



**TIDEWATER INC**

ENGINEERS / SCIENTISTS / PROGRAM MANAGERS

**RADIATION SAFETY PROGRAM ASSESSMENT PLAN**

For

**National Institute of Standards and Technology  
100 Bureau Drive  
Gaithersburg, MD 20899**

By

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## List of Attachments

Attachment A, NUREG-1556 Volume 6, Appendix K - Suggested Audit Checklist for 10 CFR Part 36 Irradiators

Attachment B, NUREG 1556 Volume 11, Appendix M - Sample Audit Program-Non- Medical

Attachment C, NUREG -1556 Volume 7, Appendix L - Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope; Including Gas Chromatographs and X-Ray Fluorescence Analyzers

# NIST RADIATION SAFETY PROGRAM ASSESSMENT PLAN

## 1.0 BACKGROUND

This activity is planned in accordance with the March 1, 2010, Confirmatory Order issued by the United States Nuclear Regulatory Commission (NRC) to the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) as a result of an alternative dispute resolution (ADR) mediation session. In this Order, NRC identifies numerous actions to be taken by NIST. One action directs NIST to contract with an independent consultant to develop an assessment plan and evaluate NIST's documented radiation safety programs and the overall effectiveness of their implementation of such for NRC licenses SNM-362 and 19-03166-06, with the primary goal of determining whether there is a high assurance of preventing significant radiological events now and in the future. Tidewater, Inc. (Tidewater) has been contracted to assist in fulfilling this commitment.

## 2.0 SCOPE OF ASSESSMENT

This Assessment Plan was developed to assess the effectiveness and adequacy of the programmatic and procedural elements of the NIST radiation safety programs. The assessment plan includes the elements necessary to assess NIST compliance with federal regulations and the requirements of NRC licenses SNM-362 and 05-03166-05. It must be noted that radioactive materials license 05-03166-05 was terminated on December 27, 2010 and replaced with license 19-03166-06. The new number and license will be referenced throughout this plan and resultant assessment report with any activities conducted under the terminated license referenced as necessary. As an independent consultant to NIST, Tidewater will conduct this assessment and provide a final report that discusses findings and recommendations for radiation safety program improvement.

## 3.0 APPROACH

### 3.1 Intent

The intent of this assessment is to determine the adequacy and implementation of the NIST radiation safety program, with regard to regulatory compliance and best industry and management practices. This will be accomplished through the following activities:

- Detailed analysis of compliance to the NIST Radioactive Materials license conditions for both licenses;
- On-site inspections of required training; receipt, storage and handling of radioactive material, especially special nuclear material (SNM); records; postings; and facilities;
- One-on-one interviews with authorized users (source handlers) and radiation workers to evaluate adequate knowledge of radiation safety principles and regulatory requirements;
- Assess training effectiveness by reviewing user knowledge and practice;
- Review of Emergency and Operational Procedures for compliance and implementation;
- Review of occupational dose records & reporting;
- Review of previous findings, notices or violations and specific corrective measures implemented; and
- Provide a complete & detailed report of findings and suggestions for program improvement.

### 3.2 Assessment Logistics

An independent assessment team of one Lead Auditor and two (2) Auditors, or more as required, will conduct a consolidated internal audit to comply with the requirements of NIST NRC licenses SNM-362 and 19-03166-06, as amended; applicable sections of Title 10 of the Code of Federal Regulations; and NIST policies and procedures. The scope of the audit will include review of the content and implementation of the NIST Laboratory Safety Manual, Chapter 8, "Ionizing Radiation Safety Manual".

Independent auditors will perform assessment activities as necessary to verify conformance to, and/or identify weaknesses in the NIST Radiation Safety Program as implemented at the Gaithersburg, Maryland and Boulder, Colorado NIST facilities. The assessment will include a review of the adequacy and effective implementation of existing radiation safety programs, plans, and procedures with respect to regulatory compliance and good radiation safety practices. The team of individuals conducting this assessment, with contact information, is presented in Table 3-1.

**Table 3-1 Assessment Team**

Assessment Role	Name/Title	Organization	Contact Information
Lead Auditor	Claude Wiblin, CHP Health Physicist	Tidewater, Inc.	410.923.4653(o) 410.353.6450(c) <a href="mailto:claude.wiblin@tideh2o.net">claude.wiblin@tideh2o.net</a>
Auditor	Michael Davidson, CHP Vice President & RSO	Tidewater, Inc.	410.421.5454(o) 410.440.8004(c) <a href="mailto:mike.davidson@tideh2o.net">mike.davidson@tideh2o.net</a>
Auditor	Wayne Gaul, Ph.D., CHP Sr. Program Manager	Tidewater, Inc.	803.732.1017(o) 803.351.8071(c) <a href="mailto:wayne.gaul@tideh2o.net">wayne.gaul@tideh2o.net</a>
Auditor	Tim Kirkham, Health Physicist	Tidewater, Inc.	765.477.0486(o) 443.532.8029(c) <a href="mailto:tim.kirkham@tideh2o.net">tim.kirkham@tideh2o.net</a>

### 3.3 Assessment Schedule, Milestones and Deliverables

Assessment schedule and milestones are presented in Table 3-2. Assessment deliverables and due dates are presented in Table 3-3.

**Table 3-2 Assessment Schedule and Milestones**

Item	Milestone	Due Date
1	Submit Assessment Plan to NRC	October 21, 2011
2	Resolve NRC comments and revise Plan	NLT 30 days following receipt of NRC comments
3	Commence Assessment	NLT 30 days following final NRC approval of Plan
4	Submit Final Assessment Report	NLT 120 Calendar Days following NRC approval of Plan

**Table 3-3 Assessment Deliverables and Due Dates**

Item	Deliverable	Due Date
1	During the on-site assessments in Gaithersburg and Boulder, daily out briefings to the Technical Information Contact (TIC) and/or designees on the results of each day's assessment.	Daily after commencement of on-site activities
2	Written progress reports to the TIC on the degree of completion of each section of the assessment report.	Every 15 Calendar days after contract award. Next Due 10/26/2011
3	Draft Report to the TIC documenting all program areas assessed, the method of assessment, and any findings, recommendations, noteworthy practices, and conclusions. Thirty copies of the report shall be provided as a confidential draft document in hard copy format and four copies in electronic form.	Within 30 Calendar days after completion of assessment.
4	Summary Report briefing to the Ionizing Radiation Safety Committee	Between 14 and 21 calendar days of delivery of draft report.
5	Final Report to the TIC and the NRC.	Within 120 Calendar days of NRC approval of Assessment Plan
6	Electronic copies of all records of project activities to the NIST Health Physics Office	Within 7 days of delivery of the Final Report.

### 3.4 Work Requirements

The NIST Technical Information Contact (TIC) will be responsible for ensuring that auditors are permitted access to appropriate NIST facilities, personnel, and documentation; training auditors on pertinent NIST safety, security, and QA requirements; providing applicable requirements documents; performing supplemental, on-site post-assessment investigations as necessary; review, comment and approval of audit documentation; and giving general audit support as necessary. The NIST TIC for this effort is Mr. Thomas O'Brien. Mr. O'Brien is also the NIST Radiation Safety Officer (RSO).

The assessment team will use the following guidance to conduct the assessment:

- Conditions identified by the team that represent an immediate safety and/or compliance risk will be promptly reported to responsible NIST personnel, the RSO, and the TIC. A summary will be included in the written Progress Report.
- Auditors will comply with the license conditions and requirements of the NRC licenses SNM-362 and 19-03166-06.
- Each auditor will conform to NIST safety and security requirements while on NIST property.
- Auditors shall notify the TIC of any identified deficient condition (requirement not met) on at least a daily basis or as necessary to prevent recurrence.
- Auditors shall coordinate site visits to NIST with the TIC and/or designee.
- Auditors shall maintain appropriate client confidentiality.

#### **4.0 ASSESSMENT AREAS FOR LICENSE SNM-362**

The NRC SNM-362 license assessment will include Licensed Operations and Program-specific Elements.

#### **4.1 Licensed Operations**

4.1.1. The assessment team will assess adequacy of licensed operations under license number SNM-362 with respect to the Root Cause, Contributing Causes, and Causal Factors identified in section 4 of enclosure 1 to the NRC Special Inspection Report. The Sections of the Special Inspection Report are as follows:

§4.1 Root Cause – Less Than Adequate Management Oversight and Accountability

§4.2 Contributing Causes

§4.2.1 Personnel Received Inadequate Training or No Training

§4.2.2 Written Operating Procedures Not Developed

§4.2.3 Plutonium Standards Obtained Without Proper Management Approval

§4.2.4 An Adequate Hazard Analysis Was Not Performed

§4.2.5 Poorly Human-Factored Experimental Setup

§4.2.6 Less than Adequate Direct Oversight of Work Involving Plutonium

§4.2.7 Use/Storage of Plutonium Sources in Mixed-Use Laboratory

§4.2.8 Less than Adequate Immediate Emergency Response to the Event

§4.3 NRC Review of NIST Causal Factors Analysis

4.1.2. The assessment team will assess the adequacy of licensed operations with respect to the program areas listed in Appendix K of NUREG 1556, Volume 6, and Appendix M of NUREG 1556, Volume 11. The audit checklist for irradiators from Appendix K of NUREG 1556, Volume 6 will be used for this assessment and appears as **Attachment A** to this assessment plan. The audit checklist from Appendix M of NUREG 1556, Volume 11 will be used for this assessment and appears as **Attachment B** to this assessment plan.

#### **4.2 Program-specific Elements**

The assessment team will assess the adequacy and implementation of the Radiation Safety Program under NRC license number SNM-362 license according to the program-specific elements and areas of focus listed below.

#### 4.2.1 Radiation Protection Procedures (Health Physics Instructions)

- Assess the adequacy of all procedures and the effectiveness of the implementation of these operating and emergency instructions.

#### 4.2.2. Research and Source Usage Protocols

- Assess that NIST radiological hazard analyses adequately address the hazards of the radiation source term considering all of the activities (as described in the research protocol) being conducted with that source with respect to safety significance and regulatory compliance.
- Assess the mechanism for ensuring that appropriate procedures and engineering controls have been verified to be in place prior to the commencement of research utilizing licensed material.

#### 4.2.3. Instruments and Equipment

- Assess the adequacy of the portable survey instruments used in radiological surveys and the knowledge, skills, and ability of personnel using these instruments.
- Assess the adequacy of the portable survey instruments calibration program.
- Assess the adequacy of the laboratory instrumentation used in radioanalysis and the knowledge, skills, and ability of HP staff using these instruments.
- Assess the adequacy of the laboratory instrumentation quality control program.

#### 4.2.4. Radiation Dosimetry Program

- Assess the adequacy of procedures associated with dosimetry operations, including issuance/use of external dosimetry, assessment of internal dose, and evaluation of and dose assessment for radiological incidents.
- Assess the adequacy of procedural requirements and the technical basis for determining when external and internal dosimetry is required.
- Assess the adequacy of methods in place for evaluating, controlling, and acting on potential internal exposures.
- Assess the adequacy of engineering and process controls in place for external and internal dose control and minimization.

#### 4.2.5. Radiation Safety Training Program

- Verify that individuals whose assigned duties involve working with ionizing radiation sources have knowledge commensurate with operational duties.
- Verify that workers are informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in safety concerns and/or violation of NRC requirements.
- Assess the adequacy of radiation safety awareness training provided to ancillary workers (such as janitorial or clerical staff), contract workers, and visitors.
- Assess the adequacy of the refresher training to cover regulation changes and/or radiation safety program changes that affect the workers.
  
- Assess the adequacy of the content of the training program to determine that it is commensurate with the individual's assigned duties including those who are involved with the transportation of radioactive materials.

#### 4.2.6. Material Control and Accountability

- Assess the adequacy of the process for approving source acquisition and facility utilization.

- Assess the adequacy of the methods used to demonstrate compliance with license possession limits and for accountability of sources.
- Assess the adequacy of the implementation of leak test procedures.
- Assess the adequacy of compliance with applicable Nuclear Materials Management and Safeguards System (NMMSS) reporting requirements.
- Assess the adequacy of procedures to control materials that have been made radioactive by use of NIST particle accelerators (including materials in the target and associated activation products in the accelerator along with its shielding).

#### 4.2.7. Posting, Labeling, and Control

- Assess the adequacy of access control to high radiation or very high radiation areas.
- Assess the adequacy of security for radioactive materials.

#### 4.2.8. Surveys

- Assess the adequacy of surveys that demonstrate compliance with public dose limits.
- Determine that surveys are conducted using approved procedures, that the survey results are appropriately reviewed, and that appropriate corrective actions, if any, have been taken.
- Assess the adequacy of individuals' knowledge in using survey instrumentation and in conducting a proper radiation survey.
- Determine that procedural requirements for surveys are adequate to demonstrate compliance with regulations and pertinent license requirements.
- Assess the adequacy of the program with respect to 10 CFR Part 36 compliance activities.
- Assess the adequacy of the emergency response program/capabilities for radiological emergencies.

#### 4.2.9. As Low As Is Reasonably Achievable (ALARA)

- Determine that high level management has made a commitment to minimize exposure to workers and has clearly defined procedures and policies to implement the ALARA philosophy.
- Ascertain that the radiation protection staff has been given authority to make certain that ALARA policies are carried out and those workers have been adequately trained to understand the ALARA philosophy and how it should be implemented at their work places.

#### 4.2.10. Radioactive Material Shipping

- Determine that the shippers of radioactive materials are knowledgeable of the shipping regulations and whether shipping personnel demonstrate adequate skills to accomplish the package preparation requirements for public transport.

#### 4.2.11. Radioactive Waste Management

- Assess the adequacy of the facility, procedures, documentation, and other controls for the processing and disposal of radioactive waste.

#### 4.2.12. Radio-effluents

- Assess the adequacy of the procedures and controls for liquid and gaseous radio-effluents.



## 5.0 ASSESSMENT AREAS FOR LICENSE 19-03166-06 (Formerly 05-03166-05)

The NRC 19-03166-06 license assessment will include Licensed Operations and Program-specific Elements.

### 5.1 Licensed Operations

5.1.1. The assessment team will assess adequacy of licensed operations under license number 19-03166-06 (Formerly 05-03166-05) with respect to the Root Cause, Contributing Causes, and Causal Factors identified in section 4 of enclosure 1 to the NRC Special Inspection Report. The Sections of the Special Inspection Report are as follows:

- §4.1 Root Cause – Less Than Adequate Management Oversight and Accountability
- §4.2 Contributing Causes
  - §4.2.1 Personnel Received Inadequate Training or No Training
  - §4.2.2 Written Operating Procedures Not Developed
  - §4.2.3 Plutonium Standards Obtained Without Proper Management Approval
  - §4.2.4 An Adequate Hazard Analysis Was Not Performed
  - §4.2.5 Poorly Human-Factored Experimental Setup
  - §4.2.6 Less than Adequate Direct Oversight of Work Involving Plutonium
  - §4.2.7 Use/Storage of Plutonium Sources in Mixed-Use Laboratory
  - §4.2.8 Less than Adequate Immediate Emergency Response to the Event
- §4.3 NRC Review of NIST Causal Factors Analysis

5.1.2. The assessment team will assess the adequacy of licensed operations with respect to the program areas listed in Appendix L of NUREG 1556, Volume 7. The audit checklist from Appendix L of NUREG 1556, Volume 7 will be used for this assessment and appears as **Attachment C** to this assessment plan.

### 5.2 Program-specific Elements

The assessment team will assess the adequacy and implementation of the Radiation Safety Program under NRC license number 19-03166-06 according to the same program-specific elements and areas of focus listed in Section 4.2 for the SNM-362 license.

## 6.0 Final Report Format

The draft Final Assessment Report will be delivered to the NIST TIC within 30 calendar days of the completion of the assessment. 30 hardcopies and four electronic copies as a confidential draft document will be provided. The Final Assessment Report will be delivered to the NRC and the NIST TIC within 120 days of NRC approval of the Assessment Plan. The draft and Final Assessment report will be formatted according to the following content outline:

- 1.0 EXECUTIVE SUMMARY
- 1.1 Introduction
- 1.2 Assessment Purpose and Scope
- 1.3 Assessment Details
- 1.4 Open Issues
- 1.5 Conclusions

- 2.0 LICENSE REVIEW
  - 2.1 Amendments and Program Changes
  - 2.2 License Condition Compliance Assessment
  - 2.3 Management Oversight
  - 2.4 Facilities
  
- 3.0 RADIATION SAFETY PROGRAM DISCUSSION
  - 3.1 Radiation Safety Organization and Staffing
  - 3.2 Radiation Safety Culture
  - 3.3 Radiation Safety Training
  - 3.4 ALARA Program
  - 3.5 Engineering Controls
  - 3.6 Radiological Instrumentation & Sources
  - 3.7 Radiological Surveys, Contamination Controls & Records
  - 3.8 Labels and Posting
  - 3.9 Contamination Control
  - 3.10 Personnel Monitoring for Radiation Exposure
  - 3.11 Research and Source Usage
  - 3.12 Material Control and Accountability
  - 3.13 Radioactive Material Shipping and Receiving
  - 3.14 Radioactive Waste Management and Transportation
  - 3.15 Effluents and Environmental Monitoring
  - 3.16 Decommissioning
  - 3.17 Trustworthiness and Reliability Program for Quantities of Concern
  - 3.18 Documents Reviewed
  
- 4.0 AUDIT RESULTS
  - 4.1 Findings
  - 4.2 Observations
  - 4.3 Noteworthy Practices
  - 4.4 Recommendations
  - 4.5 Conclusions
  
- 5.0 APPENDICES
  - 5.1 Completed Attachment A Checklist
  - 5.2 Completed Attachment B Checklist
  - 5.3 Completed Attachment C Checklist
  
- 7.0 References**
  - 7.1 NUREG-1556, Volume 6, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses, January, 1999
  - 7.2 NUREG-1556, Volume 11, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses of Broad Scope, April, 1999.
  - 7.3 NUREG-1556, Volume 7, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, December 1999.

- 7.4 Confirmatory Order issued by the NRC to NIST in connection with NRC Inspection Report 030-03721/2008-001 and NRC Investigation Report 4-2008-062, March 1, 2010.

**ATTACHMENT A**

**NUREG-1556 Volume 6, Appendix K**

**Suggested Audit Checklist for 10 CFR Part 36 Irradiators**

**Suggested Audit Checklist for 10 CFR Part 36 Irradiators**

*Note:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities and activities which have not occurred since the last audit need not be reviewed at the next audit. Specific citations from the CFR are noted in blue font in this checklist.

Licensee's name: \_\_\_\_\_ License No. \_\_\_\_\_

Date of This Audit \_\_\_\_\_

\_\_\_\_\_  
(Auditor Signature) Date \_\_\_\_\_

\_\_\_\_\_  
(Management Signature) Date \_\_\_\_\_

**Audit History**

A. Last audit of this location conducted on (date) \_\_\_\_\_

B. Were previous audits conducted at intervals not to exceed least every 12 months?  
[10 CFR 20.1101, (c)]

The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

C. Were records of previous audits maintained? [10 CFR 20.2102]

(a) Each licensee shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

D. Were any deficiencies identified during last two audits or two years, whichever is longer?

E. Were corrective actions taken? (Look for repeated deficiencies).

**Organization and Scope of Program**

A. If the mailing address or places of use changed, was the license amended?

B. If ownership changed or bankruptcy filed, was NRC prior consent obtained or was NRC notified?

C. Radiation Safety Officer

1. If the RSO was changed, was license amended?

2. Does new RSO meet the licensee's training requirements?

3. Is RSO fulfilling his/her duties?

4. To whom does RSO report?

D. If the designated contact person for NRC changed, was NRC notified?

E. Sealed Sources and Devices

1. Does the license authorize all of the NRC regulated radionuclides contained in irradiators?

2. Have copies of (or access to) SSD Certificates?

3. Are the sealed sources, and if applicable, devices in accordance with the description in the Sealed Source and Device (SSD) Registration Certificates? [10 CFR 32.210]

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a 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 installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with--

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

4. Have manufacturers' manuals for operation and maintenance?

5. Are the actual uses of the irradiator consistent with the authorized uses listed on the license?

6. Are the sealed sources used under conditions specified in the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?

**Training and Instructions to Workers**

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per [10 CFR 19.12]? Refresher training provided, as needed? Records maintained?

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be--

- (1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;
  - (2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
  - (3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material;
  - (4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;
  - (5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and
  - (6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.
- (b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

**B. Did each individual permitted to operate the irradiator without a supervisor present, receive instruction according to the license commitments and 10 CFR 36.51 before operating the irradiator?**

10 CFR 36.51 (a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

- (1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);
- (2) The requirements of parts 19 and 36 of NRC regulations that are relevant to the irradiator;
- (3) The operation of the irradiator;
- (4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and
- (5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

- (1) Changes in operating and emergency procedures since the last review, if any;

- (2) Changes in regulations and license conditions since the last review, if any;
  - (3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
  - (4) Relevant results of inspections of operator safety performance;
  - (5) Relevant results of the facility's inspection and maintenance checks; and
  - (6) A drill to practice an emergency or abnormal event procedure.
- (e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.
- (f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.
- (g) Individuals who must be prepared to respond to alarms required by §§ 36.23(b), 36.23(i), 36.27(a), 36.29(a), 36.29(b), and 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

**C. Are records of training, tests, safety reviews, and annual evaluations maintained for each authorized irradiator operator? [10 CFR 36.81(b), (c)]**

The licensee shall maintain the following records at the irradiator for the periods specified.

- (a) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Commission terminates the license for documents not superseded.
  - (b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.
  - (c) Records of the annual evaluations of the safety performance of irradiator operators required by § 36.51(e) for 3 years after the evaluation.
- 10 CFR 36.51 (a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:
- (1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);
  - (2) The requirements of parts 19 and 36 of NRC regulations that are relevant to the irradiator;
  - (3) The operation of the irradiator;
  - (4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and
  - (5) Case histories of accidents or problems involving irradiators.
- (b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.



(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

- (1) Changes in operating and emergency procedures since the last review, if any;
- (2) Changes in regulations and license conditions since the last review, if any;
- (3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
- (4) Relevant results of inspections of operator safety performance;
- (5) Relevant results of the facility's inspection and maintenance checks; and
- (6) A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by §§ 36.23(b), 36.23(i), 36.27(a), 36.29(a), 36.29(b), and 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

D. Did individuals who perform non-routine operations receive training before performing these operations?

E. Did interviews reveal that individuals know the emergency procedures?

F. Did this audit include observations of irradiator operations?

G. Do workers know requirements for the following:

1. the radiation safety program
2. annual dose limits
3. new Form NRC 4 and 5
4. 10% monitoring threshold
5. dose limits to embryo/fetus and declared pregnant worker
6. grave danger posting?

### **Radiation Survey Instruments And Radiation Monitors**

A. Are all portable survey meters calibrated at least annually to an accuracy of  $\pm 20\%$  for the gamma energy of the sources in use? [10 CFR 36.57(c)]

10 CFR 36.57 (a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must

be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in § 36.25 are exceeded, the facility must be modified to comply with the requirements in § 36.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of  $\pm 20$  percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

B. Are portable survey meters of a type that does not saturate and read zero at high dose rates?  
[10 CFR 36.57(c)]

C. Are calibration records maintained?

D. Are all operable survey instruments able to detect 0.5 microsievert (0.05 mrem) per hour?

E. Has the licensee evaluated the location and sensitivity of the radiation monitor to detect sources carried by the product conveyor system for automatic conveyor systems?  
[10 CFR 36.29(a)]

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

F. Has the licensee tested the operability and sensitivity of monitor used to detect the presence of high radiation levels in the radiation room before personnel entry at frequency specified in license application?

G. Has the licensee tested the operability and sensitivity of monitor used to detect contamination of pool water due to leaking sources? (frequency of checks as specified in license application?)

H. For underwater irradiators not in a shielded radiation room, has the licensee tested the operability and sensitivity of monitor used to detect abnormal radiation levels? (frequency of checks as specified in license application?)

### **Conductivity Meters**

A. Are appropriate operable conductivity meters possessed and used?

B. Are conductivity meters calibrated at least annually? [10 CFR 36.63(b)]

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

### **Sealed Source Accountability Program**

A. Are records maintained showing the receipt, location, transfer, and disposal of each sealed source? [10 CFR 30.51(a)(1)]

B.

a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and parts 31 through 36 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

(1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

B. Is material accountability program as described in application being implemented?

### **Personnel Radiation Protection**

A. Are ALARA considerations incorporated into the radiation protection program?  
[10 CFR 20.1101(b)]

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

B. Is documentation kept showing that unmonitored individuals receive less than 10% of limit?  
[10 CFR 20.1502(a)]

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a),

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);<sup>2</sup> and

(4) Individuals entering a high or very high radiation area.

C. Did unmonitored individuals' activities change during the year which could put them over 10% of limit?

D. If yes to C above, was a new evaluation performed?

E. Is external dosimetry provided to individuals as required by 10 CFR 36.55 and to individuals likely to receive >10% of limit?

(a) Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges (see 10 CFR 20.1501(c)). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

1. Irradiator Operators: Is the dosimetry supplier NVLAP approved? [10 CFR 20.1501(c)]

(a) Each licensee shall make or cause to be made, surveys that--

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate--

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards.

(b) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

2. Are the dosimeters exchanged monthly for film badges and quarterly for TLDs?

3. Are dosimetry reports reviewed by the RSO upon receipt?

4. Are dosimeters provided to persons who enter the radiation room of a panoramic irradiator?  
[10 CFR 36.55(b)]

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

5. Annual checks of accuracy of pocket dosimeters performed? [10 CFR 36.55(b)]  
See above.

6. Are the records NRC Forms or equivalent? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]  
a. NRC-Form 4 "Cumulative Occupational Exposure History" completed?

10 CFR 20.2104 (d) The licensee shall record the exposure history of each individual, as required by paragraphs (a) or (b) of this section, on NRC Form 4, or other clear and legible record, including all of the information required by NRC Form 4.<sup>4</sup> The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the NRC Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on the NRC Form 4 indicating the periods of time for which data are not available.

b. NRC-Form 5 "Occupational Exposure Record for a Monitoring Period" completed?

10 CFR 20.2106 (c) *Recordkeeping format.* The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

7. Declared pregnant worker/embryo/fetus

a. If a worker declared her pregnancy, did licensee comply with [10 CFR 20.1208]?

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of--

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the

licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

b. Were records kept of embryo/fetus dose per [10 CFR 20.2106(e)]?

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

F. Are records of exposures, surveys, monitoring, and evaluations maintained [10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2106, 10 CFR 36.57(a)].

10 CFR 20.2102 (a) Each licensee shall maintain records of the radiation protection program, including:

- (1) The provisions of the program; and
- (2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

10 CFR 20.2103 (a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

10 CFR 20.2106 (a) *Recordkeeping requirement.* Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions.

These records<sup>5</sup> must include, when applicable—

- (1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

- (2) The estimated intake of radionuclides (see § 20.1202);
- (3) The committed effective dose equivalent assigned to the intake of radionuclides;
- (4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;
- (5) The total effective dose equivalent when required by § 20.1202; and
- (6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) *Recordkeeping frequency.* The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) *Recordkeeping format.* The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

(d) *Privacy protection.* The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(f) The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

<sup>5</sup> Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

10 CFR 36.57 (a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

## Public Dose

A. Is public access controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? 10 CFR 20.1301(a)(1)]

(a) Each licensee shall conduct operations so that -

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

- (a) Each licensee shall make or cause to be made, surveys that--
- (1) May be necessary for the licensee to comply with the regulations in this part; and
  - (2) Are reasonable under the circumstances to evaluate--
    - (i) The magnitude and extent of radiation levels; and
    - (ii) Concentrations or quantities of radioactive material; and
    - (iii) The potential radiological hazards.

C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [10 CFR 20.1301(a)(2)]

See above.

D. Is access to sealed sources controlled in a manner that would prevent unauthorized use or removal? [10 CFR 20.1801]

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

E. Records maintained? [10 CFR 20.2103, 10 CFR 20.2107]

10 CFR 20.2103 (a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

10 CFR 20.2107(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.



## Operating And Emergency Procedures

A. Have operating and emergency procedures been developed? [10 CFR 36.53]

(a) The licensee shall have and follow written operating procedures for--

- (1) Operation of the irradiator, including entering and leaving the radiation room;
- (2) Use of personnel dosimeters;
- (3) Surveying the shielding of panoramic irradiators;
- (4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- (5) Leak testing of sources;
- (6) Inspection and maintenance checks required by § 36.61;
- (7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
- (8) Inspection of movable shielding required by § 36.23(h), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for--

- (1) Sources stuck in the unshielded position;
- (2) Personnel overexposures;
- (3) A radiation alarm from the product exit portal monitor or pool monitor;
- (4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
- (5) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
- (6) A prolonged loss of electrical power;
- (7) A fire alarm or explosion in the radiation room;
- (8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
- (9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
- (10) The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

- (1) The revisions do not reduce the safety of the facility,
- (2) The revisions are consistent with the outline or summary of procedures submitted with the license application,
- (3) The revisions have been reviewed and approved by the radiation safety officer, and
- (4) The users or operators are instructed and tested on the revised procedures before they are put into use.

B. Do they contain the required elements?

C. Does each individual working with the sealed sources have a current copy of the operating and emergency procedures (including emergency telephone numbers)?

D. Did any emergencies occur?

1. If so, were they handled properly?
2. Were appropriate corrective actions taken?
3. Was NRC notification or reporting required? [10 CFR 20.2201, 2202, 2203, 10 CFR 30.50 and 10 CFR 36.83]

10 CFR 20.2201 (a) *Telephone reports.* (1) Each licensee shall report by telephone as follows:

- (i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
- (ii) Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter, and

(ii) All other licensees shall make reports by telephone to the NRC Operations Center (301)-816-5100.

(b) *Written reports.* (1) Each licensee required to make a report under paragraph (a) of this section shall, within 30 days after making the telephone report, make a written report setting forth the following information:

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

(ii) A description of the circumstances under which the loss or theft occurred; and

(iii) A statement of disposition, or probable disposition, of the licensed material involved; and

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(v) Actions that have been taken, or will be taken, to recover the material; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(2) Reports must be made as follows:

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vii), 73.67(g)(3)(iii), 73.71, or § 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

10 CFR 20.2202 (a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions--

(1) An individual to receive--

(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where

personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours--

(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with 10 CFR 50.72; and

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center (301) 816-5100.

(e) The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under § 20.2204.

10 CFR 20.2203 (a) *Reportable events*. In addition to the notification required by § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in § 20.1201; or

(ii) The occupational dose limits for a minor in § 20.1207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or

(iv) The limits for an individual member of the public in § 20.1301; or

(v) Any applicable limit in the license; or

(vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(3) Levels of radiation or concentrations of radioactive material in—

(i) A restricted area in excess of any applicable limit in the license; or

(ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301);

or

(4) For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) *Contents of reports*. (1) Each report required by paragraph (a) of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and  
(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed<sup>1</sup> individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov); or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

<sup>1</sup> With respect to the limit for the embryo-fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.

10 CFR 36.83 (a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC regulations:

- (1) Source stuck in an unshielded position.
- (2) Any fire or explosion in a radiation room.
- (3) Damage to the source racks.
- (4) Failure of the cable or drive mechanism used to move the source racks.
- (5) Inoperability of the access control system.
- (6) Detection of radiation source by the product exit monitor.
- (7) Detection of radioactive contamination attributable to licensed radioactive material.
- (8) Structural damage to the pool liner or walls.
- (9) Abnormal water loss or leakage from the source storage pool.
- (10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

## Leak Tests

A. Were sealed sources leak tested at prescribed intervals? [10 CFR 36.59]

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State.

In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, appendix B to part 20. (See 10 CFR 30.50 for reporting requirements.)

B. Was the leak test performed according to regulatory requirements? [10 CFR 36.59]

See above.

C. Are records of results retained with the appropriate information included?

D. Were any sealed sources found leaking and if yes, were appropriate actions taken and was NRC notified? [10 CFR 20.2201, 10 CFR 20.2203, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 36.59, 10 CFR 36.83]

10 CFR 20.2201 (a) *Telephone reports.* (1) Each licensee shall report by telephone as follows:  
(i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

(ii) Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter, and

(ii) All other licensees shall make reports by telephone to the NRC Operations Center (301)-816-5100.

(b) *Written reports.* (1) Each licensee required to make a report under paragraph (a) of this section shall, within 30 days after making the telephone report, make a written report setting forth the following information:

- (i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and
- (ii) A description of the circumstances under which the loss or theft occurred; and
- (iii) A statement of disposition, or probable disposition, of the licensed material involved; and
- (iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
- (v) Actions that have been taken, or will be taken, to recover the material; and
- (vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(2) Reports must be made as follows:

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vii), 73.67(g)(3)(iii), 73.71, or § 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

10 CFR 20.2203 (a) *Reportable events.* In addition to the notification required by § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:

- (i) The occupational dose limits for adults in § 20.1201; or
- (ii) The occupational dose limits for a minor in § 20.1207; or
- (iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or
- (iv) The limits for an individual member of the public in § 20.1301; or
- (v) Any applicable limit in the license; or
- (vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(3) Levels of radiation or concentrations of radioactive material in—

- (i) A restricted area in excess of any applicable limit in the license; or
  - (ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301);
- or

(4) For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) *Contents of reports.* (1) Each report required by paragraph (a) of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

- (i) Estimates of each individual's dose; and
- (ii) The levels of radiation and concentrations of radioactive material involved; and
- (iii) The cause of the elevated exposures, dose rates, or concentrations; and
- (iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed<sup>1</sup> individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov); or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

<sup>1</sup> With respect to the limit for the embryo-fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.

10 CFR 21.21 (a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to --

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the

evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c) A dedicating entity is responsible for --

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

(d)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting --

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (d)(1) of this section must be made as follows --

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.



(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(e) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

10 CFR 30.50 (a) *Immediate report.* Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report.* Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.<sup>1</sup> To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;  
(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved;  
and

(v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the NRC using an appropriate method listed in § 30.6(a); and a copy must be sent to the appropriate NRC Regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72.

<sup>1</sup> The commercial telephone number for the NRC Operations Center is (301) 816-5100.

10 CFR 36.59 (a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these

functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, appendix B to part 20. (See 10 CFR 30.50 for reporting requirements.)

10 CFR 36.83 (a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC regulations:

- (1) Source stuck in an unshielded position.
  - (2) Any fire or explosion in a radiation room.
  - (3) Damage to the source racks.
  - (4) Failure of the cable or drive mechanism used to move the source racks.
  - (5) Inoperability of the access control system.
  - (6) Detection of radiation source by the product exit monitor.
  - (7) Detection of radioactive contamination attributable to licensed radioactive material.
  - (8) Structural damage to the pool liner or walls.
  - (9) Abnormal water loss or leakage from the source storage pool.
  - (10) Pool water conductivity exceeding 100 microsiemens per centimeter.
- (b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

### **Inspection and Maintenance Checks**

A. Are all procedures for maintenance of the irradiator being followed where applicable?

B. Are all checks to determine proper functioning and wear of the source movement systems performed at frequencies as specified in the license application?

C. Are labels, signs, and postings clean and legible?

D. Are checks for operability as required by 10 CFR 36.61(a) (not included in item 4.) performed at frequencies and according to procedures described in license application:

1. Each aspect of the access control system
2. Emergency source return control
3. Heat/smoke detectors, extinguisher system
4. Pool water replacement system high and low water indicators
5. For underwater irradiators, was the intrusion alarm tested for operability? (frequency checks as specified in license application?)  
See below.

E. Are checks for functioning and condition of equipment performed at required frequencies and according to procedures described in license application:

1. Assessment of the condition and operability of the source rack protector are performed the required frequencies [10 CFR 36.61(a)].
2. Assessment of water added to the pool to determine if there is pool leakage are performed at required frequencies as required by [10 CFR 36.61(a)(14)].
3. Assessment of radiation damage to electrical wiring are performed at required frequencies as required by [10 CFR 36.61(a)(15)].
4. Water conductivity and analysis are performed at required frequencies [10 CFR 36.63]
5. Confirmation that water circulation system is leak tight. [10 CFR 36.61(a)(7)]
6. Functioning of the source position indicator [10 CFR 36.61(a)(2)]
7. Leak tightness of water circulation system, visual inspection [10 CFR 36.61(a)(7)]

10 CFR 36.61 (a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

- (1) Operability of each aspect of the access control system required by § 36.23.
  - (2) Functioning of the source position indicator required by § 36.31(b).
  - (3) Operability of the radiation monitor for radioactive contamination in pool water required by § 36.59(b) using a radiation check source, if applicable.
  - (4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 36.29(b).
  - (5) Operability of the product exit monitor required by § 36.29(a).
  - (6) Operability of the emergency source return control required by § 36.31(c).
  - (7) Leak-tightness of systems through which pool water circulates (visual inspection).
  - (8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27 (but without turning extinguishers on).
  - (9) Operability of the means of pool water replenishment required by § 36.33(c).
  - (10) Operability of the indicators of high and low pool water levels required by § 36.33(d).
  - (11) Operability of the intrusion alarm required by § 36.23(i), if applicable.
  - (12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
  - (13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.
  - (14) Amount of water added to the pool to determine if the pool is leaking.
  - (15) Electrical wiring on required safety systems for radiation damage.
  - (16) Pool water conductivity measurements and analysis as required by § 36.63(b).
- (b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

### **Repair and Preventive Maintenance**

A. Are repair and maintenance of components related to the radiological safety of the irradiator performed by the manufacturer or person specifically authorized by the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 10 CFR 20.1301 limits)?

(a) Each licensee shall conduct operations so that -

- (1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and
  - (2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.
- (b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.
- (c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if-
- (1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

(d) A licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section;

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(e) In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190 shall comply with those standards.

(f) The Commission may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

B. Malfunctions and defects found during inspection and maintenance checks are repaired without undue delay.

## Transportation

**Note:** This section will not apply if you have not transported sealed sources during the period covered by this audit.

- A. Were sources shipped since the last audit?
- B. If so, were 10 CFR Part 71 requirements followed?
- C. DOT-Type A or Type B packages used? [10 CFR Part 71, 49 CFR 173.415, 49 CFR 173.416(b)] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? NRC-approved QA program?
- D. Package performance test records on file? [49 CFR 173.415(a)]
- E. Special form sources documentation? [49 CFR 173.476(a)]
- F. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]
- G. Package properly marked? [49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324]
- H. Package closed and sealed during transport? [49 CFR 173.475(f)]
- I. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
- J. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604]
- K. Secured against movement? [49 CFR 177. 834]
- L. Placarded on vehicle, if needed? [49 CFR 172.504]
- M. Proper overpacks, if used? [49 CFR 173.25]
- N. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]

## Auditor's Independent Survey Measurements

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits [10 CFR 20.1501(a) & 1502(a)]?

## Notification and Reports

- A. Was a telephone report made within 24 hours as described in 10 CFR 36.83(b), 10 CFR 30.50(c)(1), and a written report within 30 days as described in

10 CFR 30.50(c)(2) of any of the following: Regulations given above.

1. Source stuck in an unshielded position
2. Any fire or explosion in a radiation room
3. Damage to the source rack
4. Failure of the cable or drive mechanism used to move the source racks
5. Inoperability of the access control system
6. Detection of radioactive contamination attributable to licensed radioactive material
7. Detection of radioactive contamination attributable to licensed radioactive material
8. Structural damage to the pool liner or walls
9. Abnormal water loss or leakage from the source storage pool
10. Pool water conductivity exceeding 100 microsiemens per centimeter.

B. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]

C. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.50]

D. Did any overexposures and high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]

E. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?

F. Is the management/RSO/shift foreman licensee aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

### **Posting and Labeling**

A. NRC-Form 3 "Notice to Workers" posted? [10 CFR 19.11]

10 CFR 19.11 (a) Each licensee (except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter) shall post current copies of the following documents:

- (1) The regulations in this part and in part 20 of this chapter;
- (2) The license, license conditions, or documents incorporated into a license by reference, and amendments thereto;
- (3) The operating procedures applicable to licensed activities;
- (4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to subpart B of part 2 of this chapter, and any response from the licensee.

(b) Each applicant for and holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, each applicant for a standard design certification under subpart B of part 52 of this chapter, and each applicant for and holder of a manufacturing license under subpart F of part 52 of this chapter shall post:

- (1) The regulations in this part;
- (2) The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder; and
- (3) Any notice of violation, proposed imposition of civil penalty, or order issued under subpart B of part 2 of this chapter, and any response from the applicant or holder.

(c) [Reserved]

(d) If posting of a document specified in paragraphs (a)(1), (2) or (3), or (b)(1) or (2) of this section is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

(e)(1) Each licensee, each applicant for a specific license, each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter shall prominently post NRC Form 3, "Notice to Employees," dated August 1997. Later versions of NRC Form 3 that supersede the August 1997 version shall replace the previously posted version within 30 days of receiving the revised NRC Form 3 from the Commission.

(2) Additional copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-7232, via e-mail to [forms@nrc.gov](mailto:forms@nrc.gov), or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(f) Documents, notices, or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(g) Commission documents posted under paragraphs (a)(4) or (b)(3) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's or regulated entity's response, if any, shall be posted within 2 working days after dispatch by the licensee or regulated entity. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

#### B. NRC regulations, license documents posted or a notice posted? [10 CFR 19.11, 10 CFR 21.6]

10 CFR 21.6, (a)(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of --

- (i) The regulations in this part;
- (ii) Section 206 of the Energy Reorganization Act of 1974; and
- (iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

#### C. Other posting and labeling? [10 CFR 20.1902, 10 CFR 20.1904]

10 CFR 20.1902, (a) **Posting of radiation areas.** The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."



(b) *Posting of high radiation areas.* The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) *Posting of very high radiation areas.* The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(d) *Posting of airborne radioactivity areas.* The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) *Posting of areas or rooms in which licensed material is used or stored.* The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

10 CFR 20.1904, a) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

According to 10 CFR 36.23(g), the radiation room of a panoramic irradiator must be posted as a "high radiation area." However, 10 CFR 20.1902(c) requires that the area be posted as a "very high radiation area." There has been an oversight in not adopting in 10 CFR Part 36 the "very high radiation area" concept that is contained in 10 CFR Part 20. The NRC plans to change 10 CFR 36.23(g) to require posting as a "very high radiation area." In the meantime, the preferred posting is "very high radiation area," and irradiators posted in this manner will not be subject to enforcement action under 10 CFR 36.23(g).

## **Record Keeping for Decommissioning**

### **A. Records kept of information important to decommissioning? [10 CFR 30.35(g)]**

10 CFR 30.35, (g) Each person licensed under this part or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into

porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(ii) All areas outside of restricted areas that require documentation under § 30.35(g)(1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

B. Records include all information outlined in [10 CFR 30.35(g)]?

### **Bulletins and Information Notices**

A. NRC Bulletins, NRC Information Notices, NMSS Newsletters, received?

B. Appropriate training and action taken in response?

### **Special License Conditions or Issues**

A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

### **Deficiencies Identified in Audit; Corrective Actions**

A. Summarize problems/deficiencies identified during audit.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

### **Evaluation of Other Factors**

A. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?

B. RSO has sufficient time to perform his/her radiation safety duties?

C. Licensee has sufficient staff to support the radiation protection program?

**END ATTACHMENT A**

**ATTACHMENT B**  
**NUREG 1556 Volume 11, Appendix M**  
**Sample Audit Program- Non-Medical**

The following audit form may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before an NRC inspection). This form is not intended to be all inclusive. During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. References are included at the end of this audit form.

**1. MANAGEMENT OVERSIGHT:**

(Management support to radiation safety; RSC; RSO; program audits, including annual reviews of program and ALARA reviews; control by authorized users; appropriate follow up on events and previous audit/inspection findings)

**2. AMENDMENTS AND PROGRAM CHANGES:**

(Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition).

**3. FACILITIES:**

(Facilities as described in license; uses; control of access; engineering controls; calibration facilities; shielding; air flow)

**4. EQUIPMENT AND INSTRUMENTATION:**

(Operable and calibrated survey equipment; procedures; 10 CFR Part 21)

**5. MATERIAL USE, CONTROL, AND TRANSFER:**

(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

**6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:**

(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

**7. TRAINING AND INSTRUCTIONS TO WORKERS:**

(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users)

**8. RADIATION PROTECTION:**

(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

**9. RADIOACTIVE WASTE MANAGEMENT:**

(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method)

**10. DECOMMISSIONING:**

(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

**11. TRANSPORTATION:**

(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

**12. NOTIFICATIONS AND REPORTS:**

(Reporting and follow up of theft, loss, incidents and overexposures. Notification of change in the RSO and/or authorized user. Radiation exposure reports provided to individuals.)

**13. POSTING AND LABELING:**

(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

**14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with staff's results and regulations)

**15. AUDIT FINDINGS:**

(Describe condition, requirement, and recommendation to correct)

**References**

- A. Management Oversight
  - 1. Ionizing Radiation Safety Committee  
Applicable license conditions.
  - 2. Radiation Safety Officer  
Applicable license conditions.
  - 3. Audits, Reviews, or Inspections  
10 CFR 20.1101 Radiation protection programs.  
10 CFR 20.2102 Records of radiation protection programs.  
Applicable license conditions.
  - 4. ALARA  
10 CFR 20.1101 Radiation protection programs.
  - 5. Authorized Users  
Applicable license conditions.
- B. Amendments and Program Changes:  
Applicable license conditions.
- C. Facilities
  - 1. Access Control  
10 CFR 20.1601, 1602 Control of access to high/very high radiation areas.  
10 CFR 20.1801 Security of stored material.  
10 CFR 20.1802 Control of material not in storage.  
Applicable license conditions.
  - 2. Engineering Controls  
10 CFR 20.1101 Radiation protection programs.

10 CFR 20.1701 Use of process or other engineering controls.  
Applicable license conditions.

- D. Equipment and Instrumentation
1. Survey Instruments
    - 10 CFR 20.1501 General.
    - 10 CFR 20.1701 Use of Process or Other Engineering Controls.
    - 10 CFR 20.2103 Records of Surveys.Applicable license conditions.
  2. Safety Component Defects
    - 10 CFR 21.21 Notification of failure to comply or existence of a defect and its evaluation.
- E. Material Use, Control, and Transfer
1. License and applicable license conditions.
  2. Security and Control
    - 10 CFR 20.1003 Definitions (restricted area and unrestricted area).
    - 10 CFR 20.1801 Security of stored material.
    - 10 CFR 20.1802 Control of material not in storage.
  3. Receipt and Transfer of Licensed Material
    - 10 CFR 20.1302 Compliance with dose limits for individual members of the public.
    - 10 CFR 20.1906 Procedures for receiving and opening packages.
    - 10 CFR 20.1501 Surveys.
    - 10 CFR 20.2103 Records of surveys.
    - 10 CFR 30.41 Transfer of byproduct material.
    - 10 CFR 30.51 Records of receipt and transfer.
- F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
1. Area Surveys
    - 10 CFR 20.1302 Compliance with dose limits for individual members of the public.
    - 10 CFR 20.1501 General.
    - 10 CFR 20.2103 Records of surveys.
    - 10 CFR 20.2107 Records of dose to individual members of the public.Applicable license conditions.
  2. Leak Tests and Inventories
    - Applicable license conditions.
- G. TRAINING AND INSTRUCTIONS TO WORKERS
1. General
    - 10 CFR 19.12 Instruction to workers.
    - Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.
    - Applicable license conditions.
- H. RADIATION PROTECTION
1. Radiation Protection Program
    - a. Exposure evaluation
      - 10 CFR 20.1501 General.
    - b. Programs
      - 10 CFR 20.1101 Radiation protection programs.
  2. Dosimetry

- a. Dose Limits
  - 10 CFR 20.1201 Occupational dose limits for adults.
  - 10 CFR 20.1202 Compliance with requirements for summation of external and internal doses.
  - 10 CFR 20.1207 Occupational dose limits for minors.
  - 10 CFR 20.1208 Doses to an embryo/fetus.
- b. External
  - 10 CFR 20.1203 Determination of external dose from airborne radioactive material.
  - 10 CFR 20.1501 General.
  - 10 CFR 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.
  - Applicable license conditions.
- c. Internal
  - 10 CFR 20.1204 Determination of internal exposure.
  - 10 CFR 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.
  - 10 CFR 20, Subpart H Respiratory protection and controls to restrict internal exposure in restricted areas.

### 3. Records

- 10 CFR 20.2102 Records of radiation protection programs.
- 10 CFR 20.2103 Records of surveys.
- 10 CFR 20.2104 Determination of prior occupational dose.
- 10 CFR 20.2106 Records of individual monitoring results.

## I. RADIOACTIVE WASTE MANAGEMENT

### 1. Disposal

- 10 CFR 20.1904 Labeling containers.
- 10 CFR 20.2001 General requirements.
- 10 CFR 20.2103 Records of surveys.
- 10 CFR 20.2108 Records of waste disposal.
- 10 CFR 20.2003 Disposal by release into sanitary sewerage.

### 2. Effluents

- a. General
  - Applicable license conditions
- b. Release to septic tanks
  - 10 CFR 20.1003 Definitions (sanitary sewerage).
  - 10 CFR Part 20, Effluent Concentrations. App. B, Table 2
- c. Incineration of waste
  - 10 CFR 20.2004 Treatment or disposal by incineration.
- d. Control of air effluents and ashes
  - 10 CFR 20.1201 Occupational dose limits for adults.
  - 10 CFR 20.1301 Dose limits for individual members of the public.
  - 10 CFR 20.1501 General.
  - 10 CFR 20.1701 Use of process or other engineering controls.
  - Applicable license conditions

### 3. Waste Management

- a. General
  - 10 CFR 20.2001 General requirements.
  - (IN) 90-09 Information Notice Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees.



- b. Waste compacted  
Applicable license conditions.
- c. Waste storage areas  
10 CFR 20.1801 Security of stored material.  
10 CFR 20.1902 Posting requirements.  
10 CFR 20.1904 Labeling containers.  
Applicable license conditions.
- d. Packaging, Control, and Tracking  
10 CFR Part 20, Requirements for Low-Level Waste  
Appendix F Transfer for Disposal at Land Disposal Facilities and Manifests.  
10 CFR 20.2006 Transfer for disposal and manifests.  
10 CFR 61.55 Waste classification.  
10 CFR 61.56 Waste characteristics.
- e. Transfer  
10 CFR Part 20, Requirements for Low-Level Waste  
Appendix F Transfer for Disposal at Land Disposal Facilities and Manifests.  
10 CFR 20.2001 General requirements.  
10 CFR 20.2006 Transfer for disposal and manifests.
- f. Records  
10 CFR 20.2103 Records of surveys.  
10 CFR 20.2108 Records of waste disposal.

- J. DECOMMISSIONING  
10 CFR 30.35 Financial assurance and recordkeeping for Decommissioning  
10 CFR 30.36 Expiration and termination of licenses and decommissioning sites and separate buildings or outdoor areas.

- K. TRANSPORTATION

- 1. General  
10 CFR 71.5 Transportation of licensed material.
- 2. Shippers - Requirements for Shipments and Packaging
  - a. General Requirements  
49 CFR Part 173, Class 7 (radioactive) materials.  
Subpart I  
49 CFR 173.24 General requirements for packaging and packaging  
49 CFR 173.448 General transportation requirements.  
49 CFR 173.435 Table of A1 and A2 values for radionuclides.
  - b. Transport Quantities  
10 CFR 71.4 Definitions.
    - i. All quantities  
10 CFR 71.4 Definitions.  
49 CFR 173.410 General design requirements.  
49 CFR 173.431 Activity limits Type A and Type B  
49 CFR 173.441 Radiation level limitations.  
49 CFR 173.443 Contamination control.  
49 CFR 173.475 Quality control requirements prior to each shipment of Class 7 (radioactive) materials.  
49 CFR 173.476 Approval of special form Class 7 (radioactive) materials.
    - ii. Limited quantities  
49 CFR 173.421 Excepted packages for limited quantities of Class 7 (radioactive) materials.

49 CFR 173.422 Additional requirements for excepted package containing Class 7 (radioactive) materials.  
iii. Type A quantities  
49 CFR 173.412 Additional design requirements for Type A packages  
49 CFR 173.415 Authorized Type A packages.  
49 CFR 178.350 Specification 7A; general packaging, Type A.  
iv. Type B quantities  
49 CFR 173.416 Authorized Type B packages  
49 CFR 173.467 Package testing  
v. LSA material and SCO  
49 CFR 173.403 Definitions.  
49 CFR 173.427 Transport requirements for low specific activity Class 7 (radioactive) materials and surface contaminated objects (SCO).

c. HAZMAT Communication Requirements  
49 CFR 172.200-205 Shipping papers.  
49 CFR 172.300-338 Marking.  
49 CFR 172.400-450 Labeling.  
49 CFR 172.500-560 Placarding.  
49 CFR 172.600-604 Emergency response information.

3. HAZMAT Training

49 CFR 172.702 Applicability and responsibility for training and testing  
49 CFR 172.704 Training requirements.

4. Transportation by Public Highway

49 CFR 171.15 Immediate notice of certain hazardous materials incidents.  
49 CFR 171.16 Detailed hazardous materials incident reports.  
49 CFR 177.800 Purpose and scope of this part and responsibility for compliance and training.  
49 CFR 177.816 Driver training.  
49 CFR 177.842 Class 7 (radioactive) material.

L. NOTIFICATIONS AND REPORTS

10 CFR 19.13 Notifications and reports to individuals.  
10 CFR 20.2201 Reports of theft or loss of licensed material.  
10 CFR 20.2202 Notification of incidents.  
10 CFR 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.  
10 CFR 30.50 Reporting requirements.

M. POSTING AND LABELING

10 CFR 19.11 Posting of notices to workers.  
10 CFR 21.6 Posting requirements.  
10 CFR 20.1902 Posting requirements.  
10 CFR 20.1903 Exemptions to posting requirements.  
10 CFR 20.1904 Labeling containers.  
10 CFR 20.1905 Exemptions to labeling requirements.

**END ATTACHMENT B**

## **ATTACHMENT C**

### **NUREG-1556 Volume 7, Appendix L**

#### **Program Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope**

**Including Gas Chromatographs and X-Ray Fluorescence Analyzers**

## Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of 10 CFR 20.1101 for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before an NRC inspection). During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

The form in this Appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. In the "remarks" portions of the form, note any deficiencies that were identified and the corrective actions taken (or to be taken).

**Section 1, Audit History.** Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

**Section 2, Organization and Scope of Program.** Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license.

**Section 3, Training, Retraining, and Instructions to Workers.** Ensure that workers have received the training required by 10 CFR 19.12. Be sure that, before being permitted to use byproduct material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments. **Ensure that each worker has a copy of the licensee's procedures, (or access to them) and by interview and/or observation of selected workers that he/she can implement them.**

**Section 4, Audits.** Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with licensee commitments, and are properly documented.

**Section 5, Facilities.** Verify that the licensee's facilities are as described in its license documents.

**Section 6, Materials.** Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses.

**Section 7, Leak Tests.** Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

**Section 8, Inventories.** Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

**Section 9, Radiation Surveys.** Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103.

Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with 10 CFR 20.1301. Records of surveys must be retained for 3 years after the record is made.

**Section 10, Receipt and Transfer of Radioactive Material (Includes Waste Disposal).** Verify that packages containing byproduct material, received from others, are received, opened, and surveyed in accordance with 10 CFR 20.1906. Ensure that transfers are performed in accordance with 10 CFR 30.41. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103 and 30.51.

**Section 11, Transportation.** Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport (49 CFR 172.200, 201, 202, 203, 204 and 177.718).

**Section 12, Personnel Radiation Protection.** Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. Alternately, if personnel dosimetry is provided and required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether records are maintained as required by 10 CFR 20.2101, 2102, 2103, 2104 and 2106.

**Section 13, Auditor's Independent Measurements (If Made).** The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

**Section 14, Notification and Reports.** Check on the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, and 30. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center; (301) 816-5100.

**Section 15, Posting and Labeling.** Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 20.1902, 20.1904, and 21.6.

**Section 16, Recordkeeping for Decommissioning.** Check to determine compliance with 10 CFR 30.35(g).

**Section 17, Bulletins and Information Notices.** Check to determine if the licensee is receiving bulletins, information notices, NMSS Newsletters, etc., from NRC. Check whether the licensee took appropriate action in response to NRC mailings.

**Section 18, Special License Conditions or Issues.** Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

**Section 19, Continuation of Report Items.** This section is self-explanatory.

**Section 20, Problems or Deficiencies Noted; Recommendations.** This section is self-explanatory.

**Section 21, Evaluation of Other Factors.** Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

**Note:** All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

## Sample Checklist

Audit Report No. \_\_\_\_\_ License No. \_\_\_\_\_

Licensee's name and mailing address:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Audit of activities at (Address):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Contact at Audit Location \_\_\_\_\_ Telephone No. \_\_\_\_\_

Date of this Audit \_\_\_\_\_

Summary of Findings and Action:

- No deficiencies
- Deficiencies
- Action on previous deficiencies

Recommendations:

Auditor: \_\_\_\_\_ Date: \_\_\_\_\_  
(Signature)

1. AUDIT HISTORY  N/A (N/A means "Not applicable" - Initial Audit)

A. Last audit of this location conducted \_\_\_\_\_

B. Problems/deficiencies identified during last two audits or two years, whichever is longer  Y  N

C. Open problems/deficiencies from previous audits:

Status Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed

D. Any previous problem/deficiency not corrected or repeated  Y  N  N/A  
Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure

1. Structure is as described in license documents  Y  N

2. Multiple authorized locations of use  Y  N

3. Briefly describe scope of activities involving byproduct material, frequency of use, staff size, etc.  Y  N

B. Radiation Safety Officer  Y  N

1. Authorized on license  Y  N

2. Fulfills duties as RSO  Y  N

C. Use only by authorized individuals  Y  N  
Remarks:



3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers per [10 CFR 19.12]  Y  N
- B. Training program required  Y  N
- C. Training records maintained  Y  N
- D. Evaluation of individuals' understanding of procedures and regulations based on interviews, observation of selected workers  Y  N
1. Each has an up-to-date copy of the licensee's safe use and emergency procedures  Y  N
2. Adequate understanding of:  
    Current safe use procedures  Y  N  
    Emergency procedures  Y  N
- E. Revised Part 20
- Workers cognizant of requirements for:
1. Radiation Safety Program [20.1101]  Y  N
2. Annual dose limits [20.1301, 20.1302]  Y  N
3. New NRC Forms 4 and 5  Y  N
4. 10% monitoring threshold [20.502]  Y  N
5. Dose limits to embryo/fetus and declared pregnant women [20.1208]  Y  N
6. Procedures for opening packages [20.1906]  Y  N

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

- A. Audits are conducted  Y  N
1. Audits conducted by \_\_\_\_\_
2. Frequency \_\_\_\_\_
- B. Content and implementation of the radiation protection program reviewed annually [20.1101(c)]  Y  N
- C. Records maintained [20.2102]  Y  N

5. FACILITIES

A. Facilities as described in license application  Y  N

Remarks:

6. MATERIALS

Isotopes, quantities, and use as authorized on license  Y  N

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with NRC  
(consultant; leak test kit; licensee performed)  Y  N

B. Frequency: every 6 months or other interval, as approved by  
NRC or Agreement State  Y  N

C. Records with appropriate information maintained  Y  N

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals  Y  N

B. Records with appropriate information maintained  Y  N

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment:  Y  N

1. Appropriate operable survey instrumentation possessed or  
readily available  Y  N

2. Calibrated as required [20.1501]  Y  N

3. Calibration records maintained [20.2103(a)]  Y  N

B. Briefly describe survey requirements [20.1501(a)]:

C. Performed as required [20.1501(a)]  Y  N

1. Radiation levels within regulatory limits  Y  N

2. Corrective action taken and documented  Y  N

D. Records maintained [20.2103]  Y  N

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 20.1302(b)]  Y  N

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)]  Y  N

3. Records maintained [20.2103, 20.2107]  Y  N

Remarks:

#### 10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Procedures describe how packages are received and by whom:  Y  N

B. Written package opening procedures established and followed [20.1906(e)]  Y  N

C. If package shows evidence of degradation, monitor for contamination and radiation levels  Y  N  N/A

D. Monitoring of degraded packages performed within time specified [20.1906(c)]  Y  N  N/A

E. Transfer(s) between licensees (including "disposal") performed per [30.41]  Y  N  N/A

F. Records of receipt/transfer maintained [20.2103(a), 30.51]  Y  N

G. Transfers within licensee's authorized users or locations performed as required [L/C]  Y  N  N/A

H. Package receipt/distribution activities evaluated for compliance with [20.1301, 20.1302]  Y  N  N/A

Remarks:

11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189)

- A. Licensee shipments are:  Y  N  N/A
1. Delivered to common carriers  Y  N  N/A
2. Transported in licensee's own private vehicle  Y  N  N/A
3. No shipments since last audit  Y  N  N/A
- B. Packages  Y  N  N/A
1. Authorized packages used [173.415, 173.416(b)]  Y  N  N/A
2. Closed and sealed during transport [173.475(f)]  Y  N
- C. Shipping Papers  Y  N
1. Prepared and used [172.200(a)]  Y  N
2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, T1, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [172.200-204]  Y  N
3. Readily accessible during transport [177.718(e)]  Y  N
- D. Vehicles  Y  N
1. Cargo blocked and braced [177.842(d)]  Y  N
2. Placarded, if needed [172.504]  Y  N
3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [173.25]  Y  N
- E. Any incidents reported to DOT [171.15, 171.16]  Y  N

Remarks:

12. PERSONNEL RADIATION PROTECTION

- A. ALARA considerations are incorporated into the Radiation Protection Program [20.1101(b)]  Y  N

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit [20.1502(a)]  Y  N  N/A

**OR**

C. External dosimetry provided and required  Y  N  N/A

1. Supplier \_\_\_\_\_ Frequency \_\_\_\_\_

2. Supplier is NVLAP-approved [20.1501(c)]  Y  N

3. Dosimeters exchanged at required frequency [L/C]  Y  N

D. Occupational intake monitored and assessed [20.1502(b)]  Y  N  N/A

E. Reports  N/A

1. Reviewed by \_\_\_\_\_ Frequency \_\_\_\_\_

2. Auditor reviewed personnel monitoring records for period \_\_\_\_\_  
to \_\_\_\_\_

3. Prior dose determined for individuals likely to receive doses [20.2104]  Y  N

4. Maximum exposures TEDE \_\_\_\_\_ Other \_\_\_\_\_

5. NRC Forms or equivalent [20.2104(d), 20.2106(c)]

a. NRC Form 4 "Cumulative Occupational Exposure History"  Y  N  
Complete:  Y  N

b. NRC Form 5 "Occupational Exposure Record for a Monitoring Period"  Y  N  
Complete:  Y  N

6. Worker declared her pregnancy in writing during inspection period (review records)  Y  N  N/A

If yes, determine compliance with [20.1208]  Y  N  
check for records per [20.2106(e)]  Y  N

F. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 20.2103, 20.2106, L/C]  Y  N

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument \_\_\_\_\_ Serial No. \_\_\_\_\_ Last calibration \_\_\_\_\_

B. Auditor's measurements compared to licensee's  Y  N

C. Describe the type, location, and results of measurements:

14. NOTIFICATION AND REPORTS

N/A

A. Licensee in compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20)  Y  N  N/A

B. Licensee in compliance with [20.2201, 30.50] (theft or loss)  Y  N  None

C. Licensee in compliance with [20.2202, 30.50] (incidents)  Y  N  None

D. Licensee in compliance with [20.2203, 30.50] (overexposures and high radiation levels)  Y  N  None

E. Licensee aware of telephone number for NRC Emergency Operations Center [(301) 816-5100]  Y  N

15. POSTING AND LABELING

A. NRC-Form 3 "Notice to Workers" is posted [19.11]  Y  N

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]  Y  N

C. Other posting and labeling per [20.1902, 1904] and the license is not exempted by [20.1903, 1905]  Y  N

Remarks:

16. RECORD KEEPING FOR DECOMMISSIONING (if needed)

N/A

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination  Y  N

B. Records include all information outlined in [30.35(g)]  Y  N

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. Receipt of NRC Bulletins, NRC Information Notices, NMSS Newsletters, etc  Y  N

B. Appropriate action taken in response to Bulletins, Information Notices, etc.  Y  N

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES  N/A

A. Review special license conditions or other issues, and describe findings:

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS  N/A  
(If more space is needed, use separate sheets and attach to report.)

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS  N/A

**Note:** Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or Radiation Safety Officer (RSO) oversight  Y  N

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments  Y  N

C. Licensee has sufficient staff  Y  N

Remarks/recommendations:  
(If more space is needed, use separate sheets and attach to report.)

END ATTACHMENT C