IMC 1248, Appendix D

Training Requirements and Qualification Journal for Byproduct Material Sealed Source Device Reviewers

APPENDIX D

TRAINING REQUIREMENTS FOR SEALED SOURCE AND DEVICE REVIEWERS

A. Applicability

The training described below is required for all materials license reviewers assigned to perform radiological safety reviews of sealed source and device applications.

B. Training

1. Required Initial Training

   a. Self Study and on-the job Training

      (1) NRC Orientation

      (2) Code of Federal Regulations

      (3) Office Instructions

      (4) Regulatory Guidance

      (5) NRC Management Directives

      (6) ADAMS

      (7) Agreement States Program and Interaction

      (8) Directed Review of Selected Licensing Case Work

   b. Core Training. These course establish minimum formal classroom training requirements. Refer to Section 1248-11 for exceptions to these requirements.

      (1) Basic Health Physics Technology Course (H-122)

      (2) Licensing & Inspection Course (G-108)

      (3) Licensing Practice & Procedures Course (G-109)

   c. Specialized Training. Additional courses may be required in order to gain knowledge necessary for specialized licensing activities. Management will make this determination on an individual basis.

END

TECHNICAL REVIEWER QUALIFICATIONS JOURNAL
BYPRODUCT MATERIAL SEALED SOURCE AND DEVICE REVIEWERS

Applicability

This NRC Technical Reviewer Qualification Journal implements NRC Manual Chapter 1248, by establishing the minimum training requirements for personnel assigned to perform technical evaluations of byproduct material sealed sources and devices applications submitted to the NRC or to an Agreement State.

The NRC Technical Reviewer Qualification Journal serves as a guideline for the development of a Qualification Journal, and establishes the minimum training requirements consistent with NRC Manual Chapter 1248. The Qualification Journal must provide traceable documentation to show that minimum requirements are met for each technical reviewer.

The NRC Technical Reviewer Qualification Journal consists of a series of qualification guides and qualification cards. Each qualification card is used to document task completion, as indicated by the appropriate signature blocks. The corresponding qualification guide establishes the minimum knowledge levels or areas of study that must be completed for each qualification card.

Most of the qualification guides are divided into sections. The review sections of the qualification guides will identify references with general application to the technical reviewer's qualification. The technical reviewer should be expected to have a general familiarity with these references. Other sections of the qualification guides will identify specific references that have direct application to the review discipline. The technical reviewer should be expected to demonstrate detailed knowledge of these specific references.

In order to ensure that the safety evaluations conducted by the reviewer are technically correct and accurate, to promote consistency between like products reviewed, and to ensure that the public and the applicants are given consistent and accurate information regarding policy, regulations, rules and accepted practices associated with sealed source and device safety evaluations, the management will vest full signature authority only to those reviewers that are qualified to perform all areas of evaluation.

The potential reviewer's immediate supervisor will assign appropriate submitted applications on a case by case basis. This discretionary approach is intended to provide the prospective reviewer's management with the ability to tailor the qualification process to match the background, experience, qualifications and training levels of the reviewer. Limited signature authority may be granted by the management in specific areas to competent reviewers who do not have the required qualifications in all areas.

TECHNICAL REVIEWER QUALIFICATIONS JOURNAL
BYPRODUCT MATERIAL SEALED SOURCE AND DEVICE REVIEWERS

(Name)	(Title)	(Branch)

To complete your qualification as a Technical Reviewer of Sealed Sources and Devices you are to complete the enumerated qualification cards. All sign-offs shall include the original signature of the responsible reviewer and the date. Maintain these cards in a file along with any background or written material required by the program. This file will constitute the NRC Sealed Source and Device Technical Reviewers Qualifications Journal.

		Signature When Complete	Date
1.	NRC Orientation	First Line Supervisor	
2.	Code of Federal Regulation	First Line Supervisor	
3.	Office Instructions	First Line Supervisor	
4.	Regulatory Guidance	First Line Supervisor	
5.	NRC Management Directives	First Line Supervisor	
6.	ADAMS	First Line Supervisor	
7.	Agreement States Program and Interaction	First Line Supervisor	
8.	Directed Review of Selected Licensing Case Work	First Line Supervisor	

9. Formal Training

First Line Supervisor

Signature When Complete Date

Recommended as qualified reviewer

Second Level Supervisor
or Board Chairman

Qualification Board Acceptance

Second Level Supervisor

Certification Memo issued
granting signature authority

Second Level Supervisor

Qualification Card 1
NRC General Orientation

		Initials	Date
A.	Site Orientation		
1.	New employee processing package completed	_____ Employee	_____
2.	Facility tour and introduction	_____ First Line Supervisor	_____
B.	NRC Organization		
1.	Review of NRC headquarters and NMSS organization	_____ Employee	_____
2.	Discussion of NRC organization	_____ First Line Supervisor	_____

Qualification Card 2
Code of Federal Regulations

		Initials	Date
A.	Familiarization with selected CFR parts completed	_____ Employee	_____
B.	Discussion completed on CFR parts related to radiation byproduct material applications in industry and medicine	_____ First Line Supervisor	_____

Qualification Card 3
Office Instructions

		Initials	Date
A.	Familiarization with office policies and procedures	_____ Employee	_____
B.	Discussion completed on office policies and procedures	_____ First Line Supervisor	_____

Qualification Card 4
Regulatory Guidance

Regulatory review completed	Initials	Date
1. Regulatory Guides	_____ Employee	_____
2. Information Notices	_____ Employee	_____
3. NUREGs	_____ Employee	_____
4. Inspection Manual Chapters	_____ Employee	_____
5. Industry Codes and Standards	_____ Employee	_____
6. Sealed Source and Device Registry	_____ Employee	_____
7. Review and discuss with Management Memorandum of Understanding regarding the general concepts and elements of MOU NRC has signed with other Agencies (i.e. FDA, DOL, DOE, DOT, FBI, etc.)	_____ Employee	_____
	_____ First Line Supervisor	_____

Qualification Card 5
NRC Management Directives

	Initials	Date
A. Review of selected portions of the NRC Management Directives completed	_____ Employee	_____
B. Discussion of the application of the NRC Management Directives to the Sealed Source & Device program	_____ First line supervisor	_____

Qualification Card 6
ADAMS

		Initials	Date
A.	Review of selected portions of the ADAMS User's Manual and system access completed	_____ Employee	_____
B.	Familiarization with ADAMS station(s) and operation	_____ First line supervisor	_____

Qualification Card 7
Agreement States Program and Interaction

	Initial	Date
A. Overall coordinating role of OSTP		
	_____	_____
	Employee	
B. OSTP General Policies and procedures		
	_____	_____
	Employee	
	_____	_____
	First Line Supervisor	

Qualification Card 8
Directed Review of Selected Licensing Case Work

A. Expected Cases to be reviewed.

The reviewer is expected to review a variety of cases as outlined below. The reviewer should have participated in the full review, from start to the issuance of the certificate, and developed deficiency questions as necessary. The cases will be assigned and selected by the team leader or supervisor to represent the following:

Sources: 4
Irradiators: 1
Radiography: 1
Consumer Products: 6
Gauges: 6
Medical Devices: 2

If new cases are not available, at the discretion of the team leader or supervisor, the reviewer may review previously concluded cases. The cases will be selected by the team leader or supervisor.

This is a flexible requirement and can be modified to reflect the available applications and staff workload.

	Initial	Date
Required Case work Completed:		
	_____	_____
	Employee	
	_____	_____
	First Line Supervisor	

Qualification Card 9
Formal Training

	Initials	Date
A. Mandatory		
1. Basic Health Physics Technology (H-122) Reviewers classified as Series 1306 are exempt from this requirement.		
_____ Employee	_____	_____
_____ First Line Supervisor	_____	_____
2. Licensing & Inspection (G-108)		
_____ Employee	_____	_____
_____ First Line Supervisor	_____	_____
4. Licensing Practice & Procedures (G-109)		
_____ Employee	_____	_____
_____ First Line Supervisor	_____	_____

Note: Course selection depends on previous health physics training and on the experience of the reviewer.

B. Elective Technical Courses	Initial	Dates
1. Safety Aspects of Industrial Radiography (H-305)	_____	_____
2. Irradiator Technology (H-315)	_____	_____
3. Transportation of Radioactive Materials (H-308)	_____	_____
4. Safety Aspects of Well Logging (H-314)	_____	_____

5. Human Error Analysis/
   Human Reliability Analysis
   for NMSS (P-406) _____ _____

6. Root Cause/Incident Investigation
   Workshop (G-205) _____ _____

7. Public Outreach Meetings _____ _____

8. Media Training Workshop _____ _____

9. Q/A & QC Processes (external) _____ _____

10. Materials & Failure Analysis (external) _____ _____

11. Welding Technology and Codes
    (external) _____ _____

12. NDE: PT, MT, UT, Eddy Current,
    Fiber Optics, Microscopy,
    Electron Scanning Microscopy etc.
    (external) _____ _____

Qualification Guide 1
NRC Orientation

A. NRC Orientation

1. The qualifying individual should read and complete appropriate following forms for processing into the NRC systems:

   a. Personnel information
   b. Health insurance elections
   c. Retirement plan elections
   d. Savings elections (e.g. U.S. Savings Bonds, TSP, etc.)
   e. Fitness for Duty requirements and physical examination
   f. Any other forms which may be required by NRC Office of Human Resources
   g. Payroll forms and time and labor reporting
   h. Regulatory Information Tracking System (RITS)

2. The First Line Supervisor should orient the qualifying individual to the facility as follows:

   a. tour the facility and introduce the qualifying individual to the staff
   b. indicate to the qualifying individual the location of controlled documents, reference material, supplies, office equipment, etc.

B. NRC Organization

1. The qualifying individual should review and become familiar with:

   a. Organizational charts of division, NMSS, regions and headquarters and overall NRC organization (NUREG 0325)
   b. Role of Headquarters in policy and interpretation of regulations
   c. Role of NRC General Counsel
   d. Role of NRC Inspector General
   e. Role of NRC Public Affairs
   f. Role of NRC Office of Investigations
   g. Role of NRC Office of Enforcement
   h. Physical location of NRC offices and regions
   i. Role of NRC as a regulatory agency
      (1) 10 CFR Part 1 (Organization)
      (2) Atomic Energy Act of 1954, as amended
      (3) Energy Reorganization Act of 1974, as amended
      (4) NRC Enforcement Policy (NUREG-1600)
      (5) Incident Response Plan (NUREGs 0728 and 0845)
      (6) Energy Policy Act of 1992

2. The First Line Supervisor should discuss NRC organization and role with the qualifying individual to ensure the qualifying individual has a full understanding of NRC's organization and mission and the role of a Sealed Source and Device Technical Reviewer in the risk informed performance based mission.

Qualification Guide 2
Code of Federal Regulations

A. A selection of currently applicable CFR Parts should be made by the First Line Supervisor. The selection should include the references listed below and be documented. The qualifying individual should be expected to have a general knowledge of the topics addressed in the references. This review may be accomplished by self-study, study quizzes, or discussions.

1	10 CFR Part 1	Statement of organization and general information
2.	10 CFR Part 2	Rules of practice for domestic licensing proceedings and issuance of orders
3.	10 CFR Part 9	Public records
4.	10 CFR Part 19	Notices, instructions and reports to workers: inspection and investigations
5.	10 CFR Part 20	Standards for protection against radiation
6.	10 CFR Part 21	Reporting of defects and noncompliance
7.	10 CFR Part 25	Access authorization for licensee personnel
8.	10 CFR Part 26	Fitness for duty programs
9.	10 CFR Part 30	Rules of general applicability to domestic licensing of by product material
10.	10 CFR Part 31	General domestic licenses for byproduct material
11.	10 CFR Part 32	Specific domestic licenses to manufacture or transfer certain items containing byproduct material
12.	10 CFR Part 33	Specific domestic licenses of broad scope for byproduct material
13.	10 CFR Part 34	Licenses for radiography and radiation safety requirements for radiographic operations
14.	10 CFR Part 35	Medical use of byproduct material
15.	10 CFR Part 36	Licenses and radiation safety requirements for irradiators
16.	10 CFR Part 39	Licenses and radiation safety requirements for well logging
17.	10 CFR Part 71	Packaging and transportation of radioactive material
18.	10 CFR Part 150.20	Reciprocity
19.	10 CFR Part 170.31	Application Fees
20.	10 CFR Part 171.16	Annual Fees

B. Following completion of the qualifying individual's self study of the listed CFR Parts, a discussion will be held with the qualifying reviewer by the First Line Supervisor to test the qualifying reviewer’s knowledge of these Parts. To the extent possible, recent application of various sections, new regulatory initiatives, and current industry issues should be emphasized.

Qualification Guide 3
Office Instructions

A. Office/Division Policies and Procedures

1. Read the Office/Division Policy and Procedures Manual

2. The qualifying individual should review the Office/Division policies and practices on:

a. Travel, including Management Directive 14.1 Official Temporary Duty Travel

b. Telephone use

c. Policies on use of annual leave and sick leave and excused leave, including Management Directive 10.62, Leave Administration.

d. Work schedule, including Management Directive 10.42, Hours of Work and Premium Pay

e. Use of government equipment including computers (ADAMS) and Management Directive 13.1 Property Management

f. Union activities, including Management Directive 10.102, Labor-Management Relations Program for Federal Employees

g. Communications outside NRC

h. Policies on outside employment and acceptance of gifts

i. Participation in political activities

j. Routing of mail and procedures for sending mail and materials (via U.S. Mail, Federal Express, etc.), including Management Directive 3.23, Mail Management

k. Ordering of documents (e.g. NUREGs)

l. NMSS emergency and evacuation procedures

m. Employee appraisal system and Individual Development Plan (IDP)
(1) Employee trial period (Management Directive 10.14 Employment and Staffing)

(2) Employee appraisals (Management Directive 10.67, Non-SES Performance Appraisal System)

o. Differing Professional Views or Opinions (Management Directive 10.159, General Personnel Management Provisions)

B. The First Line Supervisor should discuss these policies and practices with the qualifying individual to ensure that the qualifying individual has a full and complete understanding.

Qualification Guide 4
Regulatory Guidance

A. A selection of currently applicable regulatory guidance should be identified by the First Line Supervisor. These references should include those listed below and should be documented. The qualifying individual should be expected to have a general knowledge of the topics addressed in the references. The review may be accomplished by self-study, study-quizzes, briefings, or discussions.

1. Regulatory Guides (use latest revisions)

6.1	Leak Testing Radioactive Brachytherapy Sources
6.9	Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material
8.29	Instruction Concerning Risks from Occupational Radiation Exposure

Others as selected by the First Line Supervisor

2. Information Notices

IN 94-89	Equipment Failures at Irradiator Facilities
IN 95-44	Ensuring Compatible Use of Drive Cables Incorporating Use of Industrial Nuclear Company Ball - Type Male Connectors
IN 96-04	Incident Reporting Requirements for Radiography Licensees
IN 96-20	Demonstration of Associated Equipment Operability
IN 96-51	Residual Contamination Remaining in Krypton-85 Handling System after Venting
IN 96-52	Cracked Insertion Rods On Troxler Model 3400 Series Portable Moisture Density Gauges
IN 96-53	Retrofit to Amersham 660 Posilock Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility
IN 96-54	Vulnerability of Stainless Steel to Corrosion When Sensitized.
IN 97-89	Distribution of Sources and Devices Without Authorization

IN 98-09	Collapse of an ISOCAM II, Dual-Headed Nuclear Medicine Gamma Camera
IN 99-23	Safety Concerns Related to Repeated Control Unit Failures of the Nucletron Classic Model High-Dose-Rate Remote Afterloading Brachytherapy Devices
IN 99-27	Malfunction of Source Retraction Mechanism in Cobalt-60 Teletherapy Treatment Units

Others as selected by the First Line Supervisor

3. NUREG Reports

NUREG-0325	USNRC Functional Organizational Chart
NUREG-0403	High Temperature Testing of Smoke Detector Sources
NUREG-1175	Environmental Assessment of Consumer Products Containing Radioactive Material
NUREG-1480	Loss of an Iridium-192 Source and Therapy Mis-Administration at Indiana Regional Cancer Center
NUREG-1556	Consolidated Guidance About Materials Licenses Vols. 1 to 20
NUREG-1600	General Statement of Policy and Procedure for NRC Enforcement Actions
NUREG-1631	Source Disconnects Resulting From Radiography Drive Cable Failures
NUREG-1717	Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials
NUREG/CR-4357	The Feasibility of Detecting the Import of Unauthorized Radioactive Materials in to the USA
NUREG/CR-5881	An examination of Source Material Requirements Contained in 10 CFR 40
NUREG/CR-6074	Investigation of Failed Radioactive Stainless Steel Troxler Gauges Vol.5

NUREG/CR-6642 Safety Testing of Industrial Radiography Devices

Others as selected by the First Line Supervisor

4. Inspection Manual Chapters

INSPECTIONS

IMC 0300 Announced and Unannounced Inspections

IMC 0303 Item Reporting

IMC 2800 Materials Inspection Program

INTERACTIONS WITH OTHER FEDERAL AGENCIES

IMC 1007 Interfacing Activities Between Regional Offices of NRC and OSHA

INCIDENT RESPONSE

IMC 1300 Incident Response Actions - Responsibility and Authority

IMC 1301 Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan

IMC 1302 Action Levels for Radiation Exposures and Contamination Associated With Materials Events Involving Members of the Public

IMC 1330 Response to Transportation Accidents Involving Radioactive Materials

IMC 1360 Use of Physician and Scientific Consultants in the Medical Consultant Program

Others as selected by the First Line Supervisor

5. Industrial Codes and Standards

ANSI N42.16 Gamma Radiography- Specification for Design and Testing of Apparatus

ANSI N42.17A	Performance Specifications for Health Physics
ANSI N43.2	Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment
ANSI N43.3	Installations Using Non-Medical and Sealed Gamma-Ray Sources, Energies Up to 10 MEV
ANSI N43.4	Classification of Radioactive Self-Luminous Light Sources
ANSI N43.6	Sealed Radioactive Source- Classification (ISO 2919)
ANSI N43.7	Safe Design and Use of Self-Contained Dry Sources Storage Gamma Irradiators (Category I)
ANSI N43.8	Classification of Industrial Ionizing Radiation Gauging Devices (ISO 7205)
ANSI N43.9	For Gamma Radiography- Specifications for Design and Testing Apparatus
ANSI N43.10	Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)
ANSI N43.15	Safe Design and Use of Self-Contained Wet Sources Storage Gamma Irradiators (Category III)
ANSI N44.1	Integrity and Test Specifications for Selected Brachytherapy sources
ANSI N44.2	Leak-Testing Radioactive Brachytherapy Sources
ANSI N449.1	Procedures for Periodic Inspection of Cobalt and Cesium-137 Teletherapy Equipment
ANSI N537	Radiological Safety Standards for Design of Radiographic and Flouroscopic Industrial X-Rays Equipment
ANSI/ISO/QSC-Q9001-2000	Quality management systems - Requirements
ISO 7205	Radionuclide Gauges - Gauges designed for permanent installation

Others as selected by the First Line Supervisor

6. Sealed Source and Device Registry

7. The First Line Supervisor will discuss with the reviewer as minimum the general concepts and elements of MOU NRC has signed with other Agencies (i.e. FDA, DOL, DOE, DOT, FBI, etc.) That impact the registration or disposal of radiological sources and devices. Review and discuss the following with Management:

   1. FDA Sealed Source and Device Applications requiring notification and/or 510K approved form
   2. DOE DOE Technical and Contractual Interfaces and TAPM Qualifications Requirements
   3. DOT The First Line Supervisor will discuss with the reviewer the DOT Technical Regulatory Interfaces

   Others as selected by the First Line Supervisor

B. The application of these guidance documents to the Sealed Source and Device review program should be studied in detail by the qualifying individual and covered by the First Line Supervisor in discussions, interviews, or oral quizzes.

Qualification Guide 5
NRC Management Directives

A. A selection of currently applicable NRC Management Directive (MD) references should be identified by the First Line Supervisor. These references should include those listed below and be documented. The qualifying reviewer should be expected to have a general knowledge of the topics addressed in the references. This review may be accomplished by self-study, study-quizzes, briefings, or discussions. The selection should include:

1.	NRC MD 3.1	Freedom of Information Act
2.	NRC MD 3.2	Privacy Act
3.	NRC MD 8.3	NRC Incident Investigation Program
4.	NRC MD 8.8	Management of Allegations
5.	NRC MD 9.1	Organization Management
6.	NRC MD 9.29	Regional Offices
7.	NRC MD 10.42	Hours of Work and Premium Pay
8.	NRC MD 10.43	Time and Attendance Reporting
9.	NRC MD 10.67	Non-SES Performance Appraisal System
10.	NRC MD 10.101	Employee Grievances
11.	NRC MD 10.130	OSHA
12.	NRC MD 10.131	Standards for Protection Against Ionizing Radiation
13.	NRC MD 10.159	Differing Professional Views or Opinions
14.	NRC MD 14.1	Official Temporary Duty Travel

Others as selected by the First Line Supervisor

Qualification Guide 6
ADAMS

A. The use and training for ADAMS will consist of a PDC course in using ADAMS; review of ADAMS USER GUIDE; and knowledge of capturing and retrieving ADAMS documents.

A. The First Line Supervisor will discuss with the reviewer in training the role of OSTP office as a single point of entry interface for coordinating the Agreement State Programs and the available course of corrective actions to match problematic Agreement State Programs.

Qualification Guide 8
Directed Review of Selected Licensing Case Work

A. Compile an Attachment in the following Format for all the case work completed

1. Type of Byproduct:

2. Applicant:

3. Type of Device or Source:

4. Status:

5. Date Completed:

6. Reviewer:

7. Total of products reviewed:

Qualification Guide 9
Required Formal Training

A. The standards for each Training Course are provided in the NRC Technical Training Center Course Catalog and will not be duplicated in the Qualification Guide.

Attachment 1
Revision History for IMC 1248, Appendix D

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution Accession Number
N/A	ML112360175 10/26/11 CN 11-022	Revision history sheet added. Combined Appendix B16 with Appendix A16 and renamed as IMC 1246 Appendix E9. Added “Training Requirements” Section from Appendix A16.	N/A	ML112360189
N/A	ML1240A155 04/19/13 CN 13-011	IMC 1248 Appendix D was created to replace IMC 1246 Appendix E9 and remove FSME activities from the NMSS qualification journal IMC 1246 series. The qualification was originally published on February 11, 2004. No changes were made to the training requirements or qualification journal since they were published on February 11, 2004.	N/A	N/A