy Act material and the Department has made the same determination for similar sources or devices containing NARM. However, in addition to the general registration criteria in 10 CFR 32.210 as referenced in OAC 3701-39-021, the rules require that the products meet certain specific requirements. These specific requirements are listed in the appropriate section (Sections 4.1 through 4.4) and need to be addressed during the product evaluation.

Some specifically-licensed products are required, by rule, to meet certain specific requirements in addition to the general registration criteria provided in 10 CFR 32.210 as referenced in OAC 3701-39-021. The specific requirements for these products are listed in Sections 4.5 through 4.8 and need to be addressed during the product evaluation.

4.1 Gas and Aerosol Detectors Containing NARM for use by Persons Exempt from Licensing Requirements

Under 10 CFR 30.20 as referenced in OAC 3701-39-021, persons are exempted from

licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.26 as referenced in OAC 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 must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable OAC 3701-39-021 references to 10 CFR Regulations
Design	30.20(a), 32.26
Maximum Radiation Levels	32.26(b)(6)
Maximum Dose Commitments	32.26(b)(13) & (14)
Labeling	32.29(b)

4.2 Devices Used Under the General License in 10 CFR 31.5 as referenced in OAC 3701-39-021

Under 10 CFR 31.5 as referenced in OAC 3701-39-021,, 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 10 CFR 32.51 as referenced in OAC 3701-39-021,. 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 OAC 3701-39-021 reference to 10 CFR Regulations
Design	31.5(a), 32.51(a)(2)(I)
Maximum Dose Commitments	32.51(a)(2)(ii) & (iii)
Labeling	32.51(a)(3)
Leak Testing	32.51(b)
Testing and Servicing	32.51(b) & (c)

4.3 Luminous Safety Devices Used in Aircraft Under 10 CFR 31.7 as referenced in OAC 3701-39-021

Under 10 CFR 31.7 as referenced in OAC 3701-39-021, 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 10 CFR 32.53 as referenced in OAC 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 must be addressed during the product evaluation, are listed below:

Area to be Addressed	Applicable OAC 3701-39-021 references to 10 CFR Regulations
Design	32.53(c) & (d)
Prototype Testing	32.53(d)(4), 32.101
Labeling	32.54
Quality Control	32.55, 32.110

4.4 Ice Detection Devices Containing Strontium-90

Under 10 CFR 31.10 as referenced in OAC 3701-39-021, 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 10 CFR 32.61 as referenced in OAC 3701-39-021,. 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 OAC 3701-39-021 references to 10 CFR Regulations
Design	32.61(c) & (e)
Labeling	32.61(d)
Prototype Testing	32.61(e)(4), 32.103
Quality Control	32.61(e)(5), 32.62, 32.110

4.5 Radiography Equipment

Persons specifically licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 CFR Part 34 as referenced in OAC 3701-39-021. 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 OAC 3701-39-021 references to 10 CFR Regulations
Design	34.20(a), 34.22
Leak Testing	34.27
Labeling	34.20
Prototype Testing	34.20
Maximum Radiation Levels	34.20, 34.21

4.6 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 CFR Part 39 Subpart C as referenced in OAC 3701-39-021,. 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 OAC 3701-39-021 references to 10 CFR Regulations
Labeling	39.31(a)
Leak Testing	39.35
Design	39.41(a)(1) & (2)
Prototype Testing	39.41(a)(3)

4.7 Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21 as referenced in OAC 3701-39-021. 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 OAC 3701-39-021 references to 10 CFR Regulations
Design	36.21(a)(2), (3), & (4)

Area to be Addressed	Applicable OAC 3701-39-021 references to 10 CFR Regulations
Leak Testing	36.59
Prototype Testing	36.21(a)(5)

4.8 Sealed Sources and Devices for Medical Use

In accordance with 10 CFR 35.49 as referenced in OAC 3701-39-021, only sealed sources and devices that are manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR 32.74 as referenced in OAC 3701-39-021 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 OAC 3701-39-021 reference 10 CFR Regulations
Labeling	32.74(a)(2)(viii) & (a)(3)
Leak Testing	32.74(b)

One exception to the above requirement is teletherapy sources. Specifically, teletherapy sources do not need to meet the requirements of 10 CFR 32.74 as referenced in OAC 3701-39-021. However, 10 CFR 35.49(b) as referenced in OAC 3701-39-021 indicates that they do need to be manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 as referenced in OAC 3701-39-021.

5 General Policies and Procedures

5.1 Sealed Source and Device Designs that do not Require a Registration Certificate

10 CFR 30.32(g) as referenced in OAC 3701-39-021 applies to all sealed sources and devices used by specific licensees and requires evaluation of the product by the Department including those devices containing naturally-occurring or accelerator-produced radioactive material (NARM). However, the possession and use of certain products does not require registration of the product by the Department. Specifically, evaluation and licensing of the following products should be handled as indicated below by the license reviewer:

5.1.1 Calibration and Reference Standards

Calibration and reference sources may be licensed without registration by the

Department 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 Section 30.71, Schedule B, 10 CFR 30 as referenced by OAC 3701-39-021, 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 materials license, use the statement "calibration or reference sources" for chemical/physical form, and state the maximum quantity for each source. Both possession and distribution to specific licensees may be authorized.

5.1.2 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 registered by the Department 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 unshielded 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 10 CFR 32.210 as referenced in OAC 3701-39-021 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 Department pursuant to 10 CFR 32.210(e) as referenced in OAC 3701-39-021, or the NRC or another Agreement State. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate."

5.1.3 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 Department for registration 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 10 CFR 30.33 as referenced in OAC 3701-39-021. Custom sealed source and devices which contain an activity greater than that listed above must be submitted to the Department for registration.

To license these custom sealed sources and/or devices, license reviewers need to identify the isotope in the material license, 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. For authorized use, the 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 registered, apply to only to the custom user of the product.

5.2 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 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.

5.3 As Low as is Reasonably Achievable

The Department's requirements to establish programs, procedures, and engineering controls for achieving doses that are as-low-as-is-reasonably-achievable (ALARA) are included in 10 CFR 20.1101 as referenced in OAC 3701-39-021. The Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains the 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. Regulatory Guide "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable" may be useful to applicants for establishing and following an ALARA philosophy during the design of a sealed source or device.

5.4 Naturally-Occurring or Accelerator-Produced Radioactive Material

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 OSP, the State, or FDA.

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).

5.5 Foreign Vendors

Foreign vendors present a unique situation for the State of Ohio in that the statehas no 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. 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, in the same vein, will only issue registrations to a distributor that has established an address in the State of Ohio.

5.6 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. In order for the Department to find this acceptable, the applicant must first demonstrate and the reviewer confirm that the standard meets or exceeds any specific regulatory requirements (e.g., compliance with American National Standards Institute (ANSI) N432-1980 for radiography equipment). The applicant and reviewer must each 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 foreign or international standard may be compared with an applicable United States standard in determining the acceptance of the standard. This may include professional judgement on

the parts of the applicant and reviewer.

If a foreign standard is used, the applicant must submit copies of both the original and English translation of the standard.

5.7 FDA-NRC Memorandum of Understanding Recognition in Ohio

The FDA and the NRC signed a Memorandum of Understanding (MOU) 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, (Federal Register Vol 58 page 47300 on Sept 8, 1993) 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 copy of the pre-marketing approval [510(k)] 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.

The Department is not bound by the FDA-NRC MOU, however, to be consistent with NRC practices, and in the interest of public health, safety, and welfare, the Department will not begin review of a medical SSD until the applicant has submitted a copy of the pre-marketing approval [510(k)] issued by the FDA.

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

5.8 Computer Software

Department 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.

5.9 Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by the Department 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 Department, the Department may modify or remove the registration certificate from the national registry. and may issue orders modifying licenses to all persons licensed by the Department to use the sealed source or device. The State of Ohio will notify the NRC in the event that Ohio revokes a registration certificate so that the Agreement States and the NRC are made aware of Ohio's actions concerning the sealed source or device.

5.10 Incidents

Incidents involving products evaluated and registered by the Department 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 Department 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 Department is kept on file by the Department for use in performing future evaluations of the products involved and products similar to those involved.

5.11 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 Ohio Revised Code.

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 "proprietary Trade Secret " "confidential," "restricted," or "is the express property of Company X," 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 ORC 1333.51, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements. Information provided that is essential to the review that constitutes a trade secret as defined in section 1333.61 of the Ohio Revised Code (ORC) is not subject to public disclosure in accordance with section 1333.51 of the ORC. (Appendix A includes a checklist for requests for withholding information from public disclosure). 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 listed above and the applicant should be notified in writing that the Department plans to honor the request. However, the notification needs to inform the applicant that the Department may have cause to review the determination in the future; 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.

5.12 Transportation

This document does not cover detailed requirements for the transportation of devices and sealed sources. The transportation requirements are contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."as referenced in OAC 3701-39-021. 10 CFR Part 71 as referenced in OAC 3701-39-021establishes:

- procedures and standards for 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 as referenced in OAC 3701-39-021); and

- requirements for quality assurance, packaging, preparation for shipment, and

transportation of licensed material.

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 10 CFR Part 71 as referenced in OAC 3701-39-021, 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.

Although the Department does not evaluate packaging or transportation requirements during sealed source or device evaluations, the Department does evaluate the effects the packaging or transportation has on normal use and operation of the product as part of the evaluation. Specifically, the Department 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.

6 How to File

No special form is required for applications for sealed source or device evaluations. However, to facilitate the review process, applicants for a sealed source or device evaluation are encouraged to do the following:

General/Format:

- Be sure to review the applicable rules 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~~ your 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 B, "Application and Review Checklist."

- Attach the balance of the application to the "Summary Data" information. The order of the information in the application should correspond to the appropriate sub-section in Section 10.

- Use the "Checklist" included in Appendix B 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 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 ~~NRC~~ Department 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 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 Department offices.

If it is necessary to submit proprietary information, see section 5.10 of this consolidated guidance for additional details.

Applications may be scanned or put through an optical character reader to convert them to electronic format. To assist with the conversion of the application to electronic media, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

7 Where to File

Applicants wishing to file a registration for a sealed source or device may file an application by mailing it to:

Technical Services

Bureau of Radiation Protection
Ohio Department of Health
PO Box 118
Columbus OH 43266-0118

8 Registration Fees

Each application for which a fee is specified, including applications for new registration certificates and registration certificate amendments, must be accompanied by the appropriate fee. For SSD applicants, the appropriate fee shall be "full cost" as described in OAC 3701-38-021. Full cost fees are invoiced quarterly. The registration certificate or amendment will not be issued until full payment of the fee has been received. Once the technical review process has begun, no fees will be refunded; application fees will be charged regardless of Ohio's disposition of an application or the withdrawal of an application.

9 Document Flow

9.1 Application Receipt and Assignment to a Reviewer

The Manager of Technical Services is responsible for managing the sealed source and device program. This includes the assurance of document maintenance in a timely and appropriate manner, and that reviews are conducted in a timely fashion.

The processing of the application is the same in all cases.

Request for safety evaluations of SSD are usually submitted by the applicant directly to the Technical Services Section of the Bureau of Radiation Protection. Applications submitted to other ODH Bureaus are forwarded to the Bureau of Radiation Protection.

When the BRP receives an application , an acceptance review is performed by the Technical Service Section to determine whether there is sufficient information to initiate the review. If there is sufficient information to initiate the review, the applicant is sent a letter acknowledging receipt of the application; if not, the entire package is returned to the applicant for re-submission of a complete document.

The Technical Services Section is responsible for tracking all applications. Applications are logged into the sealed source and device action tracking system where they await assignment to a reviewer. Each action is assigned a unique tracking number. Assignment to a reviewer is determined on a first-in basis by the Manager of Technical Services. The initial review will be assigned to a member of the technical staff who has completed all

supervisory sign off for each of the qualifying elements of Management Directive 5.6 and has signature authority for the registration certificate. This assignment will be documented in the tracking system. 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.

9.2 Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and rules, 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.

Following completion of the initial review, the Manager of Technical Services will assign an individual, other than the initial reviewer, who has completed all supervisory sign off for each of the qualifying elements of Management Directive 5.6 and has signature authority for the registration certificate, to conduct the concurrence review. ~~If such an individual is not available to conduct a single concurrence review, then a team of three members will be appointed by the Manager of Technical Services to conduct the concurrence review. The team leader must have supervisory sign off on all qualifying elements of Management Directive 5.6 and have signature authority for the registration certificate. The other team members must have supervisory sign off for those areas of the review conducted by them in accordance with Management Directive 5.6. The concurrence review by the team must cover all areas of the review.~~ This assignment must be documented in the sealed source and device action tracking system.

The results of the concurrence review will be documented to the review file with any discrepancies between the two reviews noted in a report ~~signed by the team leader~~. Otherwise full concurrence is noted.

The Manager of Technical Services will be advised of any discrepancies. He or she will assess the adequacy of documentation to make a determination, or if additional documentation is required. Once all discrepancies have been resolved, the evaluation is complete.

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

9.3 Distribution of Completed Certificates

A copy of the certificate is forwarded to the NRC.

9.4 Inclusion in the Sealed Source and Device Computerized Registration System

The NRC 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 (see Section 12.2).

10 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 Section 6 and use Appendix B as a guideline when submitting applications. Applicants should complete the "Summary Data" section of the appendix 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.

It should be noted that certain rules include specific requirements applicable to evaluation and registration of products. Section 4 lists these rules and each rule also is listed at the end of the applicable topic of this section. 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.

10.1 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. See Section 5.2 for additional information concerning custom users.

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 Department 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 Ohio, the NRC, and other 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 C. This information assists applicants and reviewers in determining the applicable rules, 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 Section 10.2, 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 byproduct 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) 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 10 CFR 32.51(b) or 32.74(b)(1) as referenced in OAC 3701-39-021 for evaluation if a longer leak test interval is requested.

The following rules incorporated under OAC 3701-39-021 should be referenced for additional information concerning leak testing:

Regulations	Applicability
10 CFR 32.51(b)	Devices used under the 10 CFR 31.5 general license
10 CFR 34.27	Sources and devices designed for use in radiography operations
10 CFR 39.35	Sources used in well-logging operations
10 CFR 36.59	Irradiator operations
10 CFR 32.74(b)	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 Section 3 "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the regulatory requirements. The Department 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). (ORC 3748.99)
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

10.2 Conditions of Use

The applicant must identify, and the reviewer evaluate, the intended use and users of the product and which standards, policies, and rules are applicable. Applicable standards or rules 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.

10.3 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 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, 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 byproduct 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 D includes a listing of references that may be useful in determining the adequacy and integrity of the product design.

The following rules incorporated in OAC 3701-39-021 should be referenced for additional information concerning product designs:

Regulations	Applicability
10 CFR 30.20(a), 10 CFR 32.26	Devices used under the 10 CFR 30.20 exemption.
10 CFR 31.5(a), 10 CFR 32.51(a)(2)	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.53(c)&(d)	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(c)&(e)	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20 & 34.22	Sources and devices designed for use in radiography operations.
10 CFR 39.41(a)(1)&(2)	Sources used in well logging operations.
10 CFR 36.21(a)(2)(3)&(4)	Sources used in irradiator operations.

10.4 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." 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." The word "Danger" may be used in lieu of the word "Caution".

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 NRC includes the sealed source model numbers in its sealed source and device computerized registration system. Therefore, the NRC 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 rules. For example, devices distributed to specific licensees must not include statements concerning use of the device under a general license.

The following rules incorporated in OAC 3701-39-021 should be reviewed for additional information concerning product labeling:

Regulations	Applicability
10 CFR 32.29(b)	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(3)	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.54	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(d)	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.
10 CFR 39.31(a)	Sources used in well logging operations.
10 CFR 32.74(a)(2)(viii) & (a)(3)	Sources and devices for medical use.

10.5 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 Department 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 N43.6-1997, "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 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 N43.6-1997 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 Appendix E. 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 rules incorporated in OAC 3701-39-021 should be referenced for additional information concerning prototype testing:

Regulations	Applicability
10 CFR 32.53(d)(4), 10 CFR 32.101	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(4), 10 CFR 32.103	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.
10 CFR 39.41(a)(3)	Sources used in well logging operations.
10 CFR 36.21(a)(5)	Sources used in irradiator operations.

10.6 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 50Sv/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 10 CFR Part 20 as referenced in OAC 3701-39-021, (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 ALARA).

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 rules incorporated in OAC 3701-39-021 should be referenced for additional information concerning radiation profiles and maximum dose commitments:

Regulations	Applicability
10 CFR 32.26(b)(6), (13), and (14)	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(2)(ii) &(iii)	Devices used under the 10 CFR 31.5 general license.
10 CFR 34.20 & 34.21(a)	Source and devices designed for use in radiography operations.

10.7 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.

The Department accepts 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. NMS-SSD-003, "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 NMS-SSD-003. It should be noted that NMS-SSD-003 discusses acceptance of programs meeting the requirements of other established QA standards.

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 rules incorporated in OAC 3701-39-021 should be referenced for additional information concerning quality assurance and control:

Regulations	Applicability
10 CFR 32.55 & 32.110	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(5), 32.62, & 32.110	Devices used under the 10 CFR 31.10 general license.

10.8 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 mounting, installing interlocks,

guards or barriers, and determining whether the installation needs to be performed by a specific licensee. General licensees may be permitted to mount products, depending on their design.

An applicant may request that general and specific licensees, without specific authorization under that license, be permitted to mount products. In order for the Department to grant such a request, the applicant must provide justification for approval (e.g., likely doses to persons mounting the device, why specific training is not necessary to perform mounting) and must provide written procedures that must be followed to mount the product safely. The reviewer must evaluate the adequacy of the procedures. These procedures must indicate the following:

- that the product must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the registration certificate;

- that the on-off mechanism (shutter) must be locked in the off position, if applicable, or that the source must be otherwise fully shielded.;

- that the product must be received in good condition (package is not damaged); and

- that the product must not require any modification to fit in the proposed location.

The "Limitations ;and/or Other Considerations of Use" section of the registration certificate must specifically state that general or specific licensees, without specific authorization under their license, may mount 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 byproduct 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 Department should be 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. See Section 13.3, "Transfers to Inactive Status."

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 rules 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 rules.

The following rules incorporated in OAC 3701-39-021 should be referenced for additional information concerning servicing:

Regulations	Applicability
10 CFR 32.51(b) & (c)	Devices used under the 10 CFR 31.5 general license

10.9 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.

11 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, 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:

11.1 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 60 days, and indicate that if a written response to the deficiency letter is not received within the 60 days specified in the letter, the reviewer will consider the application as "abandoned" for failure to provide the requested information. If the applicant requires additional time due to 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), the applicant should submit a request for additional time in writing within the 60 day period.

Prompt action (5 working days) should be taken to "void" the application after the application has been considered as "abandoned." [Note: see glossary for terms abandoned and void.] The reviewer should notify the applicant, in writing, that the application has been considered abandoned and the reviewer will place the application in the "void file."

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, the application should be assigned a new tracking number and handled as a new application. Higher priority will not be assigned solely based on the fact the application is a resubmission.

11.2 Meetings with Applicants

Department 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 the Department and applicants may be at the Department office, or at the applicant's facility if it is determined that it would enhance Department's understanding of the product.

11.3 Use of the Telephone or Electronic Mail to Obtain Additional

Information

The telephone or electronic mail may be used 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 and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented 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.

11.4 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 must be received by the Department, in writing, within the 60 day time period stated in the deficiency letter. The reviewer responds in writing to notify the applicant that an extension has been granted. All requests for extensions must be approved by Management and must be documented in a conversation record.

12 Contents of the Certificate

Registration certificates are written in a standard format. This allows 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 registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix F includes standard formats for registration certificates for a sealed source, for a device, and for an exempt device. Further clarification of the information that is included in a registration certificate is listed below.

12.1 Header

The header includes the title of the document, the registration number, date of issuance, page numbering, and the sealed source or device type. If the certificate is amended or corrected, this is indicated in the title; the page number of each corrected page(s) needs to be listed or the header notes that the certificate is amended in its entirety. The registration number is assigned by the reviewer, in accordance with the numbering procedures in Appendix G. The issue date is the date the certificate has received both reviewer and concurrence signatures.

12.2 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 or distributor 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 NRC maintained computerized registry of sealed sources and devices.

The following subsections are included in the order listed below starting on the second page of the certificate.

12.3 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 the device are also included.

Certificates for sealed sources include the chemical and physical forms of the source material. Certificates for devices 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.).

12.4 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 will be noted.

12.5 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.

12.6 Conditions of Normal Use

This section lists the environmental conditions the product is intended 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.

12.7 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 by the standard, should be stated in this section. If the product was tested in accordance with an applicable regulation, this section specifies whether the product satisfactorily met the requirements of the regulation.

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 will provide the details of the operational history or analysis and the basis for determining the design to be adequate.

12.8 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 open and closed 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 will include the levels on contact with the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) 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.

12.9 Quality Assurance and Control

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

12.10 Limitations and other Consideration 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 should be addressed by the license reviewer. This section needs to clearly indicate the services that may be performed by general-licensed users of the products, state that sources or devices should not be subjected 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 affect 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 registration certificate and the information contained within the references shall not be changed without the written authorization of the Department .

Limitations on sealed sources and devices can be divided into two 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. In addition to rules, 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 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.

12.11 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.

12.12 References

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

12.13 Issuing Agency

This section identifies the Department as the regulatory 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.

12.14 Attachments

This section typically contains diagrams, drawings, sketches, or pictures of the product, as discussed previously in Section 12.5. These provide inspectors a tool by which they can easily identify the devices in the field. The attachments also may contain designations of specific models and their characteristics, such as dimensions and sealed source activities, if a series of devices are registered.

The header for the attachments is similar to that for the main body of the registration certificate. The header contains the title of the document, registration number, date of issuance, and attachment numbering. The header does not contain the sealed source or device type.

12.15 Dimensions and use of Dual Units

The NRC's Metrication Policy (57 FR 46202) as adopted by the Department requires that documents specific to a registration certificate holder, such as the registration certificate, include dimensions in the units employed by the registration certificate holder. In addition to including the units employed by the registration certificate holder, it is recommended that registration certificates include dual-units as specified below:

- All measurements should be stated in the units employed by the registration certificate holder, followed by the appropriate English or International System of Units conversion in parentheses.
- All measurements not provided by the applicant should be specified in SI units, followed by the converted American (special) units value in brackets.
- 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 International System of Units, with the English conversion in parentheses, then all other measurements should be stated in International System of Units, with the English conversion in parentheses.
- If a value is being restated (i.e., the measurement is 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.

13 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 in Section 7. 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 is invoiced full cost fee from OAC 3701-38-021

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.

13.1 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 appropriate, the reviewer should use bold type face and strike-out to highlight the changes that have been made to the certificate. In addition, if there are still products in use that meet the previous design specifications, reviewers must ensure that previous design information remains in the registration certificate. The registration certificate also must identify, by date or serial number, when the design change is implemented.

13.2 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 5, 1776)

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.

13.3 Combining Registration Certificates

Registration certificate holders may request that Department combine two or more certificates into a single certificate. However, it is Department policy 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 Department policy and can administratively combine the registration certificates.

13.4 Transfers to Inactive Status

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

- the total number of the products sold; the number of products still in use;
- 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;
- a commitment that the registration certificate holder will no longer commercially distribute the product; and,
- 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 J 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.

13.5 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:

1 If the background information on file with the Department 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 Department requesting re-activation of the registration certificate. The letter must include commitments that the information on file with the Department is complete and accurate and that the vendor commits to abide by all information on file with the Department. The reviewer must verify the information is complete prior to assigning a new registration certificate number and re-issuing the certificate

2 If the background information on file with theDepartment 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

14 Identifying and Reporting Defects and Noncompliance

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 10 CFR 21 as referenced in OAC 3701-39-021 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 10 CFR Parts 30, 40, 50, 60, 61, 70, 71, or 72 as referenced in OAC 3701-39-021.

- 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 in OAC 3701-39-021.

All defects or failures to comply that are associated with, or could lead to, a substantial safety hazard must be reported to the Department pursuant to 10 CFR 21.21 as referenced in OAC 3701-39-021. In addition, registration certificate holders are required to meet the posting requirements specified in 10 CFR 21.6 as referenced in OAC 3701-39-021.

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

15 Glossary

"*Abandoned*" is not meant to have legal connotations. It simply means 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.

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 NRC and 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 byproduct material within the State. A complete listing of the current Agreement States, including addresses and points of contacts, can be obtained from the Nuclear Regulatory Commission, Office of State Programs.

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 NRC, an Agreement State, or the state licensing NARM. 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 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 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.

Mounting means physically positioning the product into its permanent location, including installation of fasteners (e.g., mounting bolts). Mounting does not include electrical connection, activation, or operation of the product.

NARM stands for Naturally-occurring or Accelerator-produced Radioactive Material. This material is not subject to regulation by the NRC but is regulated by the States. 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 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 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.

"*Void*" should not be thought of in its legal sense. It means here that the application is, in practical effect, nullified.

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: Checklist for Requests to Withhold Information from Public Disclosure

Checklist for Requests to Withhold Information from Public Disclosure

Information provided that is essential to the review that constitutes a trade secret as defined in OAC 3701-39-021(F) is not subject to public disclosure. In order to request that the Department withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit. The applicant should submit all of the following:	
[ ]	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
[ ]	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
[ ]	An affidavit that:
[ ]	Is notarized.
[ ]	Clearly identifies (such as by name or title and date) the document to be withheld.
[ ]	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.
[ ]	States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
[ ]	Provides a rational basis for holding the information in confidence.
[ ]	Fully addresses the following issues:
[ ]	Is the information submitted to, and received by, the Department in confidence? Provide details.
[ ]	To the best of applicant's knowledge, is the information currently available in public sources?
[ ]	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.

[ ]	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant: If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, the Department may send copies of this information to Department consultants working in that area. The Department will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, the applicant should promptly notify the Department. The applicant also should understand that the Department may have cause to review this determination in the future. In all review situations, if the Department makes a determination adverse to the above, the applicant will be notified in advance of any public disclosure.

Appendix B: Application and Review Checklist

Application and Review Checklist

The Application and Review Checklist are shown on the following pages.

<table>
<tr><th colspan="3">SUMMARY DATA</th></tr>
<tr><td colspan="2">Name and Complete Mailing Address of the Applicant:</td><td>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the Department:</td></tr>
<tr><td colspan="2">The Applicant is (check one):</td><td rowspan="5">If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</td></tr>
<tr><td></td><td>Custom User</td></tr>
<tr><td></td><td>Manufacturer</td></tr>
<tr><td></td><td>Distributor</td></tr>
<tr><td></td><td>Manufacturer and Distributor</td></tr>
<tr><td colspan="2">If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</td><td>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</td></tr>
<tr><td colspan="2">Model Number:</td><td>Principal Use Code (see Appendix E):</td></tr>
<tr><td colspan="2" rowspan="5">Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</td><td colspan="2">For Use by:</td></tr>
<tr><td></td><td>Specific Licensees Only</td></tr>
<tr><td></td><td>General Licensees Only</td></tr>
<tr><td></td><td>Both Specific and General Licensees</td></tr>
<tr><td></td><td>Persons Exempt from Licensing</td></tr>
<tr><td colspan="2">Leak-Test Frequency:</td><td rowspan="2">Principal Section of the OAC 3701-39-021 reference to 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</td></tr>
<tr><td></td><td>Periodic Leak-Testing is Not Required</td></tr>
<tr><td></td><td>6 Months</td><td>Radionuclides and Maximum Activities (including loading tolerance):</td></tr>
</table>

	Attached is justification for a leak test frequency of greater than 6 months	

CERTIFICATION:
THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.
THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 IN ACCORDANCE WITH OAC 3701-39-021 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

Certifying Officer — Typed Name and Title	
Signature:	Date:

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
Is source ANSI classification sufficient (from ANSI N43.6-1997): 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 Moist/Density 43333 Neutron Applications 43323 γ Irradiators (II, III) 43424 γ Irradiators (IV) 53424 γ Irradiators (I) 43323 Static Eliminators 22222 Smoke Detectors 32222		
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 (e.g., aluminum & steel, depleted uranium & steel, etc.)		
Shielding efficiency and integrity		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble.		

CHECKLIST		
Registration Certificate Holder: **Model:**		
DESCRIPTION	**OK/DEF**	**COMMENTS**
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		

CHECKLIST		
Registration Certificate Holder:		
Model:		
DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20 as referenced in OAC 3701-39-021)		
Permanent attachment 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 its working life.		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		
How the device will be used		
Meets dose limits of 10 CFR Part 32 as referenced in OAC 3701-39-021for distribution general licensees or persons exempt from licensing		
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.		

CHECKLIST		
Registration Certificate Holder: **Model:**		
DESCRIPTION	**OK/DEF**	**COMMENTS**
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		
Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv square law.		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to NMS-SSD-003		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers		
Mounting integrity		
Instructions to user for user installations		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent rules		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING					
The following activities may be performed by the persons indicated:					
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
Installation					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

Appendix C: Principal Use Codes and Definitions

Principal Use Codes and Definitions

CODE

A *Industrial Radiography* The examination of the structure of materials by nondestructive methods that use sealed sources of radioactive material.
B *Medical Radiography* The process of producing x-ray or gamma ray images to assist in medical diagnoses.
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 radioactive 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 (Activity greater than 1.1 GBq (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 necessary correction factors.
J *Gamma Irradiation, Category I* An irradiation 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 irradiation.
K *Gamma Irradiation, Category II* A controlled human access irradiation 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 control system.
L *Gamma Irradiation, Category III* An irradiation 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 Irradiation, Category IV* A controlled human access irradiation 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 control 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, Smoke Detectors* The use of an ion-generating source and a device to detect gases and particles created by combustion.

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

R *Gas Sources* Sealed sources containing radioactive gas 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 sources and devices such as interstitial needles, therapeutic seeds, and ophthalmic applicators.

W *Self-Luminous Light Source* A source consisting of a radioactive nuclide or nuclides incorporated in 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, 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.

Appendix D: Standard Reference Materials

Standard Reference Materials

Avallone, E. A., and Baumeister, T., "Marks' Standard Handbook for Mechanical Engineering, Ninth Edition," 1987

Belanger, R., Buckley, D. W., and Swenson, J. B., NUREG/CR-1156 "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979

Buckley, D. W., Belanger, R., Martin, P. E., Nicholaw, K. M., and Swenson, J. B., 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

Shigley, J. E., and Mitchell, L. D., "Mechanical Engineering Design, Fourth Edition," 1983

Shreir, L. L., "Corrosion, Volume 1, Metal/Environment Reactions," 1976

Willems, N., Easley, J. T., and Rolfe, S. T., "Strength of Materials," 1981

Appendix E: Industry and Consensus Standards

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)	"Radionuclide 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 - 1977	"Recommendation for Ionization Chamber Smoke Detectors in Implementations of Radiation Protection Standards"
Sources (General):		
	ANSI N43.6-1997	"Sealed Radiation Sources, Classification"
	ISO 2919-1980(E)	"Sealed Radiation Sources, Classification"
	ANSI N542-1977 (renamed ANSI N43.6-1977 in 1989)	"Sealed Radiation Sources, Classification" - (Revision of ANSI N5.10-1968) superceded by ANSI N43.6-1997
	ANSI N5.10-1968	"Sealed Radiation Sources, Classification" superceded by ANSI N542-1977
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 No.49	"Structural Shielding Design and evaluation for Medical use of X-Rays and Gamma Rays of Energies up to 10 MeV"

Appendix F: Standard Registration Certificate Formats

Standard Registration Certificate Formats

Registry of Radioactive Sealed Sources and Devices

Safety Evaluation of Sealed Source

(Amended in its Entirety)

NO.: OH-*-S-***-S DATE: PAGE 1 of 5**

SOURCE TYPE: *Short description of the source type*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR:	*Name* *Street* *City, State Zip* *(if 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 the same.)*
ISOTOPE: *List Isotopes*	**MAXIMUM ACTIVITY:** *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* Appendix C
CUSTOM SOURCE:	___Yes ___X___ No

CUSTOM USER:	*Name* *Street* *City, State Zip* *(delete entire subsection if not applicable)*

NO.: OH-***-S-***-S **DATE:** **PAGE 2 OF 5**

SOURCE TYPE: *Short description of the source type.*

DESCRIPTION: *Provide the complete description of the source.*

LABELING:

The source is engraved with the radiation symbol, 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 N43.6-1997 classification, 97C00000.

PROTOTYPE TESTING:

A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N43.6-1997 and achieved a classification of 97C00000.

NO.: OH-***-S-***-S **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 CONTROL:

XXXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by the Department. 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 NRC or an Agreement State.*

- *The device shall only be used by the custom user listed in this certificate, XXXXX.*

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*

NO.: OH-*-S-***-S DATE: PAGE 4 OF 5**

SOURCE TYPE: *Short description of the source type.*

- *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 0.005 microcurie (185 Bq) of removable contamination.*

- *The source shall not be subjected to conditions that exceed its ANSI N43.6-1997 classification, 97C00000.*

- *This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.*

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 its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

NO.: OH-*-S-***-S DATE: PAGE 5 OF 5**

SOURCE TYPE: *Short description of the source type.*

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.

- *'s application dated December 25, 0000, with enclosures thereto.*

- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*

- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

Ohio Department of Health - Bureau of Radiation Protection

Date: _____ **Reviewer:** _____

Name of 1st Reviewer

Date: _____ **Concurrence:** _____

Name of 2nd Reviewer

NO.: OH-*-S-***-S DATE: ATTACHMENT 1**
NO.: OH-*-D-***-X DATE: PAGE 1 OF 8**
DEVICE TYPE: *Short description of the source type*
MODEL: *ABC*

MANUFACTURER /DISTRIBUTOR: *Name*
Street
City, State Zip
(if 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 the 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* Appendix C
CUSTOM SOURCE:	___Yes _X_ No
CUSTOM USER:	*Name* *Street* *City, State Zip* *(delete entire subsection if not applicable)*

NO.: OH-***-D-***-X DATE: PAGE 2 OF 8

DEVICE TYPE: *Short description of the source type.*

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 10 CFR 20.1901 as referenced in OAC 3701-39-021. The labels contain the radiation symbol, 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 in accordance with 10 CFR 32.51 as referenced in OAC 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 measuring. . .
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 XXXX at their XXXXX CITY, ST facility.

DEVICE TYPE: *Short description of the device type.*

CONDITIONS OF NORMAL USE (Cont.):

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurement 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	*NE C Division 2 hazardous area possible*
Explosion.	*NEC Division 2 hazardous area possible*

PROTOTYPE TESTING:

A prototype of the Model XXXX 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 Mechanical	*Operated by a pneumatic cylinder for a total of 9320 OFF/ON cycles.*
Impact	*Dropped three times from a height of 4 feet.*
Penetration	*Dropped a 13 pound (5.9 kg), 1-1/4" (3.2 cm) diameter steel rod from a height of 40" (102 cm).*

DEVICE TYPE: *Short description of the device type.*

PROTOTYPE TESTING (Cont.):

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 sources used in the device have been tested by their manufacturers and have achieved the following ANSI {N43.6-1997, N542-1977, or 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 ANSI N43.6-1997 classification of 97C00000.
The sealed source contained in the device has achieved an ANSI N542-1977 classification of 77C00000.
The sealed source contained in the device has achieved an ANSI N5.10-1968 classification of C00000.

EXTERNAL RADIATION LEVELS:

XXXXXXXXX reports that the radiation levels from the device are not discernable from background.
XXXXXXXXX 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.
The following dose rates were reported by the manufacturer for the Model ABC transmission gauge containing a 1.0 curie (37 GBq) of Am-241 sealed source:

NO.: OH-***-D-***-X **DATE:** **PAGE 5 OF 8**
DEVICE TYPE: *Short description of the device type.*
EXTERNAL RADIATION LEVELS (Cont.):
Table 1

		Maximum Radiation Level			
Distance		*From Window*		*From Sidewall/Back*	
(inches)	*(cm)*	*(mR/hr)*	*(mSv/hr)*	*(mR/hr)*	*(mSv/hr)*
1.97	*5*				
11.81	*30*				
39.37	*100*				

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

QUALITY ASSURANCE AND CONTROL:

XXXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by the Department . 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 NRC or an Agreement State.*
- *The device may be distributed to specific or general licensees of NRC or an Agreement State.*
- *The device shall be distributed to persons generally licensed by the NRC or an*

Agreement State.

- *The device shall only be distributed to the custom user, XXXXX.*

NO.: OH-***-D-***-X DATE: PAGE 6 OF 8
DEVICE TYPE: *Short description of the device type.*
LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *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 10 CFR 31.5* as referenced in OAC 3701-39-021.

- *The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.*

- *The Model XXXXXX sealed source is approved by the Department for use in the Model ABC. 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 registration sheet and the information contained within the references shall not be changed without the written consent of the Department.*

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.*

NO.: OH-***-D-***-X DATE: PAGE 7 OF 8
DEVICE TYPE: *Short description of the device type.*
SAFETY ANALYSIS SUMMARY (Cont.):

- *Under ordinary conditions of handling, storage, and use of the device, the byproduct 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 of the limits specified in Section 20.1201(a), 10 CFR*

Part 20.

- *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:*

PART OF BODY	*DOSE*
Whole body; head and trunk; active blood-forming organs; gonads; or lens of 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 ABC, and the information and test data cited below, we {continue to} conclude that the device is acceptable for licensing purposes. Furthermore, we {continue to} conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

DEVICE TYPE: *Short description of the device type.*

REFERENCES:

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

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

Ohio Department of Health - Bureau of Radiation Protection

ISSUING AGENCY:

Ohio Department of Health - Bureau of Radiation Protection

Date: _____ **Reviewer:** _____

Name of 1st Reviewer

Date: _____ Concurrence: _____

_____

Name of 2nd Reviewer

NO.: OH-***-D-***-X DATE: ATTACHMENT 1

NO.: OH-***-D-***-X DATE: ATTACHMENT 2

NO.: OH-***-D-***-E DATE: PAGE 1 OF 2
DEVICE TYPE: *Smoke Detector/Gun Sight*
MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR:	*Name* *Street* *City, State Zip* *(if 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 the same.)*
SEALED SOURCE MODEL DESIGNATION:	*ACME Model 123*
ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	*1.0 microcurie (37 kBq)*
Hydrogen-3	*60 millicuries (2.2 GBq)*
	Not Required
LEAK TEST FREQUENCY:	(P) Ion Generator, Smoke Detectors (W) Self-Luminous Light Sources
PRINCIPAL USE:	___Yes __X__ No
CUSTOM DEVICE:	

NO.: OH-***-D-***-E DATE: PAGE 2 OF 2

DEVICE TYPE: *Smoke Detector/Gun Sight*

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 smoke detectors/gun sights are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

ISSUING AGENCY:

Ohio Department of Health - Bureau of Radiation Protection

Date: _____ **Reviewer:** _____

Name of 1st Reviewer

Date: _____ **Concurrence:** _____

Name of 2nd Reviewer

Appendix G: Assigning Registration Certificate Numbers

Assigning Registration Certificate Numbers

Each registration certificate has a unique registration number. The registration number consists of either 10 or 11 characters as described below:

OH-XXXX-D-YYY-S

Agency Code (OH): A two-letter abbreviation of the agency issuing the certificate. All certificates issued by the Department have OH as the Agency Code.

Vendor Code (XXXX): Each vendor (manufacturer or distributor) is assigned a unique three-digit number (the number may be four-digits). The vendor code used for the registration certificate number will be the vendor code for the distributor. If the company is out of business or no longer has an active registration certificate, the vendor code will between 800 and 1000 or between 8000 and 9000. The NRC maintains the listing of vendor codes and issues new vendor codes.

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

Unit Number (YYY): A separate series of three-digit numbers assigned to registration certificates for each vendor. These numbers are assigned in sequential order starting with 101 for active registration certificates and starting with 801 for inactive registration certificates. A new registration for an existing vendor is assigned the next available unit number. The issuance of unit numbers is typically controlled by the agency that regulates the vendor.

License Code (S): 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.

OHIO DEPARTMENT OF HEALTH
BUREAU OF RADIATION PROTECTION

TRAINING PROGRAM
FOR
HEALTH PHYSICS PERSONNEL

Rev. 4
Effective Date: 7 April 1999

OHIO DEPARTMENT OF HEALTH
BUREAU OF RADIATION PROTECTION

Training Program for Health Physicist

DISCUSSION

Staff members of the Bureau of Radiation Protection, including all categories of health physics personnel, e.g., HP-I, HP-II, and HP-III, who are participants in the state of Ohio and the U.S. Nuclear Regulatory Commission's Agreement State Program and who report to any of the following:

- Licensing Supervisor, Nuclear Materials Safety section;
- Medical Inspection Supervisor, Nuclear Materials Safety section;
- Non-Medical Inspection Supervisor, Nuclear Materials Safety section;
- Technical Services Manager; or
- Decommissioning Supervisor,

shall meet similar training and qualification requirements as those required to qualify to the minimum qualification of U.S. NRC Inspectors.

The Technical Services staff will be trained and qualified by a formal *Training Program for Health Physicists* and the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" as detailed later in this document. Currently, the full staff compliment for the Technical Services section are employed and qualified. This staff shall ensure no backlog of activities under their purview develop, based on the current workload.

The Bureau's training program to qualify staff consists of the following four elements:

- Completion of the in-house Core-training courses specified in this document;

- Completion of all required qualifications as outlined in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" as these qualifications apply to each position within the Agreement State Program;

Training Program for Health Physicist

- Completion of on-the-job training in license reviews and/or inspections by category including accompaniment with a mentor and/or NRC inspector. There is no expectation that NRC accompaniment in and of itself will result in supervisory sign-off or lead to an interim qualification.

  Typically, at least three inspections must be reviewed by the mentor in each category prior to submission to the supervisor. In a similar manner, three licenses in each category must be reviewed and/or analyzed before submission to the supervisor for sign off. In an inspection situation the supervisor typically accompanies the inspector in the field for the purpose of category sign-off. Individuals may be accelerated through the qualification program with a demonstration of superior experience; and

- Completion of NRC training courses. Particular emphasis is placed on the completion of inspection and licensing courses. NRC Training is divided into courses that are required for all Agreement State staff personnel (Core Training) and courses that would supplement a staff members education and training level (supplemental training). Core training courses that are suggested for State of Ohio Agreement State Program staff include:

  - G-108, *Inspection Procedures*;
  - G-109, *Licensing Practices and Procedures*;
  - G-205, *Root Cause/Incident Investigation Workshop*;
  - G-304, *Inspecting for Performance - Materials Version*;

  Supplemental courses that are suggested for Licensing (L), Inspection (I) and Decommissioning (D) staff within the Agreement State Program include:

  - H-120, *Radiological Surveys in Support of Decommissioning* (D);
  - H-121, *Multi-Agency Radiation Survey and Site Investigation Manual (D)*;
  - H-304, *Diagnostic and Therapeutic Nuclear Medicine* (L/I);

Training Program for Health Physicist

- H-305, *Safety Aspects of Industrial Radiography* (I);
- H-312, *Internal Dosimetry and Whole Body Counting* (D/L/I);
- H-313, *Teletherapy and Brachytherapy* (L/I);
- H-314, *Safety Aspects of Well Logging* (I);
- H-315, *Irradiator Technology* (L/I).

Supplemental courses recommended for Sealed Source and Device (SS&D) staff are:

- H-304, *Diagnostic and Therapeutic Nuclear Medicine*
- H-305, *Safety Aspects of Industrial Radiography*
- H-313, *Teletherapy and Brachytherapy*
- H-314, *Safety Aspects of Well Logging*
- H-315, *Irradiator Technology*

Professional staff in the Agreement State Program are required to meet the qualifications listed in their position descriptions prior to employment. In addition, staff must also meet additional training and qualification requirements as specified in the Bureau of Radiation Protection *Training Program for Health Physics Personnel* and the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" specified in the application for Agreement State status.

It is the ultimate goal of the Bureau to ensure that staff involved in the Agreement State, which includes the staff members outlined in the attached Table of Organization under the Licensing Supervisor, the Medical Inspection Supervisor, the Non-medical Inspection Supervisor, and the Decommissioning Supervisor will meet the criteria of these four elements as outlined above to be qualified for signature authority for license issue, inspections and inspection report generation and for decommissioning activities. At the signing of the Agreement, a sufficient number of trained, qualified staff shall be employed by the Department to ensure that all assigned Agreement State Program activities are conducted in a timely manner that would preclude any backlog of activities from developing.

Training Program for Health Physicist

This Training Program shall allow the full development of the staff member as a health physicist and to provide the necessary means to provide for upward mobility within the Bureau and the Department. Staff members must therefore be knowledgeable of:

- Radiation Protection fundamentals;

- the facilities, processes, and activities for those areas they inspect, license or provide enforcement actions for; and

- the criteria, techniques, and mechanics of inspections, licensing and enforcement activities.

They must be keenly aware of the possibility of adversely affecting safety or the operational status of the licensee if the work performance process involved in their evaluation of the licensee is allowed to become overly intrusive in areas of licensee operation where problems are not or have not occurred. In addition, staff member must be sensitized to the types of situations that have the potential for negative impact on the licensee.

Newly hired personnel seldom possess all these required qualifications. Therefore, formal classroom, self study, and on-the-job training (OJT) are imperative to ensure that the newly hired staff member gains the required knowledge and understanding necessary to be qualified to implement the Department's Agreement State program.

Mission Statement for the Training and Qualification Program for Health Physicist

The State of Ohio, Bureau of Radiation Protection, within the confines of the Department of Health, shall have one program goal of providing highly trained, qualified personnel for Health Physics/Radiation Protection activities and work evolutions.

The acceptance of a state by the U. S. Nuclear Regulatory Commission as an Agreement State is codified by the Atomic Energy Act of 1954, as amended, Section 274 (PL 86-373 (73 Stat. 688) to

Training Program for Health Physicist

"recognize the interests of the states in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this Act of the states and the Commission with respect to the regulation of byproduct, source and special nuclear materials;"

Whenever radioactive materials or other radiation sources are received, used, possessed, transferred, installed, serviced, or disposed of under the guidance of the Agreement State program, appropriate training of Health Physics Personnel is required. Radiation hazards and the related training programs designed to control radiation exposure is part of an overall effective Radiation Protection Program. The subject of this document is training rather than education. Training is linked to the instruction and practice that are required to develop job related skills or modes of behavior, while education, which may include training, implies achievement of a greater degree of understanding. Scientists and engineers receive training as part of their education. Health Physicists are part of the overall group called scientist and engineers. However well educated, instructions for specific job requirements are necessary for these individuals to allow for the greatest growth potential and effectiveness while on the job.

This program shall be designed to ensure that personnel are trained and qualified to allow for the maximum in safety on the job, provide a better and more secure baseline for decision making capability and to provide for a better possibility of promotion making upward mobility a success. This Training Program shall not, by intent or purpose, isolate or eliminate personnel from classifications or job positions. Training provided by the requirements of this program shall be made available to all Bureau of Radiation Protection staff.

There are at least three important reasons for training.

- The first is the development of worker skills through training which permits the performance of tasks with greater efficiency and confidence.

- The second involves the active participation that the Health Physicist will develop to accept and when possible reduce risks as part of their job performance when he or she realizes

through training that some risk is associated with that job assignment. And

- third, the number and seriousness of accidents and mistakes can be reduced through training.

A Health Physicist is therefore likely to assist in maintaining all exposures as low as reasonably achievable when trained for both normal and off-normal situations.

Every job entails the acceptance of some risk. Many of these risks are obvious and easily recognized. Other hazards are more subtle and may not be recognized or appreciated without specific instruction. Radiation exposure and exposure to other hazardous materials are some of the subtle hazards. A person may be exposed to significant levels of radiation or to hazardous levels of environmental pollutants without knowledge until exposure levels greatly exceed regulatory standards. For these reasons, instruction in radiation protection and hazardous materials operations and an understanding of the occupational risks of work at sites contaminated with these materials are essential.

Training Program for Health Physicist

STAFF MEMBER QUALIFICATION[1]

The Agreement State Program area personnel are required to understand the facilities, equipment, processes, and activities of the programs they are tasked with licensing or inspecting, as well as the criteria, techniques, and mechanics of inspection and licensing. The training and qualification process, as outlined in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure", is intended to provide inspectors, license reviewers and decommissioning staff who must also qualify as an inspector or license reviewer, with sufficient information to conduct inspections and license reviews that are technically correct and in accordance with State of Ohio statutes, rules, policies, orders and procedures.

Professional staff assigned as inspectors or license reviewers in the Agreement State Program area shall successfully complete the requirements for their individual inspection or licensing areas as indicated in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure". Individuals who inspect facilities being decommissioned must qualify as a Decommissioning Inspector in accordance with the aforementioned document. In addition to the formal requirements of the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure", professional staff shall also successfully complete the Core-Training program outlined in the details section of *this Training Program.* Any special assignments requiring specific training (e.g. SS&D review) shall have additional specific requirements outlined.

Staff will, on an as-needed basis only receive an interim qualification issued by the Bureau Chief, Radiation Protection, to qualify that person for license review, inspections of facilities or handlers or decommissioning based on education, experience, training and a review of accomplishments. The

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[1] The text for this section is quoted verbatim, excluding changing Nuclear Regulatory Commission to Department of Health when required to ensure compatibility with the Department's needs from the Nuclear Regulatory Commission *Fundamentals of Inspection* Training Course Document. (Nuclear Regulatory Commission Technical Training Document - *Fundamentals of Inspection Course Manual* - Rev. 0993)

Training Program for Health Physicist

Bureau Chief is the authorized approval authority for qualification (certification) of Bureau Professional Staff members as License Reviewers, Inspectors, SS&D reviewers, or Decommissioning Inspectors. The Bureau Chief shall work closely with the appropriate supervisor of the various aspects of the Agreement State Program to ensure that staff are qualified in a timely manner and that the qualification of the staff is maintained current.

The types of licenses and facilities eligible for inspection by staff are specified in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure".

QUALIFICATION REQUIREMENTS

Each staff member associated with the Agreement State program must complete the appropriate required training outlined in Appendix D (as derived from Appendix A to the U.S. NRC Inspection Manual Chapter (IMC) 1245), complete and submit appropriate documentation in the form of a qualification journal implemented as identified in Appendix E (as derived from Appendix B to IMC 1245) or verify through successful completion of a written and department approved equivalency examination that the desired level of knowledge in a particular specialty area has been obtained. In the event that a staff member has completed a major portion of the training or equivalency, but has not completed all the requirements, and that staff member is considered by Bureau management and supervision and the Bureau Chief concurs with this determination, then the Bureau Chief, may, upon successful completion of these criteria grant an interim qualification to that staff member for certain tasks and duties to which he/she has demonstrated adequate knowledge and training.

Training requirements for new staff members will be documented and a qualification journal implemented as identified in Appendix E (as derived from Appendix B to IMC 1245). New staff members shall be assigned to work with a mentor, a senior staff member who is fully qualifed to assist the new staff member to attain full qualification in a timely and effective manner. Completion of a formal training program and the qualification journal constitutes the minimum staff member qualification requirements and encompasses regulatory, administrative and technical practices pertinent to each area of work practices required by the Agreement State Program.

Training Program for Health Physicist

Once a staff member has completed the formal and on-the-job training, the staff member will be evaluated by Supervisory Sign-off[2] and by successfully completing an "oral board" qualification examination[3]. Successful completion of the Supervisory Sign-off results in the formal certification of a staff member as a "qualified Agreement State Health Physics Professional.[4]"

POLICY STATEMENT - U. S. NUCLEAR REGULATORY COMMISSION April 30, 1992

The following section describes the requirements of the U. S. Nuclear Regulatory Commission for qualification of personnel to serve as inspectors, licensing specialists and enforcement specialists in the Agreement State program as defined in the Atomic Energy Act of 1954, as amended, Section 274 (42USC2021).

This U.S. NRC policy statement is published as a final rule in 46FR7540, 1/23/81, effective 1/23/81, amended by PS published 7/16/81 (46 FR 36969) and 7/21/83 (48 FR 33376).

The following criteria for personnel qualification is established in this document:

Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States through Agreement

Item 20 Personnel

Qualifications of Regulatory and Inspection Personnel.

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2 Supervisory signoff is defined as a face-to-face meeting between the staff member, the mentor, the staff member's immediate supervisor, and any invited management personnel whose contribution to the sign-off meeting is deemed appropo by the supervisor or mentor. Completion of the face-to-face meeting preceeds the completion of the competency portion of the qualification journal.

3 The oral qualification board assesses the qualifications of an individual to conduct Agreement State activities. The oral qualification board is described in a later section of this document.

4 This term, "qualified Agreement State Health Physics Professional", is not a formal term as used in a Department Position Description, but is used to confer qualification or certification status to a staff member who has completed the required training program specified in this document.

Training Program for Health Physicist

The regulatory agency shall be staffed with sufficient, trained personnel. Prior evaluation of applications for licenses or authorizations and inspection of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments -- their selection, use and calibration -- laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics, and engineering, and that the personnel have had training and experiences in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source, and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training - radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform day to day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These persons should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used to initially evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection.

In determining the requirement for academic training of individuals in all of the foregoing categories proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

ADDITIONAL GUIDANCE - QUALIFICATIONS OF PERSONNEL

Additional guidance is provided by the U.S. NRC for qualification of Agreement State personnel in 59 FR 37272 published 7/21/94, Section III, *Policy Statement*, Paragraph B.5. - "Elements of an

Adequate Program/'Staffing and Personnel Qualifications'" which reads[5]:

> "The regulatory agency shall be sufficiently staffed with an adequate number of qualified personnel to implement the radiation control program effectively. Agreement State staff shall be qualified using criteria no less stringent than criteria used for NRC staff."

Competency and Knowledge

A professional person is a technically competent individual in the field of his or her specialty. In addition, many professionals work within the framework of the policies and programs of an institution, company or government organization, To be fully successful as a professional under such circumstances, the individual must acquire detailed knowledge of the policies and programs of that entity. In the Department, it is especially important that the staff member maintain current technical and program knowledge so that he or she may deal effectively with counterparts in licensee organizations.

Technical Knowledge

A Bureau health physicist involved in the Agreement State Program shall possess a specialized body of knowledge in engineering, physical science or a combination of physical and biological science, such as health physics.[6] To acquire this knowledge, the staff member shall have obtained a minimum of a bachelor's degree from a recognized university and/or received extensive training in the

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5 This text is taken verbatim from the referenced Federal Register sections.

6 The text for this section and much of this document is taken as closely to verbatim as possible, excluding Changing Nuclear Regulatory Commission to Department of Health when required to ensure compatibility with the Department's needs from the Nuclear Regulatory Commission *Fundamentals of Inspection* Training Course Document. Requirements expressed for Technical and Programmatic Competence, Job Performance, and Objectivity are those requirements that are met by Nuclear Regulatory Commission Staff personnel. (Nuclear Regulatory Commission Technical Training Document - *Fundamentals of Inspection Course Manual* - Rev. 0993)

technology combined with practical experience.

However, that acquired knowledge becomes obsolete in today's rapidly changing world unless the staff member makes an effort to keep up to date with new technical knowledge as it becomes available. The staff member can meet the need by reading technical journals, participating in technical societies, taking short courses, or some combination of these activities.

In addition, in order to make acceptable conclusions regarding the safety significance of an issue, the staff member must understand the reactor, radioactive materials, or fuel facility technology with which he or she is dealing, including potential accident scenarios and how system design, operating and emergency procedures, and other safety features would prevent and/or mitigate the various classes of accidents. To keep up to date in this area, an inspector should be familiar with the safety experience of the category he/she inspects. This is usually done through review of licensee event reports, meetings to discuss licensee experience, and careful reading of NRC information notices, bulletins and reports of studies performed by the NRC Office for Analysis and Evaluation of Operational Data (AEOD).

Program Knowledge

While being a competent professional in terms of academic and technological knowledge is important, the staff member can succeed only if he/she possess detailed knowledge of the Department's policies and programs dealing with licensing, inspection, and enforcement. Initially, this knowledge is acquired through the orientation and training program for new staff personnel, but as time goes on, the regulations are revised and new rules established, policies are established or modified, and new approaches are adopted. In order to be current in the program area, a staff member shall become familiar with changes in statutes, rules, recent "NUREG" documents, and regulatory guides, including those activities generated by the NRC that affect the Agreement State Program in Ohio, Department decisions, and new or revised inspection procedures and temporary instructions.

The staff member also needs to maintain general knowledge of other Department programs and

policies outside of the one in which he/she is working. Such knowledge enables a staff member to put his/her efforts into better prospective and to represent the Department more effectively in contacts with licensees and the general public. Examples of topics that fall into the general knowledge category are the State relations/agreements program, AEOD studies, and assessment of inspection/enforcement fees on licensees.

Training Program for Health Physicist

1.0 SCOPE

This program provides criteria for the selection, training and qualification of personnel for assignment as Health Physicist 1, Health Physicist 2 and Health Physicist 3 for the Ohio Department of Health (ODH), Bureau of Radiation Protection (BRP). With the advent of Agreement State status, the criteria for selection, qualification and training of Health Physics personnel is being directed along those lines specified and approved by the Nuclear Regulatory Commission in various documents including:

- *Summary of the U.S. Nuclear Regulatory Commission's Agreement State Program*, June 1992;
- The Atomic Energy Act of 1954, as amended, Section 274;
- 46FR7540, *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*;
- 57FR22495. *NRC Review of Agreement State Radiation Control Programs; Final General Statement of Policy*;
- 59FR37269, *Adequacy and Compatibility for NRC and Agreement State Radiation Control Programs Necessary to Protect Public Health and Safety; Draft Statement of Policy*;
- State Agreement Program, Division I, Internal Procedures, Appendix 2, B. *Policy*, B.7 - *Criteria for Compatibility Determinations*;
- Title 10 Code of Federal Regulations Part 20, *Standards for Protection Against Radiation*
- Title 10 Code of Federal Regulations Part 61, *Licensing Requirements for Land Disposal of Radioactive Waste*
- NUREG 1199, *Standard Format and Content of a License Application for a Low-level Radioactive Waste Disposal Facility*, Section 8.3
- NUREG 1220, *Training Review and Criteria*
- Regulatory Guide (Reg Guide or RG) 1.8 - 1987, "*Qualification and Training of Personnel for Nuclear Power Plants*". This Reg. Guide describes a method acceptable to the NRC staff for complying with those portions of the Commission's regulations with regard to the training and qualifications of nuclear power plant personnel [and personnel covered under Title 10,

Code of Federal Regulations Part 50, "*Domestic Licensing of Production and Utilization Facilities*".

- NRC Management Directive 5.6, "*Integrated Materials Performance Evaluation*"

The qualifications of personnel for specified positions with the Bureau of Radiation Protection, Nuclear Material Safety Section, Technical Services Section, and the Environmental Radiation Safety Section are specified in developed and approved Job Position Descriptions for those positions.

The Bureau of Radiation Protection Training Program for Health Physics personnel shall consist of several separate components: Initial (Core-Training) Training for personnel hired into Health Physicist positions, retraining for all Bureau Health Physics personnel, Continuing Training for personnel in Health Physicist 2 and 3, Supervisor Health Physics and Program Administrator positions, Specialized Training and Detailed Training Tasks. Training conducted under the auspices of this training program shall consist of training conducted:

- in-house by personnel qualified by letter by the Bureau Chief - Bureau of Radiation Protection;
- within the Department of Health (ODH), under the auspices of the Training Department, ODH;
- Outside the auspices of the ODH, via training by the NRC, EPA, DOE, or other organizations, including training by consulting organizations contracted to the ODH/BRP;
- within the Bureau by contract personnel experienced in the requirements of the program or training sessions offered.

This Program will provide for overall training descriptions. Specific Training Requirements (SRT) for Health Physicist Job Position shall be described in Appendices to this Program.

2.0 PURPOSE

Training Program for Health Physicist

The program is designed to provide guidelines for training for personnel to achieve initial qualification as an Health Physicist (Levels 1, 2, and 3) through formal classroom and on-the-job training. The program shall also identify mandatory and optional requirements for Health Physics personnel after achieving initial qualification status. The Program shall also provide for additional training opportunities for the experienced Health Physicist in identified specialty areas, i.e., Hazardous Waste Operations and Emergency Response (HAZWOPER), low-level radioactive waste handling, processing, storage and transportation, etc.

Each section shall apply this Program to the functional levels and job descriptions described in the appropriate appendix to this Program. This Program is not intended to prescribe specific job titles or responsibilities of organizational positions. Each section is required to define its organizational structure, responsibilities of individuals within the operating section. These organizational responsibilities shall provide guidance for specific training described in the Appendices to this Program. Qualification requirements including education, experience and training shall be defined as derived from appropriate Regulatory references (see Section 10.0 - References). This program requires a systematic approach to training based on an analysis of the performance required for each Ohio Department of Health, Bureau of Radiation Protection Classification Specification and as such does not prescribe specific training content.

3.0 DEFINITIONS

Certification - Documented confirmation by an individual or group of the successful completion of a qualification program. Confirmation shall be by an individual or group other than the individual that provided the training.

Collective Qualifications - Sum of individual qualifications for the people of the functional level in the organization.

Education - Successful completion of the requirements established by an accredited educational institution.

Training Program for Health Physicist

Experience - Application work in Health Physics or Radiation Protection in design, construction, preoperation, and startup/testing activities, operations, maintenance, onsite activities or technical services. Observation of others performing work is not experience.

Interim Qualification - Qualification of an Agreement State Professional Staff member to conduct independent activities associated with the Agreement State in specified areas before completion of all qualification journal requirements.

Job Analysis - The analysis process used to determine the performance areas and tasks comprising a particular job.

NARM (Naturally Occuring and Accelerator Produced Radioactive Materials) - Radioactive Materials that are found in nature, such as Uranium, Thorium, Radium and its daughter products and Radioactive Materials produced by particle accelerators.

Nuclear Facility - As used in this Program, a nuclear facility is a nuclear power plant, nuclear naval shipyard, facility involved in the Uranium fuel cycle, nuclear test reactor or research facility, or any NRC licensed facility involved in the handling, processing, storage or shipping of by-product, source or special nuclear material.

Operating Section - The ODH section which has overall legal, financial and technical responsibility for Health Physics activities in one or more processes within the Bureau of Radiation Protection.

Participation - To take an active role in the duties and responsibilities relative to the function for which the candidate is being considered. Simple observation is not considered participation.

Process - The ODH Operating Section divisional category responsible for providing Health Physics personnel for Oversight, sampling, licensing, coordination, review, data validation and verification, surveying, and providing general Radiation Protection guidance under a common program.

Qualification - The combination of knowledge, skill and ability required to meet specific job performance criteria. This is synonymous to "certified".

Shall, Should and **May** - The work "Shall" is used to denote a requirement; the work "Should" is used to denote a recommendation; and, the word "May" is used to denote permission, neither a requirement nor a recommendation.

Systematic Approach to Training (SAT) - A documented Training Program that outlines requirements for Job/Task Analysis (JTA), developed Lesson Plans utilizing Enabling Objectives and Terminal Objectives for determining JTA compliance, developed student handouts, detailed Visual and Learning Aids, and Examinations. Included in the SAT is the requirement for the development and conduct of written and/or oral boards for qualification of personnel. These examinations shall meet the requirements developed in Enabling and Terminal Objectives for each JTA identified in the developed Lesson Plan.

Task Analysis - The systematic process to identify conditions, standards, elements, and required skills or knowledge to perform a task.

Task - A well defined unit of work having an identifiable beginning and end and is a measurable function of the job duties and responsibilities.

Training - Instructional program designed to develop or improve on-the-job-performance.

4.0 FUNCTIONAL LEVELS AND ASSIGNMENT OF RESPONSIBILITY

The Bureau of Radiation Protection is divided into four sections, Nuclear Material Safety, Technical Services, Decommissioning and Radiological Assistance. These four sections are further divided into Operating Processes as follows:

Training Program for Health Physicist

Each of the sections listed above has definitive tasks and assignments, with several of the sections having overlapping responsibilities for the Agreement State Program.

The Radiological Assistance section is also mentioned in this document, however the Radiological Assistance section is not responsible for any aspect of the overall Agreement State Program.

The **Technical Services** section consists of three staff members, including the Manager of Technical Services as the Radiation Safety Officer and two staff health physicists.

The Technical Services section interfaces with the Agreement State Program by providing:

- technical assistance;
- review of technical documents;
- development of rules pertaining to the Agreement State Program, nuclear material safety and decommissioning, and operational programs;
- development and implementation of implementing procedures;
- review of recently released NRC rules and regulations for incorporation into the Agreement State rules, policies, programs, and procedures;
- review and evaluation of sealed sources and devices for inclusion in the NRC Sealed Source and Device Registration database. The Technical Services section shall also be tasked with review and evaluation for approval of any contractual assistance required in this area;
- preparation of work instructions and inspection checklists; and

- development, testing, implementation, and updating other necessary documents to assist in an orderly, effective program for the regulatory oversight of radioactive materials.

The Technical Services section also provides oversight of the radioactive waste program (low-level radioactive waste, high level radioactive waste, and all radioactive materials transportation issues as well as any special projects requested by Bureau management or the Radiation Advisory Council).

At this time, Ohio will not site and regulate a regional low-level radioactive waste disposal facility; however, Ohio has requested the authority to do so in the Agreement State application. If a commercial low-level radioactive disposal facility is to be sited, Ohio estimates that four Health Physicist III positions plus a program supervisor will be required to staff the regulatory aspects of that facility. The fee rule (OAC 3701-38-021) already provides for this funding capacity through full cost recovery for a facility of this type.

Radiological Instrumentation is also the responsibility of Technical Services, requires staff to be responsible for:

- the inventory;
- maintenance;
- calibration; and
- issuance of instruments

used by technical professional health physicists in their day-to-day activities. Other RSO functions include personnel dosimetry, and the control of sources possessed by the Bureau. The Technical Services section also provides training materials development, trainers, and other support functions for in-house training.

Finally, the Technical Services section houses the Quality Assurance and Quality Control

functions for the Bureau. This area of responsibility includes, but is not limited to, the planning and conduct of:

- audits;
- inspections;
- surveillances;
- reviews; and
- observations of activities involving the licensing and inspections areas of the Agreement State Program.

The **Nuclear Materials Safety** section consists of several areas all of which are involved directly in the Agreement State Program. These areas are licensing of radioactive materials, inspection of facilities and handlers of radioactive materials, enforcement of statutes and rules, and incident response.

A necessary step in determining the manpower requirements for the Agreement State Program is the determination of the available man-year[7] for conducting field and licensing activities. This available man-year is the basis for determining Full-Time Equivalents (FTEs) in the licensing, inspection, and decommissioning programs.

Licensing - the Licensing Section is composed of a licensing supervisor (currently vacant), three Health Physicist III (all filled positions) and two Health Physicist II professional staff members (both vacant). A high priority has been placed on filling the licensing supervisor position. Until this position is filled, the initial supervisory review of licenses following peer review at the staff level is being performed by the Medical Inspection Supervisor at the direction of the Bureau Chief. The majority of license reviews to date have been completed

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[7] A Man-year is determined by reducing a 52-week year for holidays(2 weeks), average vacation(2 weeks), sick leave(2 weeks), personal leave(0.8 weeks), and training(3.2 weeks). This leaves 42 weeks /year for conducting field and licensing-related activities.

in this manner. The Program Administrator provides a final review of all licenses for final signature by the Director of Health. This current method provides five FTE's for the purpose of reviewing license applications, license amendments, and license renewals.

To ensure adequate qualifications, four professional staff members are being sent to NRC - Region 3, one each during the months of July, August, September, and October for on-the-job training with NRC staff for license review. These staff have requested license training assistance with:

- irradiators;
- manufacturing and distribution broad scope;
- broad scope research and development;
- industrial radiography fixed and temporary job sites;
- well logging;
- teletherapy;
- high dose rate afterloaders; and
- mobile high dose rate afterloader licenses with NRC staff.

Specific requests have been made to NRC for individual staff members to receive various types of license review experience to provide the Bureau with an overall adequate base of knowledge in the licenses categories specified in this paragraph. The existing Licensing staff have collectively reviewed more than 100 license applications and, will be qualified on an interim basis to review:

- broad scope licenses (all categories);
- medical applications (all categories);
- gauges;
- source material and special nuclear material;
- irradiators; and
- well logging operations/industrial radiography,

by completion of the requirements of the appropriate sections of the attached "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" combined with selected NRC training courses, Ohio radioactive material license application review and issuance, NRC license review in Region 3, and specific in-house training.

New staff will be qualified by completion of the appropriate training areas as delineated in the attached "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure and by being mentored by a qualified Health Physicist III in gauges and non-QMP medical operations. This will allow these staff members to be qualified in those two areas by the time the agreement is signed.

The Licensing staff is also responsible for incident response activities. It is calculated that 150 person-days are committed to incident response with Licensing responsible for a total of 65 person-days response time (averaged over a period of one year with a calculated 75 incidents per year at 2 person-days per incident response which includes the development and issuance of an Incident Report).

The Licensing staff is responsible for on-site inspection activities to accompany the issuance of a license. This inspection responsibility enables each Licensing staff member to inspect the license applicant's facility to ensure the information provided in the license application is correct and accurate, particularly where radiation levels may impact the general public. As anticipated, more than one inspection could be conducted in a day if the facilities are in the same geographical area. Therefore, a man-hour estimate of 5 hours per inspection per license is anticipated for each new license issued. It is anticipated that the inspection activities will require a time expenditure of 145 person-hours per staff member per annum.

Inspections - The Inspection Section is divided into two groups: Medical Inspections and Non-Medical Inspections. In addition to assuming that the agreement becomes effective

Training Program for Health Physicist

January 31, 1999, the assumptions for the Inspection Program are detailed in the attached spreadsheet titled "Numbers of Licenses for Inspection". Each group has a designated supervisor, however, until a Non-Medical Supervisor is hired, the Inspection section is under the leadership of the Medical Inspection Supervisor serving in an interim position. The Inspection section is staffed as follows: Medical Inspections includes two Health Physicist III (one position vacant) and two Health Physicist II (one position filled and the second to report for work during July). The Non-Medical Section has one Health Physicist III, two Health Physicist II (one vacant), and two Health Physicist I staff members (one vacant).

Ohio has determined that we need the equivalent of two qualified inspectors for broad scope license inspection, including a primary inspector and a second inspector as back-up. This requirement is partially met (the medical broad scopes) and will be completely met through NRC accompaniment, in-house training, and subsequent ODH supervisory sign-off in the intervening period before signing of the agreement.

The Medical Inspection area is estimated to require the equivalent of four qualified inspectors which includes two primary inspectors and two additional inspectors as back-up. Ohio believes that the equivalent of two staff are fully qualified today with an additional two staff being qualified through NRC accompaniment, in-house training, and ODH supervisory sign-off in the intervening period before signing of the agreement.

Gauges are estimated to require the equivalent of two inspectors which includes a primary inspector and one additional inspector qualified as back-up. This requirement is met and will be expanded through NRC accompaniment in the period of time between submission of the application and signing of the agreement.

Well logging inspection will require two inspectors, including a primary inspector and one additional inspector as back-up. This requirement is currently met. Additional emphasis will be placed on this area to assure that inspection, as well as Licensing staff, are qualified in well logging through staff accompaniment and in-house training.

Training Program for Health Physicist

The staffing qualification is currently partially met for irradiators by a primary inspector. The staffing complement of two inspectors (one primary and one backup) will be met through a combination of NRC accompaniment plus on-the-job training at an irradiator in the Central Ohio area prior to signing of the agreement.

The inspectors for the remaining license types will be qualified through in-house training and on-the job training prior to the signing of the agreement as detailed in the attached "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure".

Staff who are hired between the submission of the final application and the signing of the agreement will be given the Ohio Core-Training program as outlined in a later section of this staffing plan document and by successful completion of NRC sponsored training courses, with emphasis on the licensing and inspection courses.

The Inspection staff is committed to performing 294 inspections per year, with an average man-day commitment of three days per inspection. This leads to a total commitment of 882 person-days per year for the Inspections staff.

In addition, the Inspection staff has committed (1) to perform reinspection at approximately 25% of all facilities due to deficiency reporting, unscheduled inspections, etc. (2) to supporting incident response with inspection staff for a calculated 150 person-days, a total of 65 person-days response time responsibility (averaged over a period of one year with a calculated 75 incidents per year at 2 person-days per response.)

Enforcement actions are also the responsibility of this section of the Bureau, however, no definite staff member is assigned for enforcement since this activity will be the purview of the Bureau as a whole, with final assignment of enforcement actions the responsibility of the Director of the Department of Health.

Training Program for Health Physicist

The **Decommissioning** Section consists of several independent sections including those facilities licensed under the Agreement State Program, Sites Decommissioning Management Plan (SDMP) facilities, Formerly Utilized Sites Remediation Action Program (FUSRAP) facilities, Formerly Utilized Defense Sites(FUDS), and Agreement in Principle (AIP) facilities. Although Ohio does not know of any sites contaminated with byproduct material as defined in Section 3748.01(A)(2) of the Revised Code (11.e.2 sites), staff in the Decommissioning Program would be called on to manage those sites if the need presented itself.

Decommissioning - The Decommissioning section is under the guidance of a Supervisor of Decommissioning. This supervisor has four Health Physicist III (two vacant positions) and two Health Physicist II (one vacant). Of these staff members, two HP III's are also responsible for work efforts involving U.S. DOE/U.S. EPA Superfund sites with partial support from another HP II. The three existing vacant positions are to be posted and filled by end of August or mid-September. This staffing level of six Health Physicists is predicated on the U.S. NRC assessment of their Decommissioning staffing commitments for contaminated sites in Ohio as indicated in a meeting with NRC staff held in Ohio on May 14, 1998.

All decommissioning staff, in addition to the Core-Training program outlined in a later section of this staffing plan, and the equivalent training for Decommissioning inspectors outlined in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" will also be provided with training in MARSSIM, decommissioning, and an approved radiological environmental sampling course. In addition, we plan to prepare staff through successful completion of the Core-Training program as outlined in a later section of this staffing plan, US EPA/DOE sponsored training courses and other NRC-training courses. Through these mechanisms, we will qualify all staff in the decommissioning program by the time the agreement is signed.

The **Radiological Assistance** section consists of three separate programs, the Indoor Radon

Program, Emergency Response for Fixed Nuclear Facilities (Nuclear Power Stations), and administration of emissions program for fixed nuclear power facilities in the State of Ohio. At this time, the Radiological Assistance section is not a part of the Agreement State Program and staff training and qualification for this section is not included in this *Staffing Plan.*

Within each of the sections, Health Physics personnel and non-health physics personnel i.e., clerical, public information, etc. shall be assigned. The requirements of this program apply only to personnel that are titled as Health Physicists (Classification Specification No.s 84641, 84642, and 84643) as described by the Ohio Department of Administrative Services Employment Services and Ohio Department of Health Human Resources and as covered by the Bargaining Units of OCSEA/AFSCME. Within the separate Processes, additional job/task specifications can be adopted such as, but not limited to, Radioactive Material Licensing Technician/Specialist, Radioactive Material Inspector, Decommissioning Inspector, Environmental Specialist, Contaminated Site Coordinator, etc.

The qualifications for Program Administrator, Health Physics Supervisor and Health Physicist are stated in this program. Collective qualifications for Program Administrator and Health Physics Supervisors shall exceed the sum of the minimum individual requirements described in this program.

Personnel who do not fully meet the requirements of this program may be temporarily assigned related duties within their current classification period for a period of up to three months. This temporary assignment should not be confused with Interim Qualification of an Agreement State professional staff member. Temporary Assignments shall not be used as a means of reducing the level of minimum collective qualifications as established by this program. The personnel filling positions due to the absence of a principal shall, as a minimum, possess the qualifications of that discipline.

When personnel are replaced, a reasonable amount of time should be provided so that the new personnel have an adequate understanding of their new duties and responsibilities prior to assuming these duties.

5.0 QUALIFICATION

Health Physics personnel (HPs) shall possess skills, knowledge, and abilities that are in accord with their responsibilities. This Program establishes minimum qualification and is intended to assure that adequate skills, knowledge and abilities exist in individuals and the collective staff. Qualifications are defined in terms of education, experience, training and special requirements (e.g., license or certificate).

The Bureau Chief - Bureau of Radiation Protection has the overall responsibility to ensure that minimum qualification criteria are established by an evaluation of the total organization. The need for specific skills, knowledge, and abilities differ for each level in the organization. At the higher functional level, managerial expertise as well as technical knowledge is a requirement, whereas technical competence is the dominant need at other functional levels. This shift in relative importance of managerial and technical competence shall be considered by management staff in establishing qualification requirements.

Program Administrator Qualifications

(This position includes the titles of Program Administrator - Nuclear Material Safety and Environmental Radiation Safety)

The functional level of Program Administrator provides intermediate management between the Supervisors and Bureau Chief. Typically, Program Administrators are responsible for the development and administration of programs and policies in their specified area. The Program Administrator implements programs and may have one or more Supervisors reporting to them. Education, experience and training requirements for individuals in the Program Administrator classification are specified below. An individual may be accepted for the position of Program Administrator if the individual meets the minimum requirements of that position.

Program Administrators responsible for management of the Radiation Protection program shall meet

or exceed the following minimum qualifications:

Education - Completion of college level course work equivalent to a bachelors degree in health physics, radiation physics, radiological sciences, engineering, physical sciences, or life sciences[8]

Experience - Minimum experience for the position:

Documented completion of the required training for the health physicist 3; or documented completion of equivalent course training (similar course titles, difficulty level, written test of class content, and certificate of completion).
Has had at least 8 years of full time work experience covering a wide range of radiation issues including licensing and inspection of radioactive materials and at least 2 years of this full time work experience must be in supervising staff in a complex radiation control program with equivalent tasks to those of an NRC agreement state program. This program can be within another state or federal agency, as the RSO of a large medical, industrial, or university that has a broad scope license for radiation and would include technical staff supervision within the radiation safety office. Experience in handling LLRW preferred.

Supervisor - Health Physics

(This position includes the Supervisory titles of Licensing Supervisor, Medical Inspection Supervisor, Non-medical Inspections Supervisor in the area of Nuclear Materials Safety, Supervisor - Decommissioning, Supervisor - Radiological Assessment, and/or Supervisor Health Physics LLRW)

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[8] This requirement is directed to meet the stated educational requirements established by the U.S. NRC for Agreement State Status - re: 59FR37269, 46FR7540, 57FR22495, et al.

Training Program for Health Physicist

The functional level of Supervisor - Health Physics is the first line of management and describes those individuals who direct the actions of Health Physicist 1, 2, and 3. Their duties include assuring work is performed in compliance with procedures, policies, and industrial safety practices.
Supervisors - Health Physics are responsible for supervision of the Radiation Protection activities and shall meet or exceed the following minimum qualifications:

Education - Completion of college level course work equivalent to a bachelors degree in health physics, radiation physics, radiological sciences, engineering, physical sciences, or life sciences

Experience - Minimum experience for the position:

Documented completion of the required training for the health physicist 3; or documented completion of equivalent course training (similar course titles, difficulty level, written test of class content, and certificate of completion).
Has had at least 6 years of full time work experience covering a wide range of radiation issues including licensing and inspection of radioactive materials and at least 1 years of this full time work experience must be in project management in a complex radiation control program with equivalent tasks to those of an NRC agreement state program. This program can be within another state or federal agency, as the RSO of a large medical, industrial, or university that has a broad scope license for radiation and would include technical staff supervision within the radiation safety office. Experience in handling LLRW preferred.

Health Physicist

(This position includes the classifications for HP1, HP2, HP3)

Health Physicist are responsible for the calibration, operation and performance of radiation protection

duties in completing assigned jobs and tasks related to their skill level. Individuals may perform work without the direction and observation of a qualified individual if they are qualified to perform these specific tasks.

HEALTH PHYSICIST 1

Education - Baccalaureate Degree in Health Physics, Radiological Sciences, engineering, physical sciences or life sciences.[5] (If degreed in unrelated field of study, must have additional 24 months experience with radiation, radioactive materials or radiological health safety.)

Experience - Minimum experience for the position

Applied Radiation Protection with 3 courses (or 6 months) experience in radiation theory.	6 months

Training - As specified in Section 7.0 "Training"

HEALTH PHYSICIST 2

Education - Baccalaureate Degree in Health Physics, Radiological Sciences, engineering, physical sciences or life sciences.[5] (If degreed in unrelated field of study, must have additional 24 months experience with radiation, radioactive materials or radiological health safety.)

Experience - Minimum experience for the position

Applied Radiation Protection	12 months

Training - As specified in Section 7.0 "Training"

Training Program for Health Physicist

HEALTH PHYSICIST 3

Education - Baccaluareate Degree in Health Physics, Radiological Sciences, engineering, physical sciences or life sciences. (If degreed in unrelated field of study, must have additional 36 months experience with radiation, radioactive materials or radiological health safety.)

Experience - Minimum experience for the position

Applied Radiation Protection	24 months

Training - As specified in Section 7.0 "Training"

SPECIAL AREAS

(A) SEALED SOURCE AND DEVICE REVIEW

This program is a part of the Technical Services Section but has very specific qualifications so it has been separated from the routine training program for all staff. Staff qualification to participate in the SS&D review program are those listed in management Directive 5.6 "*Integrated Materials Performance Evaluation Program*"

(1) Education and Training (for both initial and concurrence reviewers)

- Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences.
- Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal, and likely accidental conditions of use
- Understand and interpret test results
- Read and understand blueprints and drawings
- Understand how the device works and how safety features operate
- Understand and apply the appropriate regulations
- Understand the conditions of use

Training Program for Health Physicist

- ➢ Understand external dose rates, source activities, and nuclide chemical form
- ➢ Understand and utilize basic knowledge of engineering materials and their properties
- ➢ Review of incidents to detect possible manufacturing defects and the root causes of these incidents

(2) Training Assistance

(1) Prior to being assigned to perform and sign off on reviews, staff shall have an understanding of licensing, inspection, and incident response

(2) The individual will attend the SS&D workshop sponsored by NRC

(3) The individual will spend at least 2 weeks in on the job training at NRC headquarters, or at a state program under the auspices of a reviewer fully qualified to conduct an independent review, where the fully qualified SS&D reviewer ~~NRC staff~~ will look at how past education and experience may satisfy a portion of the NRC Management Directive 5.6 criteria. The individual will review cases with the fully qualified SS&D reviewer ~~NRC staff~~ during the on the job training session. A written evaluation of progress will indicate whether the individual has demonstrated the skills necessary to act as an initial reviewer and sign off on the reviews. Supervisory sign-off will be granted for each category of qualification achieved pursuant to NRC Management Directive 5.6. A record of an individual's qualification in each area will be maintained on file. A reviewer will not be permitted to participate in any review, unless the individual has received supervisory sign-off for all categories of qualification pursuant to NRC Management Directive 5.6.

(4) No individual will be a signatory to a certificate unless that individual is fully qualified pursuant to NRC Management Directive 5.6 to conduct an initial review alone.

If at the end of the on the job training period, performance does not indicate the knowledge,

skills, and abilities to provide the review sign off, the Bureau management may use the recommendations of the fully qualified SS&D reviewer ~~NRC~~ to assign additional training or return the individual to his/her previous duties.

After at least 2 Bureau staff have been qualified to sign the reviews and have had experience through at least Ohio's initial IMPEP review, those individuals may work with potential candidates after their attendance at the SS&D workshop and prior to any ~~the~~ on the job training with NRC or a state program under the auspices of a reviewer fully qualified to conduct an independent review, to assure the best chance for success ~~in the 2 weeks with NRC~~.

(3) REFRESHER TRAINING

Periodically staff will get refresher training. This training will be consistent with that proposed by NRC in the new SS&D program criteria after the strategic assessment and rebaselining when the criteria is published in final form.

6.0 SELECTION OF PERSONNEL

The Ohio Department of Health has a selection process for initial hiring and transferring/promoting individuals into the Operating Sections of the Bureau of Radiation Protection. This process involves personal face-to-face interviews and both written and verbal testing to verify experience levels. Additionally, the face-to-face interview process involves both Human Resource personnel and Bureau of Radiation Protection Management personnel, which may include the Bureau Chief, Program Administrators and Supervisors of Health Physics. During the face-to-face interview, selection factors such as problem solving ability, background, experience, educational level and mechanical aptitude are considered. Selection is based on the ability to meet position qualification criteria with reasonable amounts of training.

7.0 TRAINING ACTIVITIES

Personnel assigned as Agreement State Professional Staff members must successfuliy complete the requirements for their individually assigned activities within the Agreement State Program. This includes information contained in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" and in the appropriate Qualification Journal.

- A written examination will be used for designated courses to evaluate the candidate's understanding of the material. The passing grade for most examinations is considered to be 70%.

- Not all courses have formal examinations. In these cases, satisfactory course completion is determined by attendance and completion for class activities.

- Individuals who fail examinations may be given the opportunity to review the material through self-study and mentoring, and may then be reexamined. If deemed desirable, individuals who fail an examination that means failure of a training course, may also repeat the course in accordance with established Bureau policy.
- In all cases, completion of formal training courses will be documented by official correspondence from the provider of the training in accordance with the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure" and will be documented in the Bureau training tracking system.

Qualification Journal Completion

Newly assigned Agreement State professional staff members will be assigned a Qualification Journal. The journal consists of a detailed series of activities and study areas as assigned by Bureau management and supervision to be completed in a specified period, usually within two years, although portions of the Qualification Journal may require completion within the probationary period.

Staff members who are due re-qualification will also be assigned a Qualification Journal This journal must be completed prior to the end of the qualification period.

Interim Inspector and License Reviewer Qualification

An inspector (medical, non-medical or decommissioning) or license reviewer who has not completed all requirements for final qualification and certification in one of the areas to which he/she is tasked may obtain interim qualification to independently perform tasks and activities to which they are assigned in specified areas for which prescribed training has been completed. To establish an interim qualification, the individual's supervisor will evaluate the individual's qualifications and identify the categories for which the interim qualification is appropriate. A request for interim qualification shall then be developed by the supervisor and forwarded to the Bureau Chief for the identified areas. Approval of interim qualifications will be documented and a record kept in the individual's training file.

The Training Program requires that a schedule be established and maintained for each section and process to ensure that personnel within that section and process are qualified and trained to successfully complete jobs and tasks assigned by the Supervisor - Health Physics of the section. The objective of the training program shall be to provide qualified personnel to operate and maintain the areas of responsibility under their cognizance in a safe and efficient manner as well as in compliance with its license (Agreement State License, CRCPD Recognition for NARM, etc.), technical specifications and appropriate regulations. Training programs are reviewed annually by the Bureau Chief - Bureau of Radiation Protection (or his/her designee). This review shall ensure that the training program is up-to-date to reflect changes to the Bureau and the Department of Health, operating and technical procedures, regulations and quality assurance requirements as well as industry operating experience. The training program shall ensure that the Bureau has the necessary numbers of qualified, trained support personnel necessary to support Radiation Protection activities and evolutions as might be assigned to the jurisdiction of the Ohio Department of Health. The concept of training personnel as a team, stressing team communications and interaction, should be used where job functions require team solutions.

Training Program for Health Physicist

Initial and continuing training programs ensure that personnel are qualified to the performance requirements of the job. This shall be achieved by using a systematic approach to training and should be based on industry program accreditation requirements as available. Acceptable guidelines for Health Physics personnel training are delineated in the References Section of this Program. The basic elements for establishing a systematic training program includes:

- Systematic analysis of the job to be performed. Job descriptions identified in the appendices of this program shall be analyzed to determine the tasks, skills, and knowledge required for competent job performance. A job or task analysis, or both (JTA), may be considered an appropriate vehicle for making this determination. Because of the varied complexity and scope of job functions, the degree of analysis necessary to determine the skill and knowledge requirements may vary.
- Establishment of education, skills, and knowledge required for entry into the training program.
- Design and development of training programs based on job performance requirements.
- Evaluation of trainee ability to meet job performance requirements as indicated by satisfactory completion of work expectations.
- Evaluation and revision of the training program.

Training program updates shall be developed to reflect results of program evaluations, changes to regulations, changes in the facility and lesson learned from industry experience. Each operating section shall utilize a "Required Reading" list to provide for periodic review and continuing training by personnel within the Operating Section. The form for Required Reading is Attachment A, "*Required Reading Form - BRP*" to this program.

The Initial Training Program shall develop and/or enhance existing skills, knowledge and ability of personnel to perform job assignments. Personnel in the Initial Training Program of this Program shall not make decisions or take actions affecting radiological safety until they meet the performance requirements of the job position assigned. However, they may independently perform specific tasks or job assignments for which they have been qualified based on the completion of tasks and items

under the Supervisor Sign-off forms.

The Initial Training Program has been developed for individuals with entry level qualifications. It is recognized that some individuals may already be qualified for certain of their identified job performance requirements based on their prior experience and training. These individuals may be exempted from that specific training. Proficiency Testing Examinations results shall be used for exemption to initial training requirements. In situations where there is a limited number of available training openings for a class, personnel shall be chosen on the following basis, in descending order:

A. Job Description Requirement - First Priority
B. Seniority - Second Priority
C. When two people require training based on Job Description Requirement with only one opening, seniority shall take precedence, unless otherwise directed by the Bureau Chief - Radiation Protection.

The Continuing Training Program shall ensure that personnel assigned as Health Physicist maintain and enhance their efficiency and proficiency within the Operating Section. Continuing Training Programs shall be structured commensurate with specific program needs and as a minimum shall include the following as important to job functions:

- Applicable ODH/BRP procedural changes as related to the assigned Operating Section
- Applicable Industry operating experience
- Selected fundamental with emphasis on seldom used knowledge and skills necessary to assure nuclear safety, i.e., dose buildup calculations for shielding effects, ion production and linear travel of various radiations in select media.
- Other training needed to correct performance problems of the position incumbent.

The Continuing Training Program includes retraining sessions that maintains the proficiency of skills and knowledge required for acceptable performance.

Training Program for Health Physicist

Personnel may be exempted from portions of the continuing training programs for which they maintain or demonstrate minimum required proficiency. Proficiency Testing results shall be used for exemption for Continuing Training. This testing and other materials required for the Training Program shall be developed by a Training Specialist for Health Physics and the examinations shall be verified by the training department of the Ohio Department of Health.

All personnel titled as Health Physicist, including Supervisors and Program Administrators shall attend Retraining programs, such as Title 49 Code of Federal Regulations Part 172, Subpart H, Training Requirements and Title 29 Code of Federal Regulations Part 1910.120 and 1926.65, HAZWOPER Training, when the required retraining period is applicable.

Program Administrators and Supervisors shall receive instruction in the following supervisory skills commensurate with their job responsibilities:

- Leadership
- Interpersonal communication
- Command responsibilities and limits
- Motivation of personnel
- Problem analysis and decision making
- Administrative policies and procedures.

This training is considered a part of the Ohio Department of Health required training for supervisory personnel as stated in Title 20 Code of Federal Regulations Parts 600 - 699, *Employment and Training Administration,* Department of Labor

8.0 RECORDS AND DOCUMENTATION

All training sessions shall be documented using the information contained in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure". All training records shall be maintained for five years following the completion of the training.

Records for Initial and Continuing Qualification of Health Physics personnel for specific job and tasks shall be maintained for seven years following qualification. Records shall be retained in hard copy for a minimum of two years and then may be reproduced in any visual media that allows for reproduction in hard copy form except for magnetic disk or tape. Transfer of training records to digital Laser Disk is acceptable after two years. The Librarian, Nuclear Materials Safety Section, shall be responsible to maintain records of training in both hard copy and visual media.

9.0 APPENDICES

- Appendix A - Health Physics Training - Initial, Continuing and Retraining Requirements.
- Appendix B - Specialized Training for Bureau of Radiation Protection Health Physics Professionals
- Appendix C - Specialized Environmental Awareness Training Requirements
- Appendix D - Classification Position Descriptions
- Appendix E - Detailed Training
- Appendix F - NRC Required Training - Agreement State

10.0 REFERENCES

- Code of Federal Regulations
  - 10CFR50, Appendix E, (F)
  - 20CFR600-699
  - 29CFR1910.120(e)
  - 29CFR1926.65(e)
  - 40CFR265.16
  - 49CFR172, Subpart H

- US Nuclear Regulatory Commission Regulatory Guides
  - 1.8 "Qualification and Training of Personnel for Nuclear Power Plants"
  - 1.58 "Qualification of Nuclear Power Plant Inspection Examination and Testing Personnel"
  - 8.27 "Radiation Protection Training for Personnel at Light Water Cooled Nuclear Power Plants"
  - 1199 "Standard Format and Content of a License Application for a Low-level Radioactive Waste Disposal Facility", Section 8.3
  - 1220 "Training Review Criteria and Procedures"
- ANSI/ANS - ANSI/ASME
  - 3.1 - 1987, "Selection, Qualification and Training of Personnel for Nuclear Power Plants"
  - NQA-1 - 1989, "Quality Assurance Program Requirements for Nuclear Facilities"

- United States Nuclear Regulatory Commission
  - NRC Inspection Manual Chapter 1245, "Inspector Qualifications"

- NRC Management Directive 5.6

- Conference of Radiation Control Program Directors, Inc. (CRCPD)
  - CRCPD Publication 94-8, "CRCPD Recognition of Licensing States for the Regulation and Control of NARM"

- National Council on Radiation Protection and Measurements
  - NCRP Report No. 71, "Operational Radiation Safety Training"

11.0 ORAL QUALIFICATION BOARD

The oral qualification board assesses the qualifications of an individual to conduct prescribed duties assigned to that individual as part of the Agreement State activities for the section or area to which the individual is assigned. The oral qualification board shall recommend to the Bureau Chief whether or not the individual should be qualified (certified) for the activities examined.

The Bureau Chief's qualification statement (certification) will be documented in the Agreement States professional staff member's official personnel file and the date entered in the Bureau training tracking system. This date determines when refresher or requalification training is due for each individual.

The minimum number of staff required to constitute an oral qualification board will be three. A cross-section of qualified personnel should be included and can range from a peer-level professional staff member to a Division Chief. Management of at least the section level should be included on each board.

The Bureau Chief shall instruct the Manager of Technical Services to develop a list of questions, or question bank, that includes all areas of the Qualification Journal. These questions should allow and encourage the individual to answer in such a way as to demonstrate a depth of knowledge and understanding of a given area, rather than to simply answer "yes" or "no". Questions should focus on those situations that require the Agreement State professional staff member to demonstrate a knowledge of Bureau policy and programs, as they relate to the licensee and implementation of the Agreement State program. Questions of a technical nature should not be excluded; however, they

should not represent a major area of the oral boards questioning.

12.0 EXCEPTIONS

Agreement State professional staff members who through prior experience and education, possess sufficient knowledge and expertise to meet minimum requirements, may validate specific courses through satisfactory completion of equivalency examinations. Requests for equivalency examinations should be made by the individual's supervisor to the Bureau Chief. The request should consider the candidate's ability to conduct inspections or licensing activities without the additional knowledge and regulatory perspective which would be gained by attending a specific training coures. Use of these examinations is generally expected to be a rare occurrence. The Bureau Chief has the authority to grant exceptions.

The Bureau Chief has the authority to waive any requirement listed for an Agreement State professional staff member delineated in this training program. Justification for the waiver will be documented and entered into the individual's training file.

13.0 POST QUALIFICATION TRAINING

This program identifies the training requirements beyond those that are required for initial qualification for the experienced Agreement State professional staff member. For those staff members who have received certification of initial training, additional training is required as identified in the "Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure". This additional training recognizes that the staff member's qualification does not stop with initial qualification, but that training should be made available for the experienced staff member on the basis of need, special circumstances, and the necessity of keeping current with inspection and licensing programs and procedures.

Attachment A

Required Reading Form - BRP

Under Development

NOTE: This Required Reading list shall include:

State Statutes
State Rules
U.S. NRC Regulations
U.S. DOT Regulations
U.S. EPA Regulations
State of Ohio Programs
State of Ohio Procedures

Required Reading shall be established such that each professional staff member shall be tasked with reading and signing as read supporting documentation on a quarterly basis. An example is given below:

BUREAU OF RADIATION PROTECTION
TRAINING PROGRAM FOR HEALTH PHYSICS PERSONNEL

Attachment A

Required Reading Form - BRP

Assigned to: _____ Date assigned: _____

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1st Quarter, 1999

By my initials I verify that I have read the listed document on the date indicated:

init.	Date	Document/Statute/rule/program/procedure
		TYPEICAL FORM
____	_____	Chapter 3748 Ohio Revised Code
____	_____	Rule 3701-38-05 Ohio Administrative Code
		THIS IS NOT AN ACTUAL READING LIST
____	_____	Rule 3701-38-021 Ohio Administrative Code
____	_____	Licensing Program, State of Ohio
____	_____	Licensing Guide, Instructions for completing a NARM Application
____	_____	Licensing Guide, Specific Instructions for completing a Sealed Source and Device Application for the Review and Approval of a Portable Gauge
____	_____	Implementing Procedure, NMS-EP-001, Rev. 0
____	_____	Implementing Procedure, NMS-LG-003, Rev. 1
____	_____	Implementing Procedure, NMS-IN-007, Rev. 0
____	_____	Implementing Procedure, NMS-IN-011, Rev. 2