September 14, 2001

Roger L. Suppes, Chief
Bureau of Radiation Protection
Ohio Department of Health
P.O. Box 118
Columbus, OH 43266-0118

Dear Mr. Suppes:

Enclosed is the draft qualifications journal for individuals that wish to conduct sealed source and device evaluations. You had requested this document during the Management Review Board meeting on August 9. 2001.

If you have any additional questions, please contact me at 301-415-2819.

Sincerely,

/RA/
Dennis Sollenberger, Senior Health Physicist
Office of State and Tribal Programs

Enclosure:
As stated

Roger L. Suppes September 14, 2001

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ML012570093 **STP-AG-31**

BYPRODUCT MATERIAL SEALED SOURCES AND DEVICES REVIEWER
NRC SAFETY AND TECHNICAL REVIEWER QUALIFICATIONS JOURNAL

(Draft, 10/15/99)

SECTION XIV

BYPRODUCT MATERIAL SEALED SOURCES AND DEVICES REVIEWER
NRC SAFETY AND TECHNICAL REVIEWER QUALIFICATIONS JOURNAL

Applicability

This NRC Safety and Technical Reviewer Qualification Journal implements NRC Manual Chapter 1246, Appendix B, Section XIV, by establishing the minimum training requirements for personnel assigned to perform safety and technical evaluations of byproduct material sealed sources and devices applications submitted to the NRC or to an Agreement State.

The NRC Safety and 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 1246. The Qualification Journal must provide traceable documentation to show that minimum requirements are met for each safety and technical reviewer.

The NRC Safety and Technical Reviewer Qualification Journal consist of a series of qualification guides and signature cards. Each signature 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 signature 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 safety and technical reviewer's qualification. The safety and 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 safety and technical reviewer should be expected to demonstrate detailed knowledge of the safety and technical review specific references.

In order to ensure that safety and technical evaluations conducted by the reviewer are technically correct, accurate and 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 sources and devices 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 bases. 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.

NRC SAFETY AND TECHNICAL REVIEWER JOURNAL

_____	_____	_____
(Name)	(Title)	(Branch)

To complete your qualification as an NRC Safety and Technical Reviewer of Sealed Sources and Devices you are to complete the enumerated signature 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 NRC SSD Safety and Technical Reviewers Qualifications Journal.

	Signature When Complete	Date
1. General Orientation.....		
2. Code of Federal Regulation.....		
3. Regulatory Guidance.....		
4. NRC Inspection Manual.....		
5. Industry Codes and Standards.....		
6. A/S Program and Interaction.....		
7. Inspection Accompaniment.....		
8. Required Formal Training.....		
9. Policy and Guiding Directives.....		
10. Allegation Management.....		
11. Communications Outside NRC.....		
12. FDA MOU.....		
13. DOE MOU.....		
14. DOT Regulations and Approach.....		

15. List below specific case work staff member has been involved with or completed and indicate the person who signed the registration certificate of deficiency letter if any.....

16. Identify other academic preparation, technical training/experience or regulatory experience germaine to qualifications as an SSD Safety and Technical reviewer. The entries are to be coordinated with and approved by management. Attach Summary information.....

	Signature	Date
Recommended as qualified reviewer.....		
Qualification Board Acceptance.....		
Certification Memo issued.....		

Qualification Card 1
NRC General Orientation

	Initials	Date
A. Site Orientation		
1. New employee processing package complete	_____ 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
Regulatory Guidance

Regulatory review completed

1. Regulatory Guides

_____
Employee

2. Information Notices/
Bulletin

_____
Employee

3. NUREGs

_____
Employee

4. Generic Letters

_____
Employee

5. Federal Register Notices

_____
Employee

6. Policy and Guidance Directives

_____
Employee

_____
First Line Supervisor

Qualification Card 4
NRC Inspection Manual

		Initial	Date
A.	Review of appropriate NRC IM chapters completed		

_____
Employee

		Initial	Date
B.	Discussion of NRC IM chapters and their relation to byproduct materials		

_____
First Line Supervisor

Qualification Card 5
Industry Codes and Standards

		Initial	Date
A.	Review of selected ANSI & ISO Standards completed		
		_____ Employee	
B.	Discussion of the application of codes and standards to the byproduct material		
		_____ First Line Super-visor	

Qualification Card 6
Agreement States Program and Interaction

	Initial	Date
1. Overall coordinating role of OSP		
2. OSP General Policies and procedures		

_____
Employee

_____
Employee

_____
First Line Supervisor

Qualification Card 7
Inspection Accompaniments

	Initials	Date
A. Inspections completed		
1. Manufacturer	_____ Employee	
2. Manufacture	_____ Employee	
3. Distributor	_____ Employee	
4. Distributor	_____ Employee	

Discussion of inspection and NRC staff role

_____
First line supervisor

Qualification Card 8
Required Formal Training

	Initials	Date
A. Mandatory		
1 Applied Health Physics ORAU 5 week course (H309)		
2. Licensing & Inspection (G-108)		
3. Licensing Practice & Procedures (G109)		

_____
Employee

_____
First Line Supervisor

B. Elective Technical Courses

1. Industrial Radiography.....

2. Irradiator Technology.....

3. Transportation of RAM.....

4. Safety Aspects of Well Logging.....

5. Q/A & QC Standards.....

6. Materials & Failure Analysis.....

7. Welding Technology and Codes.....

8. NDE: PT, MT, UT, Eddy Current, Fiber Optics,.....
Microscopy, Electron Scanning Microscopy etc.

Qualification Card 9
Policy and Guiding 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 byproduct materials and Inspection and Q/A program		

_____
First line supervisor

Qualification Card 10
Allegation Management

	Initials	Date
1. Discuss applicable procedures and reporting requirements		
2. Discuss different types of allegations, professional practice, civil rights and human harassment		

_____
Employee

_____
First Line Supervisor

Qualification Card 11
Communication Outside NRC

	Initials	Date
1. Communications Completed with OSP, States, Regions, Vendors other Government Agencies		

_____
Employee

_____
First Line Supervisor

Qualification Card 12
FDA Memorandum of Understanding

	Initials	Date
1. Review and discuss with Managements SDD Applications requiring Notification and/or 510K approved Form		

_____
Employee

_____
First Line Supervisor

Qualification Card 13
DOE Memorandum of Understanding

	Initials	Date
1. Review and discuss with Management DOE Technical and Contractual Interfaces		
2. TAPM Qualification Requirements		

_____
Employee

_____
First Line Supervisor

Qualification Card 14
DOT Memorandum of Understanding

Initials Date

1. Review and discuss with Management
   DOT Technical regulatory Interfaces

_____
Employee

_____
First Line Supervisor

Qualification Card 15
Specific Case Work

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

Type of Byproduct:

Applicant Type of Device or Source Status Date Completed Reviewer

Total of products reviewed:

Expected Cases to be reviewed. (This is a flexible requirement and can be modified to reflect the available applications and manpower loadings)

Sources: 10
Irradiators: 3
Radiography: 5
Consumer Products: 6
Gauges: 20
Medicaal Devices: 5

Initial Date

Required Case work Completed:

_____
Employee

_____
First Line Supervisor

Qualification Card 16
Professional Experience

Attach a summary (2-3 Pages) of your education, membership, awards and record of experience.

Initial Date

Professional Experience Summary provided:

_____
Employee

_____
First Line Supervisor

Qualification Guide 1
NRC Orientation

A. NRC Orientation

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

- Personnel information
- Health insurance elections
- Retirement plan elections
- Savings elections (e.g. U.S. Savings Bonds, TSP, etc.)
- Fitness for Duty requirements and physical examination
- Any other forms which may be required by NRC Office of Human

Resources
- Payroll forms and time cards
- Regulatory Information Tracking System (RITS)

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

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

B. NRC Organization

The qualifying individual should review and become familiar with:

- Organizational charts of region, NMSS, and headquarters and overall NRC organization
- role of Headquarters in policy and interpretation of regulations

Role of NRC General Counsel

Role of NRC Inspector General

Role of NRC Public Affairs

Physical location of NRC offices and regions

Role of NRC as a regulatory agency

- 10 CFR Part 1 (Organization)
- Atomic Energy Act of 1954, as amended
- Energy Reorganization Act of 1974, as amended
- NRC Enforcement Policy (NUREG-1600)
- Incident Response Plan (NUREGs 0728 and 0845)
- Energy Policy Act of 1992

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 SSD Safety Technical Reviewer in the risk informed performance based mission.

Qualification Guide 2
Code of Federal Regulations

A. Slection 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, briefings, or discussions.

- 10 CFR Part 0 Conduct of employees
- 10 CFR Part 1 Statement of organization and General information
- 10 CFR Part 2 Rules of practice for domestic licensing proceedings and issuance of orders
- 10 CFR Part 9 Public Records
- 10 CFR Part 19 Notices, instructions and reports to workers;
- 10 CFR Part 20 Standards for protection against radiation
- 10 CFR Part 21 Reporting of defects and noncompliance
- 10 CFR Part 25 Access authorization for licensee personnel
- 10 CFR Part 26 Fitness for duty programs
- 10 CFR Part 30 Rules for general applicability to domestic licensing of byproduct material
- 10 CFR Part 31 General Licenses for byproduct materials
- 10 CFR Part 32 Specific domestic licenses to manufacture or transfer certain items containing byproduct materials
- 10 CFR Part 33 Specific licenses of broad scope for byproduct material
- 10 CFR Part 34 Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations
- 10 CFR Part 35 Medical uses of byproduct materials
- 10 CFR Part 36 Licenses and radiation requirements for irradiators
- 10 CFR Part 39 Licenses and radiation safety requirements for well logging
- 10 CFR Part 71 Packaging and transportation of radioactive material
- 10 CFR Part 170 Fees for facilities and materials licenses and other regulatory services under the atomic energy act of 1954

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 & Regulatory Guidance

A. NMSS Office Policies and Procedures

The qualifying individual should review the NMSS policies and practices on:

a. NMSS Policy Documents Manual

b. Travel (including Management Directive 14.1 Official Temporary Duty Travel)

C. Telephone use

d. Policies on use of annual leave and sick leave and excused leave.

e. Work schedule

f. Use of government equipment

g Union activities

h. Communications outside NRC

i. Policies on outside employment and acceptance of gifts

j. Participation in political activities

k. Routing of mail and procedures for sending mail and materials (via U.S. Mail, Federal Express, etc.)

1. Ordering of documents (e.g NUREGs)

m. NMSS emergency and evacuation procedures

n. Employee appraisal system and Individual Development Plan (IDP)
- Probationary period (Management Directive 10.1 Employment)
- Management Directive 10.67 (Non-SES Performance Appraisal System)

o. Differing Professional Opinions

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 3
Office Instructions & 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

- Regulatory Guide 6.1 Leak Testing Radioactive Brachytherapy Sources

- Regulatory Guide 6.9 Establishing Quality Assurance Program For The Manufacture And Distribution of Sealed Sources and Devices Containing Byproduct Material

- Regulatory Guide 7.10 Establishing Quality Assurance Programs Used in Radioactive the Transport of Radioactive Material

- Regulatory Guide 8.7 Instructions for Recording and Reporting Occupational Exposure Data

- Regulatory Guide 8.29 Instruction Concerning Risks from Occupational Radiation Exposure

- Regulatory Guide 8.13 Instruction Concerning Prenatal Radiation Exposure

2. Information Notices

- IN 94-89 Equipment Failures at Irradiator Facilities

- IN 95-44 Ensuring Compatible Use Of Drive Cables Incorporating Industrial Company Ball Type Male Connector

- IN 95-88 10 CFR 34.20; Final Effective Date

- IN 96-04 Incident Reporting Requirement for Radiography Licenses

- IN 96-20 Demonstration of Associated Equipment Compliance With 10 CFR 34.20

- 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 Gauge

- 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 97-29 Distributing Sources and Devices With out Authorization

3. NUREG Guides

- NUREG 0325 USNRC Functional Organizational Chart

- NUREG-1103 Contaminated Maxican Steel Incident

- NUREG-1480 Loss of an Iridium-192 Source and Therapy Mis-Administration at Indiana Regional Cancer Center

- NUREG-1556 Consolidated Guidance About Materials License Vols. 1 to 16

- NUREG-1175 Environmental Assessment of Consumer Products Containing Radioactive Material

- NUREG-4357 The Feasibility of Detecting the Import of Unauthorized Radioactive Materials in to the USA

- NUREG-5881 — An examination of Source Material Requirements Contained in 10 CFR 40
- NUREG-6074 Vol. 5 — Investigation of Failed Radioactive Stainless Steel Troxler Gauges
- NUREG-0403 — High Temperature Testing of Smoke Detector Sources
- NUREG-1631 — Source Disconnects Resulting From Radiography Drive Cable Failures
- NUREG 1600 — General Statement of Policy and Procedures for NRC

5. Enforcement Manual

The First Line Supervisor will discuss with the reviewer the categorizations of incidents non- escalated and escalated enforcement processes.

6. Federal Register Notice

Discuss the procedures and requirements for posting of Notices in the Federal Register

7. Policy, Directives and Orders

Discuss who issue's theses type of documents. Briefly discus the following:

- Computer Operations and Telecommunication Programs
- Information Management
- Financial Management
- Government Relations and Public Affairs
- Internal Management
- Legal an Ethical Guidelines
- Licensee Oversight Programs
- Personal Management
- Procurement
- Security
- Travel, Transport

Qualification Guide 4
NRC Inspection Manual

A. A selection of currently applicable NRC Inspection Manual Chapter (IMC) and Inspection Procedure (IP) references with direct application to the byproduct materials and iradiators should be identified by the First Line Supervisor. The application of the specific references to the inspection program should be studied in detail by the qualifying individual.

INSPECTIONS

IMC 0300	Announced and Unannounced Inspections
IMC 0303	Inspection Follow-up System
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 Non-Emergency Incidents Involving Radioactive Material
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

Qualification Guide 5
Industrial Codes and Standards

A. A selection of currently applicable industry codes and standards should be identified by the First Line Supervisor. These references should include those 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, briefings, or discussions.

- ANSI N42.16 Gamma Radiography- Specification for Design and Testing of Apparatus
- 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 N43.6 Sealed Radioactive Source- Classification
- ANSI N43.4 Classification of Radioactive Self-Luminous Light Sources
- ANSI N43.9 For Gamma Radiography- Specifications for Design and Testing Apparatus
- ANSI N43.10 Safe Design an Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)
- ANSI N44.1 Integrity and Test Specifications for Selected Brachytherapy sources
- ANSI N44.2 Leak-Testing Radioactive Brachytherapy Sources
- ANSI N432 Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography (ISO 3999)
- ANSI N433.1 Safe Design and Uses of Self-Contained Dry Sources Storage Gamma Irradiators (Category 1)
- 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 N538 Classification of Industrial Ionizing Radiation Gauging Devices (ISO 7205)

- ANSI N542 Sealed Radiation Sources Classification (ISO 2919)

Qualification Guide 6
A/S Program and Inspection

The First Line Supervisor will discuss with the reviewer in training the role of OSP 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 7
Inspection Accompaniments

A. Each SSD Safety and Technical Reviewer should accompany an NRC inspector visiting at least two manufactures and distributors.

The discussions regarding inspection accompaniment program should include preparation for inspection for announced and unannounced inspection, elements determining scope of inspection, entrance and exit interviews.

A qualified NRC Inspector should discuss with the reviewer the fundamental methods of conducting inspections, accumulation of data, and submission of reports for different types of inspections. i.e morning reports, non routine license reports, abnormal events, and non-compliance, augmented, and reactive reports.

Qualification Guide 8
Required Formal Training

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

Qualification Guide 9
Policy and Guiding Directives

The First Line Supervisor should discuss with the reviewer in training the purpose and occasions on which these documents are issued, the steps involved, highest level of approval required and distribution.

Preliminary Notification

Telephonic and Written Preliminary Notifications"

NRC Bulletins and Information Notices"

Management Directives

NUREGs

Regulatory Guides

Generic Letters

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 10.98	Conduct of Employees
11.	NRC MD 10.101	Employee Grievances
12.	NRC MD 10.114	Employee Benefits Program
13.	NRC MD 10.13	OSHA
14.	NRC MD 10.131	Standards for Protection Against Ionizing Radiation
15.	NRC MD 10.159	Differing Professional Views or Opinions
16.	NRC MD 14.1	Official Temporary Duty Travel

Qualification Guide 10
Allegations Management

The First Line Supervisor will discuss with the reviewer in training broad categories of allegations. (Safety related issues, civil right violations and sexual harassment). Confidentiality denial or grating procedures will be discussed with the reviewer.

Qualification Guide 11
Communications Outside NRC

Use of Consultants of NRC

Management Directive 5.5 Public Affairs Program

Management Director 3.6 Distribution of Unclassified NRC Staff/Contractor Generated Reports

Qualification Guide 12
MOU With other Federal Agencies

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, FBI, etc.) That impact the registration or disposal of radiological sources and devices.