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Consolidated Guidance About Materials Licenses

Guidance About Administrative Licensing Procedures

Draft Report for Comment

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ABSTRACT

As part of its redesign of the materials licensing process, The United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 20, "Consolidated Guidance about Materials Licenses: Guidance About Administrative Licensing Procedures," dated July 2000, is the twentieth guidance volume developed for the new process and is intended for use by NRC staff. It will also be available to Agreement States, applicants, and licensees. This document combines and updates the guidance for NRC license reviewers and licensing assistants previously found in the documents listed in Appendix A. When published in final form, NRC licensing staff will use these administrative procedures to process license applications and prepare licenses. Note that this document is strictly for public comment and is not for use in preparing or reviewing license applications until it is published in final form.

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG-1556, Volume 20 draft in your comments, and send them by the date published in the Federal Register Notice to:

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For any questions about the material in this report, please contact:

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The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a series of NUREG reports. Below is a list of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance about Self-Shielded Irradiators	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	Final Report
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft
10	Program-Specific Guidance about Master Material Licenses	Draft
11	Program-Specific Guidance about Licenses of Broad Scope	Final Report
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution	Draft
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses	Final Report
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Draft
16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licensees	Draft
17	Program-Specific Guidance About Licenses for Special Nuclear Material of Less Than Critical Mass	Draft for Comment

Vol. No.	Volume Title	Status
18	Program-Specific Guidance About Service Provider Licenses	Draft for Comment
19	Guidance For Agreement State Licensees Proposing to Work in NRC Jurisdiction (Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters) and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Under Development
20	Guidance About Administrative Licensing Procedures	Draft for Comment

The current document, draft NUREG-1556, Vol. 20, "Consolidated Guidance about Materials Licenses: Guidance About Administrative Licensing Procedures," dated July 2000, is the twentieth guidance developed for the new process. It is intended for use by NRC license reviewers and licensing assistants. It combines and updates the guidance for NRC licensing staff previously found in the documents listed in Appendix A.

A team composed of NRC staff from Headquarters and Regional Offices drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to materials licensing. Representatives of NRC's Office of the General Counsel provided legal perspectives.

This guidance represents a step in the transition from the current paper-based process to the new electronic process. This draft document is available on the Internet at the following address: <http://www.nrc.gov/NRC/NUREGS/SR1556/V20/index.html>.

This draft report is strictly for public comment and is not for use in processing license applications, nor preparing licenses, until it is published in final form. It is being distributed for comment to encourage public participation in its development. NRC is requesting comments such as whether a risk-informed, performance-based approach to licensing is valid, as well as comments on the information provided about administrative licensing procedures. Please submit comments within 75 days of the draft report's publication. Comments received after that time will be considered, if practicable.

Address comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays. Comments may also be submitted through the Internet by addressing electronic mail to dlm1@nrc.gov.

Draft NUREG-1556, Vol. 20, "Consolidated Guidance about Materials Licenses: Guidance About Administrative Licensing Procedures," dated July 2000, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this draft report are provided for information and comment only.

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ABBREVIATIONS

ACMUI	NRC Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agency-wide Document Access and Management System
AEA	Atomic Energy Act
ALARA	As Low as Reasonably Achievable
BPR	Business Process Redesign
BRS	Bibliographic Retrieval System
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOJ	U.S. Department of Justice
DRAT	IMNS Division Response Action Tracking System (ticket tracking system)
DWM	NRC Division of Waste Management
EA	Environmental Assessment
EPA	U.S. Environmental Protection Agency
FCSS	NRC Division of Fuel Cycle Safety and Safeguards
FONSI	Finding of No Significant Impact
GAP	Generic Assessment Panel
GLTS	General License Tracking System
GPO	U.S. Government Printing Office
HQ	Headquarters
IMNS	NRC Division of Industrial and Medical Nuclear Safety
IN	Information Notice
LA	Licensing Assistant
LER	Licensee Event Report
LTS	Licensing Tracking System
NARA	U.S. National Archives and Records Administration
NEPA	National Environmental Policy Act of 1969
NIST	U.S. National Institute of Standards and Technology
NMED	Nuclear Materials Events Database
NMSS	NRC Office of Nuclear Materials Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NUDOCS	NRC Nuclear Documents System
OAR	Official Agency Record
OC	NRC Office of the Controller
OCFO	NRC Office of the Chief Financial Officer
OCR	Optical Character Recognition
OE	NRC Office of Enforcement
OGC	NRC Office of the General Counsel
OI	NRC Office of Investigations
OIG	NRC Office of the Inspector General
OMB	U.S. Office of Management and Budget
QA	Quality Assurance
P&GD	Policy and Guidance Directive (guidance for NRC licensing staff)
RG	Regulatory Guide

RI	NRC Region I
RII	NRC Region II
RIII	NRC Region III
RIV	NRC Region IV
RIDS	NRC Regulatory Information Distribution System
RPDC	Regulatory Product Development Center
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RTS	Reciprocity Tracking System
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SFPO	NRC Spent Fuel Project Office
SSSS	Sealed Source Safety Staff
std	Standard
STP	NRC Office of State and Tribal Programs
TAR	Technical Assistance Request
TTC	NRC Technical Training Center
U.S.C.	United States Code

1 PURPOSE OF DRAFT REPORT

This document is strictly for public comment and is not for use in the processing of license applications or the preparation of licenses until this document is published in final form.

This draft report provides guidance to NRC license reviewers and licensing assistants on administrative licensing procedures. It includes procedures for acknowledging requests for licensing actions, tracking the progress of actions, maintaining files, preparing licenses, distributing documents, and other administrative matters. It is intended for NRC staff; however, applicants may find this information useful when preparing license applications or requesting the status of licensing actions. This document contains information on inspection frequencies, license fees, and other matters beyond the control of NRC licensing staff. This information is provided for convenience only. Any questions or issues concerning these matters will be referred to the NRC office responsible for that matter.

The applicability of this draft report is limited to the materials program area currently overseen by the Division of Industrial and Medical Nuclear Safety (IMNS) in the Office of Nuclear Materials Safety and Safeguards (NMSS). Many of the guidance documents used to prepare this report are more than 10 years old. Reorganizations over the years have resulted in the transfer of oversight responsibilities for some program areas originally under IMNS (i.e., fuel cycle, transportation) to other technical divisions in NMSS. This draft report is intended for the materials program area only. Although some information in this report is applicable to other program areas, it is not intended to supersede administrative licensing procedures established by other technical divisions.

Volume 20 is being issued in loose-leaf form to allow individual sections and/or appendices to be updated as administrative procedures change. Much of the information needed by NRC licensing staff is provided in the appendices. Readers should note the following information:

- Appendix B contains standard forms used to complete licensing actions.
- Appendix C contains checklists that are helpful for documenting the acceptance review of certain categories of licensing actions.
- Appendix D contains standard letters that may be edited to meet case-by-case requirements.
- Appendix E contains the list of standard license conditions.
- Appendix G defines the program codes in the Licensing Tracking System.
- Appendix J contains sample denial letters.
- Appendix K contains generic exemptions that the Regions may authorize without approval from Headquarters.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal Agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees ask their local contact for the Federal Agency controlling the site (e.g., Contract Officer, Base Environmental Health Officer, District Office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available from NRC upon request.

Table 2.1 provides a quick way to check on which Agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal Agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, US territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site not subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

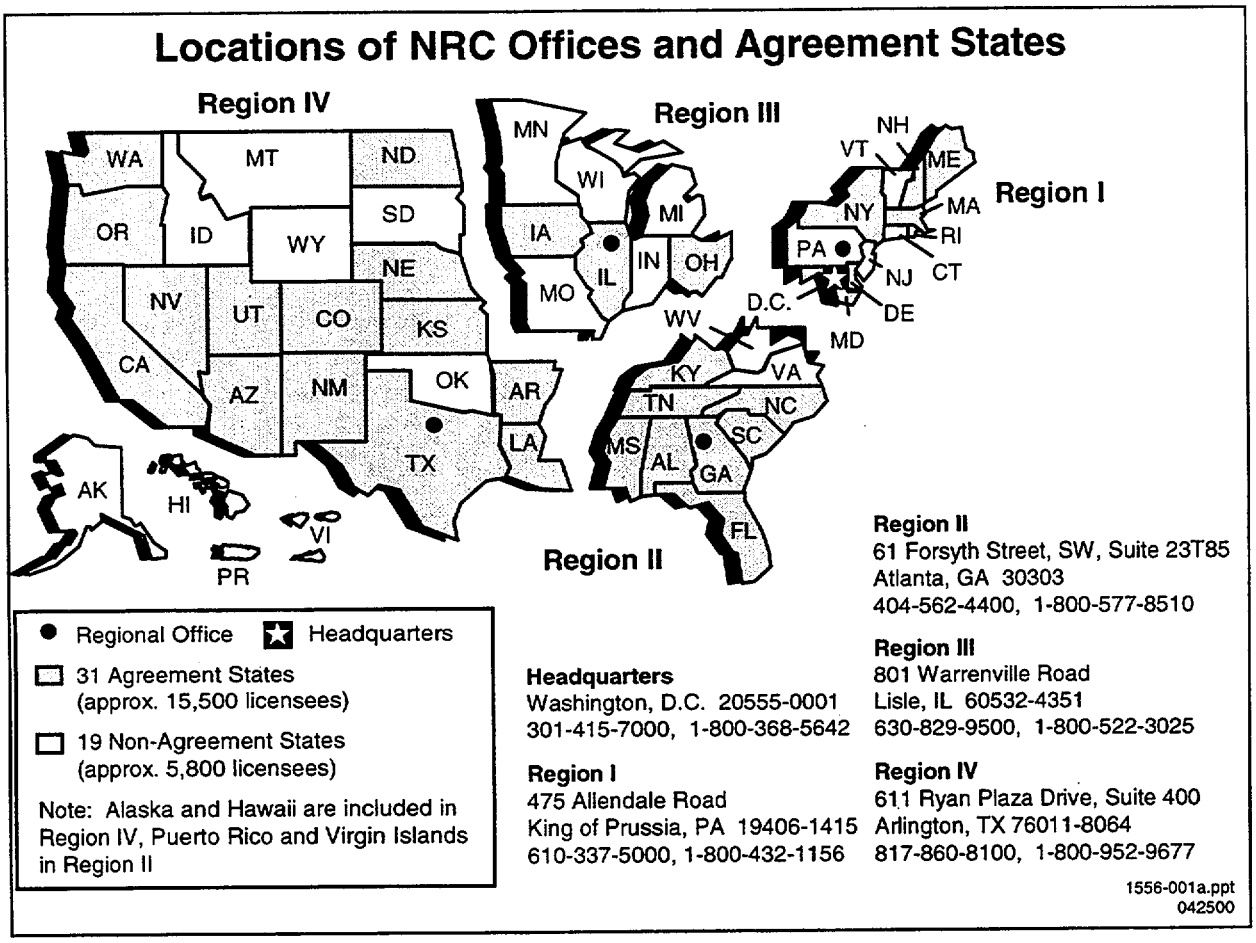

Figure 2.1 U.S. Map. *Location of NRC Offices and Agreement States.*

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available by choosing "Directories" on the NRC Office of State and Tribal Programs' (STP's) Home Page, <http://www.hsrd.ornl.gov/nrc/home.htm>. As an alternative, interested parties can request the list from NRC's Regional or Field Offices.

All Agreement States Letter, SP-96-022, dated February 16, 1996, is available on STP's Home Page, <http://www.hsrd.ornl.gov/nrc/home.htm>. Choose "NRC-State Communications," then choose "All of the Above," and follow the directions for submitting a query for "SP96022." As an alternative, interested parties can request the letter from STP by calling NRC's toll-free number (800) 368-5642 and then ask for extension 415-3340.

3 LICENSING ASSISTANT GUIDANCE

The purpose of this chapter is to provide Licensing Assistants (LA) and other appropriate staff with basic administrative procedures for processing, managing, and tracking licensing actions from the time each action is received by the Agency until the action is issued. The information provided in this chapter is not comprehensive, and it does not fully describe the duties of the LA.

3.1 LICENSING TRACKING SYSTEM

The Licensing Tracking System (LTS) is the computer system for tracking each license issued for the use of byproduct, source, and special nuclear material. In addition to maintaining a record of each license, LTS is used to track each license application from receipt to completion of all licensing actions. The system supports a standardized review process and management reports. It also includes inspection data, and supports timely responses to inquiries and specialized, ad-hoc queries. Each license application is tracked using a variety of methods to support different reports and queries. This creates a large number of fields for licensing staff to complete. Different levels of access are assigned to NRC users according to their needs. LTS was designed using software that is no longer supported. There are plans to upgrade LTS after work on the General License Tracking System (GLTS) is complete, but no rollout date for the upgrade has been established. The upgrade could take several years to complete. The existing system will continue to be used for the foreseeable future.

NRC users should follow the guidance in the LTS User's Guide. This guide was revised during the Year 2000 renovation of NRC-maintained systems. If you have questions about the LTS User Guide or other LTS issues, contact your licensing assistant, or the LTS System Administrator at Headquarters (in the Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety).

When a request for a licensing action is received, the licensing assistant will create an LTS record to track it and print an LTS data entry form for the license reviewer. Each license reviewer must review and complete the data entry form using the procedures and formats in the LTS User Guide and the additional guidance provided in Appendix F. LTS identifies the various operations authorized under a license by assigning primary and secondary program codes. Program code definitions are provided in Appendix G.

3.2 ADMINISTRATIVE PROCEDURES

3.2.1 INITIAL PROCESSING OF INCOMING LICENSING ACTIONS

Incoming licensing documents shall be entered into ADAMS and distributed per ADAMS Document Processing Template No. NMSS/RGN Materials - 002, "Incoming Licensing-Related Correspondence (Including Incoming Licensing Actions)." This template is subject to change as the Agency gains more experience with the ADAMS computer system. The license assistant, or

designate, should watch for change notices and periodically confirm that they have the latest version of the template.

Documents containing proprietary information should be entered into ADAMS in their entirety, but the file should be designated as non-publically available (see Section 4.13 of this NUREG). Documents which contain other sensitive information should be processed in accordance with applicable procedures.

The LA, or designate, receives and dockets all materials license applications. All material licenses are assigned unique license and docket numbers that are tracked in the LTS database for the life of the license. Each licensing action is assigned a unique mail control number that is tracked in the LTS database from receipt of a request for licensing action to completion. These control numbers are linked to the licensee's license number and docket number.

For new licensing actions for current licensees, the LA will assign a mail control number and enter the appropriate information into the LTS. For new applicants (ones who do not have a current license), the LA will assign a mail control number and an institution code. The institution code will later be used to assign a license number. The LA will then enter the action into the LTS. The LTS will assign the docket number, which is unique for the specific license. After the LA completes the entries and prints the LTS worksheets, the action is ready for the license reviewer to conduct the technical review of the licensing action.

To handle the large number of requests for licensing actions effectively and efficiently, each licensing action should receive an acceptance review at the time of its receipt. This acceptance review can be performed by the LA or designate. This initial processing does not in any way replace the required technical review specified in the NUREG-1556 series.

Acceptance Review Procedure

1. Within 30 days of receipt of a request for any licensing action, the NRC Regional Offices should perform an acceptance review of the request and take the following actions:
   - Issue a "deemed timely" letter (for renewals only) within 5 working days of the LTS entry, because it notifies the licensee that their license will not expire until final action has been taken by the appropriate licensing office.
   - Determine that all necessary sections of the application form (normally NRC Form 313) are completed and the form has been signed by the applicant's certifying official.
   - Verify that attachments identified by the applicant are, in fact, included in the submittal.
   - Identify any requests for expedited review for safety-significant concerns (e.g., change in the Radiation Safety Officer (RSO) or amendment requests resulting from identification of safety-significant violations) or business reasons (e.g., change in ownership or other financial concerns).

- Determine if the submittal is a renewal application that requests amendments or new authorizations that may need to be expedited by a license amendment rather than being delayed for review of the entire application.
- Identify if the licensee requests any exemptions from the regulations.

2. After the acceptance review, an acknowledgment letter or card (see samples in Appendix D) is to be sent to the applicant to:
   - Acknowledge that the request for a licensing action has been received. For renewals, insert the "deemed timely" statement that is specified in the acknowledgment letter.
   - Clearly inform the licensee that the submittal has undergone an initial processing that is an acceptance review.
   - Note any administrative deficiencies/omissions that were identified during the initial review that could delay the technical reviewer's complete review of the licensee's action.
   - Inform the licensee that the technical review may identify additional omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with Headquarters or other Regional Offices.
   - Provide the licensee with an estimated time for completion of the licensing action. These estimates need only be estimates for types of licensing actions (i.e., a specific date does not have to be estimated for each licensing action). The estimated time for completion should account for any request for an expedited review and be in accordance with guidance outlined in the NUREG-1556 volume for the specific program area.
   - Inform applicants that are subject to a fee (i.e., new applicants, or applicants whose request will require full-fee recovery), that a copy of their correspondence has been forwarded to the Office of the Chief Financial Officer (OCFO) for fee processing.

The acknowledgment is adequate documentation of the acceptance review. Each acknowledgment should be entered into ADAMS using Document Processing Template No. NMSS/RGN Materials-001, "Outgoing Licensing Correspondence (Including Outgoing Licensing Actions)."

3.2.2 RESPONSIBILITY FOR REVIEW OF LICENSE APPLICATIONS

To insure uniformity of relationships between licensees and Regions, and to minimize licensing and inspection conflicts, the responsibility for reviewing a license application should be assigned to the Region where the licensed activities are inspected.

In cases where an application or license authorizes use of material in more than one Region, the mailing address of the parent company should be used to determine the Region that will conduct the review and issue the license.

Certain types of licenses and certificates are reviewed and issued by NMSS staff at Headquarters (e.g., exempt distribution, sealed source and device registrations, certain source and special nuclear materials licenses, etc.). Contact the Division of Industrial and Medical Nuclear Safety in NMSS if it unclear who has responsibility for the review.

3.2.3 PROCESSING MISDIRECTED MATERIALS LICENSING APPLICATIONS

Applications that licensees misdirect to Headquarters, either to the Office of Nuclear Material Safety and Safeguards (NMSS) or to the Office of the Chief Financial Officer (OCFO), will be handled in the following manner:

1. The original application will be entered into ADAMS in the Headquarters Central Mail Room.
2. The applications received by NMSS will be entered into the LTS and processed through milestone 02, and the original application and duplicate will be forwarded to OCFO. NMSS will designate the proper licensing Region that should receive the application after the fee review is complete. It will be the receiving Region's responsibility to enter milestone 10 into LTS, along with subsequent milestones.
3. The applications received by OCFO will be processed by them for fee purposes if the proper fee has been submitted, or if it is fee exempt. OCFO will then forward the application to the appropriate Region for entry into the LTS. The Region must call OCFO to let them know when the milestones 01 and 02 have been entered, so that OCFO can enter the fee milestones.
4. An application received by OCFO without the proper fee, or with no fee, will be sent to NMSS for entry into the LTS and then will be processed as in step 2, above.
5. If the misdirected application is for a Federal licensee (always fee exempt) or an action that does not require a fee (amendments and renewals), NMSS will forward the action directly to the licensing Region.

Those applications that are misdirected to the Regions should be handled in a similar manner, whether they are Headquarters' or another Region's responsibility. This includes NRC Form 483 (see Section 3.2.9) and any other submittal that should go to another office. The appropriate licensing office should send a reminder to the licensee to forward future correspondence to the proper address.

The above procedures should result in the original misdirected application being forwarded to the appropriate office within 5-7 days.

3.2.4 FOLLOW-UP ON MAIL RETURNED FROM LICENSEES

A small fraction of mail sent to licensees is returned to NRC as undeliverable. It is important to follow up on these cases because returned mail may indicate any number of problems, ranging from a clerical error to loss of control of a licensed program. The following procedure should be followed with regard to returned mail:

1. Mail returned to the NRC as undeliverable should be checked against the license file to assure that the address on the envelope corresponds with the address provided by the licensee on the original application. If the address differs, the LTS and the license database should be corrected. Also, an administrative corrected copy of the license should be sent to the licensee, if appropriate.
2. Any pending application related to the license should be checked for information on the correct mailing address.
3. For mail returned to NRC for any reason other than an NRC clerical error, the procedure to be followed is similar to the procedure followed when a license is expired (see Section 3.2.5). The Regional licensing staff should coordinate with the inspection staff, as appropriate. The licensee should be informed that he must submit a change of address request, along with any amendment requests associated with the change of address.
4. When the licensee can be located through telephone contact or other sources, the Returned Mail Follow-up letter in Appendix D has been found to be useful in following up on the returned mail.
5. A tracking system should be maintained and periodically checked to assure adequate follow-up.

3.2.5 FOLLOW-UP ON EXPIRED MATERIAL LICENSES

Identification and investigation of expired licenses is an important part of the material licensing and inspection program. The following procedure should be followed with regard to expired licenses:

1. On or about the fifth of each month, each Region should identify from the LTS Management Report No. 15 all material licenses (byproduct, source, and special nuclear materials) that expired the previous month.
2. A license is considered expired if a renewal application has not been received or postmarked on or before the expiration date. The computer automatically distinguishes between licenses under timely renewal and licenses that are truly expired, as long as the Regional Offices and Headquarters have correctly classified the renewal as an Action Type 3. Please note that an expired license cannot be renewed; however, it can be superseded by a new license.

3. If a termination request is pending for a license, the computer will show it as expired after the expiration date if final action has not been taken on the termination request; therefore, the list of expired licenses should be checked against the computer printout of pending actions. Follow-up action on an expired license should be coordinated with any pending termination request in order to avoid duplication of effort.

4. The Regional licensing staff should coordinate with the inspection staff and take appropriate follow-up action. This may include a visit to the facility. The results of the inspection should be forwarded to the Regional or NMSS licensing staff, as appropriate, depending on who has licensing authority.

5. The licensing staff should make the final decision on retirement of the license. Before the license is retired, there must be sufficient documentation in the file to demonstrate: (1) that a new license has been issued superseding the expired license; or (2) that the licensee has ceased operations, properly transferred or disposed of all radioactive material, and provided documents demonstrating that the facility is suitable for release for unrestricted use.

6. For expired licenses in categories where the Region has licensing responsibility, the Regional licensing staff should retire the licenses, as appropriate, in accordance with current retirement procedure outlined in NUREG-0910, NRC Comprehensive Records Disposition Schedule, and change the license in the computer to retired status. For all licenses that are retired, there should be a statement indicating that a new license has been issued, or a Form 314 or equivalent is filed in the official docket file, along with supporting documentation verifying the disposition of the material and that the facility is free of excess contamination.

7. Questions concerning proper document retirement procedures and disposition of working files may be directed to the Records Management Branch, Office of the Chief Information Officer.

3.2.6 PREPARATION AND DISTRIBUTION OF COMPLETED LICENSING DOCUMENTS

Completed licensing documents shall be prepared and distributed per ADAMS Document Processing Template No. NMSS/RGN Materials - 001, "Outgoing Licensing Correspondence (Including Outgoing Licensing Actions)." These instructions are subject to change as the Agency gains more experience with the ADAMS computer system. Licensing staff should watch for change notices and periodically confirm that they have the latest version of the template.

1. It is recommended, but not mandatory, that all licenses be amended in their entirety. This will assist inspectors and provide a complete, up-to-date license in ADAMS. (If the license is not being renewed, be careful not to change the expiration date.) After the license is dispatched, the license and all supporting documents for the current action must be placed into ADAMS, unless it is already in the system.

2. The reviewer should verify that the correct program code has been assigned to the license in LTS. When more than one program code is assigned, the code with the highest inspection priority should be the primary code.

3. The docket number, license number, mail control number, and accession number must be typed on all correspondence in order to assist in the identification of documents being processed.

4. Historically, after issuing the final licensing action to the applicant, distribution has been limited to the docket file and the Public Document Room for most materials licenses. Consult the ADAMS template for the latest distribution instructions.

5. Completed material licensing documents should be saved in ADAMS folders as specified in the ADAMS template. In addition, ADAMS packages may be used to associate documents that are dispatched together as part of a physical package. For system performance reasons, it is best to use ADAMS-stored searches whenever practical, and minimize the use of folders and packages. However, it is acceptable to create ADAMS folders and packages in accordance with approved procedures. Please consult your ADAMS team leader before constructing large folder structures.

6. OCFO should be notified of completed packages using the ADAMS Send function. OCFO will conduct a final fee review on completed licensing actions.

7. No classified information or safeguards information should be scanned into ADAMS. If classified or safeguards information is received, it should be handled in accordance with MD 12.2, "NRC Classified Information Security Program," and MD 12.6, "NRC Sensitive Unclassified Information Security Program."

8. All correspondence involving the Advisory Committee on the Medical Uses of Isotopes should be marked "Official Use Only." These documents will be profiled in ADAMS as non-publically available.

9. Each Regional office should coordinate with the states in their Region and determine what licensing documents they wish to receive. If a State requests to receive licensing documents issued by NMSS (i.e, distribution licenses), the Region should inform NMSS of the request.

3.2.7 AVAILABILITY, SECURITY, AND INTEGRITY OF MATERIAL LICENSE FILES

Currently, the Agency's official docket files are maintained in NRC's Central File for licenses issued by NMSS and in each of the Regional Offices for licenses issued by the Regions. In the future, the official docket files will be managed in ADAMS. ADAMS is NRC's new electronic record system. It reduces the need to maintain paper-based record collections. It replaces the Nuclear Documents System (NUDOCS), the Public Document Room's Bibliographic Retrieval System (BRS), and the Regulatory Information Distribution System (RIDS).

Most of NRC's Official Agency Records (OARs) and other nonrecord reference materials will be kept in ADAMS. ADAMS will keep the OARs of all unclassified documents received or newly created by NRC. This includes programmatic and administrative records that were kept in paper record keeping systems, except for unclassified safeguards information and records determined to be inappropriate for electronic maintenance. Records will be added to ADAMS using the guidance provided in the appropriate final ADAMS Document Templates located in the ADAMS Document Manager.

An OAR is statutorily defined in the Federal Records Act as a —

> book, paper, map, photograph, machine readable material, or other documentary material, regardless of physical form or characteristics, made or received by an Agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that Agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data contained in these materials. Library and museum material made or acquired and preserved solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference, and stocks of publications and processed documents are not included in the definition of the term "Official Agency Record" (36 CFR Part 1220).

Some examples of documents that contain OARs requiring preservation under Federal regulations are as follows:

- Documents related to NRC programs, policies, organizations, decisions, decision making, minutes, or agendas
- Documents that contain unique information that explain why the Agency made a decision or took an action
- Documents that direct one to take an action or that one uses to direct another to act
- Information that the NRC creates or acquires via e-mail, facsimile, telephone record, or meeting notes, about a licensing matter or an inspection of a licensee's facility that contains (1) unique information; (2) the rationale for an NRC decision; or (3) guidance that is not documented in the OAR.

The partial listing of materials and publications below will provide further information on this subject:

- Management Directive 3.1, "Freedom of Information Act"
- Management Directive 3.4, "Release of Information Act"
- Management Directive 3.5, "Document Management"

- Management Directive 12.2, NRC Classified Information Security Program"
- Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program"
- 10 CFR 2.790, "Public Inspections, Exemptions, Requests for Withholding."

3.2.8 COORDINATORS FOR CERTAIN FEDERAL ORGANIZATIONS

Certain Federal organizations coordinate licensing actions through a central office. This may involve a single, multi-site license, or it may involve several, specific licenses issued to the same Federal organization. The coordinators for these Federal organizations are listed in Appendix H. These coordinators are subject to change, and we intend to issue periodic revisions to Appendix H to keep the list current.

3.2.9 PROCESSING FORM 483 FOR IN VITRO TESTING UNDER GENERAL LICENSE

This section provides guidance to licensing staff on the processing of NRC Form 483, "Registration Certificate - in vitro Testing with Byproduct Material Under General License," (see Appendix B). The regulations in 10 CFR 31.11 grant a general license to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital for the possession and use of specified byproduct material "in prepackaged units" not exceeding certain quantities for in vitro (outside the body) clinical or laboratory testing. Such testing must not involve administration to human beings or animals. Applicants for a general license under 10 CFR 31.11 must register with the Commission by filing NRC Form 483 and receive an acknowledgment of the registration before receiving byproduct material under the general license.

Responsibilities and Authorities

Division of Industrial and Medical Nuclear Safety, NMSS

1. Provide a copy of NRC Form 483 to new applicants requesting a general license for use of byproduct material for in vitro clinical or laboratory testing.
2. Review NRC Form 483 when received to ensure that the applicant is eligible for the general license and that the proposed activities are in accordance with 10 CFR 31.11 and the procedures below. If activities are not in accordance, contact the applicant regarding the lack of conformance with the NRC general license in 10 CFR 31.11.
3. Distribute the signed NRC Form 483 with an assigned registration number to the applicant. Signature authority for the reviewing official of the general licensed activities, as requested by NRC Form 483, should be designated according to IMNS policy.

4. Retain the NRC Form 483 requests until a records disposition schedule is approved by the National Archives and Records Administration. These records are unscheduled and must be retained (see NUREG-0910, "NRC Comprehensive Records Disposition Schedule").

Registration Requirements

1. Any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital requesting a general license for the possession and use of specified byproduct material not exceeding certain quantities in "prepackaged units" for in vitro clinical or laboratory testing is subject to 10 CFR 31.11. Before accepting receipt of byproduct material under a general license, a general licensee (with the exception of Part 35 medical use licensees) must register with the Commission by filing NRC Form 483 with the Director of Nuclear Material Safety and Safeguards (NMSS) and must receive, from the Commission, an acknowledgment of the registration by way of a validated Form 483 with a registration number assigned.

   Note: There is no fee for filing for a general license under 10 CFR 31.11.

2. A person who receives, possesses, or uses byproduct material under a general license for use for certain in vitro clinical or laboratory testing must comply with the regulations in 10 CFR 31.11 (found in total on NRC Form 483).

   Notes: 10 CFR 32.71 authorizes the manufacture and distribution of products for use under general license pursuant to 10 CFR 31.11.

   General licensees under 10 CFR 31.11 are limited to specific radioisotopes and unit quantities of radioactive material.

   Persons authorized by a license under Part 35 for the medical use of byproduct material may receive, acquire, possess, use, or transfer byproduct material under the general license without filing NRC Form 483.

The in vitro testing must not involve the internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

"Prepackaged units" include individual reagent vials, radioassay kits, and/or calibration sources.

Processing of NRC Form 483

Physicians, veterinarians, clinical laboratories and hospitals are required to file NRC Form 483 before receiving byproduct material for in vitro clinical laboratory testing. The NRC's Headquarters office will take the following actions in processing NRC Form 483:

1. Receipt - Verify that the applicant is a physician, veterinarian in the practice of veterinary medicine, a clinical laboratory, or hospital.

   Note: NRC Form 483 requests will be processed through the Headquarters Document Control Desk into ADAMS upon receipt. The hardcopy of the request will be forwarded directly to the licensing section for processing.

2. Process NRC Form 483 - Immediately upon receipt of NRC Form 483, search the file to see if the applicant already has a validated Form 483 on record. If there is no record for the applicant, obtain the next validation number from the log book and enter it onto the hardcopy Form 483. The validation number should also be entered into the electronic version of the Form 483 in ADAMS. Sign and date the hardcopy, and indicate signature and date on the electronic copy in ADAMS. Mail the signed, original, Form 483 with an acknowledgment letter back to the applicant. A sample acknowledgment letter is provided in Appendix D.

3. Revisions to NRC Form 483 - For revisions to the initial NRC Form 483, pull the last Form 483 on file and record the validation number (from the initial filing) onto the revised NRC Form 483 (hardcopy and ADAMS). Sign and date the Form 483 (hardcopy and ADAMS), and mail the signed, original, Form 483 with an acknowledgment letter back to the applicant.

   Note: All new NRC Form 483 requests will be maintained in ADAMS. The historical NRC Form 483 requests are maintained in IMNS. The forms are filed in alphabetical order, by State, based on the applicant's address of use. These hard copy files will not be scanned into ADAMS; therefore, these records should be searched for previously submitted NRC Form 483s (in addition to searching ADAMS) before completing the request and adding the validation number.

4. Deficient NRC Form 483 - If NRC Form 483 is deficient (i.e., does not contain the required information, or indicates that the applicant does not qualify), try to resolve the problems by telephone contact with the applicant. If the deficiencies can be resolved through telephone contact, mark the form with the corrections. If the deficiencies cannot be resolved by telephone, send a letter requesting the necessary information.

3.2.10 PROCESSING RECIPROCITY APPLICATIONS (FORM 241)

This section provides guidance to licensing staff on processing NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters," and revisions to NRC Form 241. Agreement State licensees wishing to perform licensed activities in non-Agreement States, areas of exclusive Federal jurisdiction, or in Federal offshore waters are subject to the general license regulations in 10 CFR 150.20. Under this provision, the Commission recognizes and allows certain Agreement State licensees to work in areas of NRC jurisdiction under their Agreement State license.

Note: This section duplicates much of the guidance in Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." It was included in this NUREG because processing forms and issuing procedures letters are considered to be administrative licensing functions.

Jurisdiction

NRC/Agreement State jurisdiction can be very complex. Reviewers should refer to the definitions and guidance in Volume 19 of NUREG-1556 to determine whether NRC has jurisdiction over the proposed activities.

Responsibilities and Authorities

Division of Industrial and Medical Nuclear Safety, NMSS

Maintain the computer-based Reciprocity Tracking System (RTS) to track reciprocity activities, in order to assist in the planning of inspections of those activities and to provide summaries of reciprocity activities and inspections on an Agency-wide basis; and to establish the following procedures and guidelines for use in processing NRC Form 241.

Regional Offices

1. Each year, before January 1, issue a procedures letter (see sample in Appendix D) to reciprocity licensees from the previous year with information for filing NRC Form 241 for reciprocity.
2. Provide a procedures letter to new applicants requesting reciprocity.

3. Review NRC Form 241 when received, to ensure that the proposed activities of Agreement State licensees are in accordance with 10 CFR 150.20 and are authorized under the Agreement State license, in accordance with the procedures below. If activities are not in accordance, contact the licensee regarding the lack of conformance with the NRC general license in 10 CFR 150.20.

4. Enter the licensee information into the RTS and ADAMS, distribute the signed NRC Form 241, and provide notification to the appropriate authorities, including the NRC Regional office having jurisdiction in the area(s) in which the Agreement State licensee intends to operate. Signature authority for the reviewing official of the reciprocity activities, as requested by NRC Form 241, should be designated according to Regional policy.

5. Maintain records of reciprocity activities in the RTS.

Form 241 Requirements

1. Agreement State licensees requesting reciprocity for activities conducted in non-Agreement States, areas of exclusive Federal jurisdiction, or in Federal offshore waters are subject to 10 CFR 150.20. The first time within a calendar year that an Agreement State licensee conducts activities in non-Agreement States or in Federal offshore waters, it must file a completed NRC Form 241, one copy of its Agreement State license, and the appropriate fee as specified in fee category 16 of 10 CFR 170.31, unless the exemption in 10 CFR 170.11(a)(4) is applicable. See 10 CFR 150.20(b)(1) for further details.

   Notes: A licensee operating under reciprocity pursuant to 10 CFR 150.20 does not have to obtain affirmative authorization from NRC before performing activities requested on NRC Form 241. Licensees who do not qualify for the general license will be informed that work is not to be performed in areas of exclusive Federal jurisdiction, non-Agreement States, or in Federal offshore waters, until NRC receives the required information.

   All fee payments and questions concerning fees should be referred to OCFO.

2. In completing NRC Form 241, the Agreement State licensee must provide sufficient information to enable NRC to conduct inspections.

   Note: The reviewer should assure that the Form 241 contains sufficient information to find the exact place of use.

3. The Agreement State licensee should only identify work to be conducted during a single calendar year.

4. In general, the preferred method of filing is through the facsimile transmission of NRC Form 241, a copy of the Agreement State license, and a copy of the check or credit card application, as this method avoids many delays that may be caused by the mail. If the facsimile method is used, the transmission must be received by NRC 3 days before the

licensee engages in the activity. In addition, the licensee must also file NRC Form 241, one copy of the Agreement State license, and the check for the fee within 3 days of facsimile transmission. Alternatively, the licensee may file the required information through the mail or other means as long as NRC receives the information at least 3 days before the licensee engages in the activity.

5. If the facsimile or other acceptable method for filing all of the required information is not available to the licensee because of an emergency or for other reasons, the Regional Administrator (or designate) can waive the time requirements specified in 10 CFR 150.20(b)(1) for the filing of NRC Form 241, provided the Agreement State licensee:

   a. informs the Region by telephone of initial activities or revisions to the information submitted on the initial NRC Form 241 (e.g., additional locations of work or changes to the radioactive material or work activities); and

   b. receives oral or written authorization for the activity(is) from the Region; and

   c. files NRC Form 241, one copy of the Agreement State license, and the check or credit card application for the fee payment within 3 days after the telephone notification.

Processing of NRC Form 241

Agreement State licensees are required to report their proposed activities in non-Agreement States to the NRC Regional Administrator of the Region in which the Agreement State is located. The Regional Office shall take the following actions in processing NRC Form 241.

1. Receipt - Verify that the filing is timely. Stamp or otherwise note the date of receipt on the NRC Form 241. The form must normally be received by NRC at least 3 calendar days before the licensee's beginning work.

   Notes: The Regional Administrator (or designate) may consider a waiver of the 3-day time requirement, as provided in 10 CFR 150.20(b)(1).

   An NRC Form 241/reciprocity request will be scanned into ADAMS upon receipt. The ADAMS file should be a draft document because the NRC portion of the form is incomplete. The original, hard copy form and the ADAMS file will be forwarded to the licensing staff for processing. The licensing staff will complete and sign the hard copy form (for return to the licensee), and enter the same information into the ADAMS file (for NRC record keeping). The ADAMS file will be declared an "Official Agency Record" after processing is complete.

2. Process Initial NRC Form 241

   a. Immediately upon receipt of NRC Form 241, verify that the required information has been provided and that the certification block has been signed and dated by the Radiation Safety Officer or management representative.

b. Verify that a check or credit card application (fee payment) for the appropriate fee and one complete copy of a valid, active Agreement State license are included with the initial NRC Form 241. Process the check and forward it to the NRC Lockbox in accordance with the general guidelines in Section 05.01.01 of this NUREG.

Notes: For NRC Forms 241 received without a fee payment, notify the licensee, by telephone, that the required fee (10 CFR 170.31) must be provided, before conducting activities under reciprocity.

In cases where the Agreement State licensee seeks a waiver of the time requirements from the Regional Administrator, the reviewing personnel in the Region may authorize reciprocity activities before receipt of the fee only after contacting OCFO for approval.

c. Review the Agreement State license that was submitted with NRC Form 241 to verify that the proposed activities are authorized by the license and that the license will be in effect during the time of the proposed activities.

Note: The Agreement State licensee cannot qualify for a general license under 10 CFR 150.20, if the specific license issued by the Agreement State limits the activity authorized by the license to specified installations or locations; only if the license authorizes temporary job site locations will the general license of 10 CFR 150.20 apply.

d. For initial NRC Forms 241, enter the Agreement State licensee and fee information into the Reciprocity Tracking System (RTS).

Note: Information concerning the actual use of the RTS can be found in the US NRC Reciprocity Tracking System 36.15 User Guide (RTS Users Guide).

e. Enter work location information into the RTS.

Note: The Location Reference Number (LRN) is generated by the RTS and is necessary for the tracking of NRC Form 241 and any revisions to NRC Form 241 and is described in the RTS Users Guide. This number should be entered on NRC Form 241 for use by the licensee on subsequent revisions.

f. If NRC Form 241 is deficient (i.e., does not contain the required information, or the information provided indicates that the applicant does not qualify), see the procedure for deficient forms below.

Note: For cases where NRC Form 241 is received and the filing indicates that the licensee does not qualify for a general license under 10 CFR 150.20, notify the licensee by telephone and send a follow-up letter within 3 days of receipt of the NRC Form 241 request, explaining that the licensee does not qualify for reciprocity and indicate to the licensee that work is not to be performed in areas of exclusive Federal jurisdiction, non-Agreement States, or in Federal offshore waters.

g. When it is determined that the required information has been submitted and the fee payment has been provided, sign and date NRC Form 241 as the reviewing official and forward a copy to the Agreement State licensee with an acknowledgment letter (see sample in Appendix D). This copy may be transmitted via facsimile.

Note: Signature authority for the reviewing official of the reciprocity activities as requested by NRC Form 241 should be designated according to Regional policy.

h. Process the check and forward it to the NRC Lockbox in accordance with the general guidelines in Section 05.01.01 of this NUREG. The Regional Office will declare the completed reciprocity package an "Official Agency Record" in ADAMS.

i. Promptly notify, by e-mail, the inspection staff responsible for inspecting the area where the reciprocity activity will be conducted.

j. Notify the State(s) where the work is to be performed.

3. Revision to NRC Form 241

a. Verify that NRC Form 241 indicates a request for a revision for additional work locations, or changes to the radioactive material, or work activities different from the information previously identified by the licensee on the initial Form 241.

b. Verify that the appropriate fee for the revision is included with the request and that the certification block has been signed and dated by their RSO or Management representative. Process the check and forward it to the NRC Lockbox, in accordance with the general guidelines in Section 05.01.01 of this NUREG.

Notes: For revisions to NRC Form 241 that are received without a fee payment, notify the licensee by telephone that the required fee (10 CFR 170.31) must be provided before NRC's review of the revision request.

Because of the time limitations often associated with reciprocity activities, revisions to NRC Form 241 may be authorized before receipt of the fee; however, the reviewer should first contact OCFO for verbal approval before authorizing activities listed on NRC Form 241.

c. Confirm that the information on file in the RTS for the initial NRC Form 241 is current and correct before revising the licensee's reciprocity record in the RTS.

d. Obtain the number of total usage days to date from the RTS (number of days activities are conducted and/or licensed material is stored in non-Agreement States) and record on NRC Form 241.

e. For new locations of work, additional dates, or different activities, enter the information into the RTS. Assign an LRN for each new location of work listed on NRC Form 241.

f. If NRC Form 241 is deficient (i.e., does not contain the required information, or the information provided indicates that the applicant does not qualify), see the procedure for deficient forms below.

Note: For cases where revisions to NRC Form 241 are received and the filing indicates that the licensee no longer qualifies for a general license under 10 CFR 150.20, notify the licensee as soon as practicable to cease licensed activities in NRC jurisdiction. Issue a letter immediately after the notification (within 3 days of the submittal) explaining why the licensee does not quality for reciprocity and confirming that licensed activities should cease. The package should still be forwarded to OCFO for fee processing.

g. When it is determined that the required information has been submitted and the fee payment has been provided, sign and date NRC Form 241 as the reviewing official and forward a copy with an acknowledgment letter to the Agreement State licensee (see sample in Appendix D). This copy may be transmitted via facsimile.

Note: It is not necessary for the licensee to resubmit the Agreement State license unless the license has been amended since the filing of the initial NRC Form 241.

h. Forward the completed reciprocity package to OCFO for fee processing. After determining that the appropriate fee has been paid, OCFO will enter the fee payment information on the form and return the completed package to the reviewing official. The Regional Office will declare the completed reciprocity package an "Official Agency Record" in ADAMS.

i. Promptly notify, by e-mail, the inspection staff responsible for inspecting the area where the reciprocity activity will be conducted.

j. Notify, by e-mail, if applicable, the State(s) where the work is to be performed, of the ADAMS accession number for the completed NRC Form 241.

4. Clarifications of NRC Form 241 - Licensees should notify NRC of clarifications to the initial NRC Form 241, that define or delete specific locations or work sites, work site contacts, or dates of work previously identified by the licensee. Clarifications do not require a fee.

a. Verify that NRC Form 241 indicates a request for a clarification and that the information provided does not constitute a revision.

Note: If the information provided does not meet the criteria stated above for a clarification, notify the licensee of this fact by telephone within 3 days of receipt of the NRC Form 241 request. If the request constitutes a revision, inform the licensee that a fee is required for revisions and that the required fee must be provided before NRC's review of the request. For the processing of revision requests, see procedure above.

b. Confirm that the information on file in the RTS for the initial NRC Form 241 is current and correct before revising the licensee's reciprocity record in RTS.

c. Obtain the number of total usage days to date from the RTS (number of days activities are conducted and/or licensed material is stored in non-Agreement States) and record on NRC Form 241.

d. When it is determined that the information submitted only contains clarifications, sign and date NRC Form 241 as the reviewing official, indicating that the clarifications have been reviewed and found sufficient, and forward a copy to the Agreement State licensee. This copy may be transmitted via facsimile.

e. As no fees are involved for clarifications, the Regional Office will declare the completed reciprocity package an "Official Agency Record" in ADAMS.

f. Promptly notify, by e-mail, the inspection staff responsible for inspecting the area where the reciprocity activity will be conducted.

g. Notify, by e-mail, if applicable, the State(s) where the work is to be performed, of the ADAMS accession number for the completed NRC Form 241.

5. Deficient NRC Form 241

a. If NRC Form 241 contains omissions or errors, try first to resolve them by telephone contact with the Agreement State licensee within 3 days of receipt of the NRC Form 241 request. If the discrepancies can be resolved by telephone contact (i.e., minor deficiencies), mark the form with the corrections and emphasize to the licensee the need to comply with the requirements of 10 CFR 150.20.

b. If the deficiencies cannot be resolved by telephone (i.e., significant deficiencies), send a letter requesting the necessary additional information, identifying to the licensee the errors, omissions or deficiencies. Emphasize to the licensee the need to comply with the requirements of 10 CFR 150.20 before conducting activities under reciprocity and notify the licensee that further review will continue on receipt of the requested information.

c. If the discrepancies cannot be resolved with the Agreement State licensee, notify the licensee by telephone and send a follow-up letter, within 3 days of receipt of the NRC Form 241 request, explaining that the licensee has not submitted the required information and thus does not qualify for a general license under 10 CFR 150.20. Indicate to the licensee that work is not to be performed in areas of exclusive Federal jurisdiction, non-Agreement States, or in Federal offshore waters until NRC receives the required information.

d. Process the check and forward it to the NRC Lockbox in accordance with the general guidelines in Section 05.01.01 of this NUREG.

e. The Regional Office will modify the ADAMS file to indicate that the form has been approved or disapproved (as appropriate) and declare the file an "Official Agency Record" in ADAMS.

f. For Agreement State licensees whose proposed reciprocity activities are approaching or would exceed the 180-day limit, the licensee should be notified by telephone or mail that a specific NRC license must be applied for and obtained if activities in non-Agreement States in excess of 180 days are to be conducted within the calendar year.

6. Apparent Non-Compliance with 10 CFR 150.20 - If the NRC Form 241 describes activities that appear to be in noncompliance with the Agreement State specific license or other regulatory requirements, the following actions shall be taken:

a. Where the Agreement State license limits use to a specific address or location, advise the licensee, by telephone or in writing (notify the appropriate Agreement State) within 3 days of receipt of the NRC Form 241 request, to apply to the Agreement State licensing authority for a license amendment permitting temporary job site locations, or to the appropriate NRC Regional Office, for a specific NRC license.

b. Cases where activities were started before the initial NRC Form 241 was submitted; where the Agreement State license is expired, limits locations, or otherwise is ineligible for reciprocity; or where the 180-day limit is exceeded are violations of 10 CFR 150.20 and should be treated in accordance with the NRC Enforcement Policy, NUREG-1600.

7. NRC Form 241 - Equivalence or Misdirection

a. Equivalence - There may be cases where the Agreement State licensee submits a letter in lieu of NRC Form 241. This is acceptable, provided that the submittal contains all of the information required by NRC Form 241, including one complete copy of a valid Agreement State license, if applicable, and the required fee payment.

b. Misdirection of NRC Form 241 - If an Agreement State licensee inadvertently submits an NRC Form 241 to NMSS or the wrong Regional Office, the receiving office shall promptly notify the appropriate Regional Office, and forward the submittal.

Retention and Disposal of Reciprocity Licensing Documents

All reciprocity licensing documents, the initial NRC Form 241s, revisions, clarifications, and 10 CFR 2.790 requests must be retained and/or destroyed in accordance with the approved records disposition schedules contained in NUREG-0910, "NRC Comprehensive Records Disposition Schedule." NRC Schedule 2-24.4.d requires that license files be retained for 20 years after license termination. Documents associated with a Form 241 should be retained for 20 years following the year for which the Form 241 was effective.

4 LICENSE REVIEWER GUIDANCE

4.1 INTRODUCTION

This chapter provides guidance and criteria to the license reviewer for processing license applications for new applicants, amendments and renewals. This guidance assumes that applications will be filed and reviewed in accordance with the guidance set forth in the NUREG-1556 series, although the licensee's use of the NUREG-1556 series is voluntary. If the licensee does not use the NUREG-1556 series, the review of the applicant's submittal may take longer.

Reviewers should use all available NUREG-1556 tools, including process, criteria, and checklists when reviewing license applications to standardize and simplify the review process. An applicant may request authorization to use licensed materials in more than one program type. In this case, the reviewer would need to use more than one NUREG volume to review the application. A complete list of the documents in the NUREG-1556 series is located in the Foreword to this document. The reviewer should review and compare the specific licensing criteria for each program type to identify the common criteria and the unique issues. The applicant's radiation safety program must adequately address all of the criteria for each program type to be authorized. However, reviewers should avoid requesting information not identified in the NUREG. When adding new or multiple program types to a single license, the reviewer should refer to the Inspection Manual Chapter 2800 to identify the program code with the highest priority for inspection. This program code should be identified as the primary program code in the LTS and will dictate the inspection frequency for this license.

If the NUREG does not request information thought to be critical to a particular licensing action, Headquarters should be informed so that the NUREG can be revised, if necessary, to include the information. If additional guidance is needed, it should be requested in a technical assistance request (TAR). Refer to Section 4.14 for specific guidance about TARs.

4.2 PROCESSING NEW APPLICATIONS

Applicants for new licenses are expected to provide all the information specified on NRC Form 313. All items in the application should be completed in enough detail for the reviewer to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect health and minimize danger to life and property. The reviewer should perform a comprehensive review of the application. This review should consist of a comparison of all material submitted by the applicant, with the requirements in the appropriate regulations, guidance in the appropriate NUREG-1556 volume, and guidance supplemented in relevant TAR responses.

Parts of the application that do not conform to, or fail to address areas in the appropriate guidance, are deficiencies that must be resolved before the license is issued. The application should be reviewed against the checklist/suggested format in the appropriate NUREG-1556

volume(s). All deficiency findings should be clearly documented and communicated to the applicant. Communications with the applicant are official agency records. Checklists and other notes prepared by reviewers for their own use do not have to be made part of the official agency record, if the resulting decisions are documented in communications with the applicant. Reviewers should apply the guidance to the extent suitable to the applicant's proposed activities and should not apply any standards or criteria that are not contained in the guidance, or for which there is no specific regulatory basis. Reviewers should accept procedures or proposals that result in a level of safety equivalent to that provided for in NRC guidance.

4.3 PROCESSING AMENDMENTS

The licensee is obligated to keep the license current. If any of the information in the original application changes, and affects matters concerning NRC jurisdiction, the licensee must submit an application for a license amendment to reflect the change, before the change takes place. The licensee should identify the specific changes in the amendment request and also discuss the basis for the changes. The reviewer should focus the evaluation on only those areas that the licensee indicates need revision. If the licensee completely resubmits their application, the reviewer should request that the licensee specifically identify the requested changes. The licensee may opt to resubmit their request and only discuss the specific changes, or may identify the changes by marking the text.

4.4 PROCESSING RENEWALS

NMSS has developed a license renewal system that focuses resources on applications from licensees whose performance indicates potential programmatic weaknesses, and on program areas that have undergone major changes that affect radiation safety. Each renewal application will be reviewed to determine whether the application will receive a comprehensive review or a limited review by comparing the licensee's performance against the performance indicators discussed in this section.

4.4.1 DETERMINING REVIEW STATUS

The first task for the reviewer is to review the Docket and NRC data bases (such as the Nuclear Materials Events Database (NMED) and the Licensee Event Reports (LERs)) to compare the licensee's performance against the specified performance indicators. An application submitted by a licensee that demonstrates the presence of one or more of these performance indicators will receive a Comprehensive Review. Applications from licensees who do not exhibit any of these performance indicators will receive the Limited Review. The evaluation of each renewal application will be documented using the checklist in Appendix C, entitled, "Performance Evaluation of Renewal Applications."

However, based on an evaluation of the specific circumstances associated with the presence of a performance indicator, NRC licensing management may decide that a comprehensive review is not warranted. Further, NRC licensing management may choose to perform a comprehensive review of a renewal even though the application is from a licensee that does not trigger any of the formal performance indicators but that may exhibit other characteristics warranting a comprehensive review. Such decisions must also be documented in the performance evaluation checklist.

4.4.2 PERFORMANCE INDICATORS

The reviewer should complete the performance indicators on the checklist provided in Appendix C (Section 12.1) using the following guidance. This checklist is an OAR because it is the basis of decision that is not documented elsewhere.

1. Enforcement History

   A licensee that is or has been the subject of an ongoing investigation by the Office of Investigations (OI), or escalated enforcement action within five years will be considered for a comprehensive review of the renewal application. Escalated enforcement action includes any Order, civil penalty, or Notice of Violation issued at Severity Levels III, II, or I.

   Note: Licenses should not be renewed if they are the subject of an ongoing investigation (OI) or pending enforcement action without the written concurrence of the appropriate office.

2. Loss of Material

   Any licensee who has lost control of a reportable quantity of licensed material presumed to be in the public domain, associated with a violation of regulatory requirements within the five-year period immediately before the proposed renewal, will be considered for a comprehensive review of their renewal application.

3. Unauthorized Disposal or Release of Material

   If the licensee has been cited with a violation regarding unauthorized disposal or release of material in the last five years, the license application will be considered for a comprehensive review.

4. Overexposure

   If the licensee has been cited for an exposure in excess of regulatory requirements in the last five years, a comprehensive review of the license application will be considered. Exposures at issue would include those to members of the public as well as to occupationally-exposed individuals.

4.4.3 COMPREHENSIVE REVIEWS

Reviewers should conduct the same comprehensive review required for new applications. Please refer to Section 4.2, Processing New Applications, for guidance.

4.4.4 LIMITED REVIEWS

Reviewers should use the limited review checklist in Appendix C (Section C.2). A limited review of a renewal application will only evaluate the following areas for conformance with the guidance from the appropriate NUREG-1556 volume on the content of the application:

1. Administrative Items

   Review administrative items, including the licensee's name and address and other items, such as the Radiation Safety Officer's name. Also, ensure the renewal application is signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee.

2. Financial Assurance

   Reviewers should check the possession limits and confirm that decommissioning financial assurance requirements have not changed. If new possession limits invoke new requirements, ensure that the application contains the required documents. For those licensees that must provide a financial assurance instrument, ensure the instrument is adequate for the current scope of the program.

   Note: If the licensee submitted a Decommissioning Funding Plan and the new expiration date is greater than five years, include the following condition on the license: "A revised Decommissioning Funding Plan must be submitted no later than five years from the date of issuance of this license."

3. Program Management

   Review those portions of the application that address program management, including:

   a. Organizational structure (assure that appropriate elements are present and are assigned necessary authority and responsibility);

   b. The qualifications of key personnel, such as the Radiation Safety Officer, authorized users, radiographers, well loggers, irradiator operators, authorized medical physicists, and authorized nuclear pharmacists; and

   c. The licensee's radiation safety audit program.

4. Equipment and Facilities

   Review those portions of the application that address equipment and facilities.

5. Environmental Assessments

   Review those portions of the application that need an environmental assessment because they do not conform to the categorical exclusions in 10 CFR Part 51.

6. Unreviewed Requests

   Review any new authorizations, requested by the licensee, that have not been previously reviewed, and any major program elements that require change as a result of the new authorization. Also review the licensee's inspection reports for changes in the licensee's scope of operations that are not referred to in the renewal package. These areas should undergo a focused review, as opposed to a comprehensive review of the entire application. Some examples of requests that should receive focused reviews are:

   a. New broad scope authority; introduction of iodination with millicurie quantities of iodine-131 or iodine-125 requiring major facility additions or changes; additional research and development activities (human and non-human); additional medical therapy modalities.

   b. Any new high-risk technology uses being added to an existing license, to ensure that the licensed program can safely manage and use the new technology. Specific conditions and requirements associated with new technologies may be added to the license. Examples include new license categories, use of intravascular brachytherapy, or Boron Neutron Capture Therapy in humans.

7. Change in Key Staff Members

   If there has been a change in key staff members directly responsible for the radiation safety program, conduct a focused review of the affected area.

8. Major Areas

   A brief overview is made of the remainder of the application to determine if the major areas discussed in the guidance on the contents of the application from the appropriate NUREG-1556 volume are present. If detected, an obvious failure or a deficiency in a significant area should result in a thorough review of that area. A finding that more than one area is not addressed or contains a significant deficiency could result in a comprehensive review of the license application. Change to a comprehensive review should be approved by licensing management, and the reason for changing from a limited review to a comprehensive review must be clearly documented on the limited review checklist in Appendix C (see Section C.2).

   Note: Each Region determines from its review of the licensee's Docket file and NRC data bases whether a comprehensive review is necessary. The licensee's submission of an application that does not use the NUREG-1556 series is not a performance indicator, and failure to use NUREG-1556 does not determine the level of review necessary. Although the application may take longer to review, it does not preclude a limited review with a focused review on those areas that depart from the NUREG guidance.

4.5 DEFICIENCY LETTERS, CALLS, FAXES, AND E-MAILS

Once issues and deficiencies have been identified in an application, use the most efficient process available to fully communicate issues to licensees, document the request, and elicit the appropriate applicant response. Use the telephone, facsimile, and e-mail to communicate with licensees and reduce reliance on formal letters. All substantive communications must be clearly documented. Draft documents from the applicant should not be used as the basis for a licensing action.

Efforts should also be directed to improving, reducing, and eliminating reviewers' requests for additional information. Ensure that each requested item for additional information is clear (i.e., provides a description of the deficiency and a statement of what is needed); is essential to protect safety; and is linked to regulatory requirements and NUREG-1556. Once a request for information (deficiency letter, telephone call, facsimile or e-mail) is sent to the licensee, the action is tracked in the LTS database. The time parameters for certain actions outlined below are based on "tickler" dates established in the LTS and can be extended, if necessary, as approved by supervisors granted that authority by management.

Application for a New License or for an Amendment

A. Complex Deficiencies

1. Any significant or complex deficiencies in an application for a new license or license amendment should be described in a deficiency letter to the applicant. A sample deficiency letter is provided in Appendix D. This letter can be sent by regular mail, e-mail, or facsimile. The letter to the applicant should contain a statement that specifies that we shall assume that the applicant does not wish to pursue its application if we do not receive a reply within 30 calendar days from the date of the letter. The reviewer should complete the appropriate LTS worksheet and instruct the LA to enter a milestone 14 for the specific licensing action to the LTS database for appropriate tracking.

2. If a response to the deficiency letter is received within 35 calendar days from the date of the letter, proceed with review of the response.

3. If a response to the deficiency letter is not received within 35 calendar days from the date of the letter, we should consider the application as "abandoned" for failure to provide the requested information "without prejudice" to the resubmission of the application. Prompt action (five working days) should be taken to "void" the application after it has been deemed "abandoned."

   "Abandoned, without prejudice, and void" are not meant to have legal connotations. "Abandoned" means simply that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment. "Without prejudice" means that the applicant can resurrect its application within some reasonable time without

having to pay another fee, having its application redocketed, etc. "Void" means that the application is, in practical effect, nullified. These terms are to be used only for our own bookkeeping purposes.

4. If a response to the deficiency letter is received after the application has been voided, and the response is received not more than one year from the date of the letter, the application should be assigned a new control number, and review should proceed. Typically, no additional fee is necessary. An exception would be an application subject to full cost recovery. The "voiding" of such an application should be coordinated with OCFO.

B. Simple Deficiencies

1. To accelerate issuance of a license or license amendment, reviewers are encouraged to use the telephone to obtain clarifying information from an applicant and to notify an applicant of simple deficiencies. Simple deficiencies include a model number for a source, model number of a leak test kit, need for a commitment for frequency of change of personnel monitoring equipment, etc. Simple deficiencies do not include training and experience of individuals, descriptions of radiation safety programs, etc.

2. The reviewer should document the call, complete the appropriate LTS worksheet, and instruct the LA to enter a milestone 15 for the specific licensing action. Documentation of the call should be entered into ADAMS as outgoing licensing correspondence. If the applicant does not respond within 15 calendar days, a confirmatory letter should be sent to the applicant not more than 20 calendar days after the telephone call that specifies the deficiencies. A sample letter confirming the telephone conversation is in Appendix D.

3. After the confirmatory letter has been sent, monitor the licensee's response with the LTS tickler system. If a response is not received within 35 calendar days, void the action.

Application for License Renewal

A. Complex Deficiencies

1. Any significant or complex deficiencies in an application for license renewal may need to be sent in a deficiency letter to the applicant, however, the reviewer is encouraged to use the simplest process available to communicate issues fully to licensees. A sample deficiency letter is provided in Appendix D. The letter should request the applicant to respond within 30 calendar days from the date of the letter, but it should not include a formal warning. A milestone 14 should be entered into the LTS database for the specific licensing action.

   The goal is to have no more than one request for additional information for each renewal application. If a second request is needed, escalate it quickly to NRC and licensee management to resolve open issues. If the applicant does not provide adequate information after such an exchange, complete the licensing action that can be completed, inform the

licensee of issues that cannot be approved, and explain why not. Avoid multiple rounds of requests for additional information.

2. If a response to the deficiency letter has not been received within 35 calendar days from the date of the letter, a denial warning letter (second letter) should be sent. A sample denial warning letter is provided in Appendix D. This letter will notify the applicant that unless a response to the deficiency letter (first letter) is received within 30 calendar days, it may be necessary to deny the application. Such a denial would require divestiture of all material in the applicant's possession.

3. If a response to the denial warning letter is not received within 35 calendar days, the reviewer should proceed to deny the application as described in Section 4.11.

B. Simple Deficiencies

To accelerate issuance of a renewal, reviewers are encouraged to use the telephone, as described above, for new applications and amendments. If the licensee does not respond to the confirmatory letter, the reviewer should proceed to deny the renewal as described in Section 4.11.

Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. Appropriate milestone entries into the LTS should be made in order to track each application properly and record extensions of time for responses. This may be accomplished by changing the "tickler" date. The reviewer should keep NRC management informed of licensees' requests for extensions.

4.6 CREATING THE LICENSE

4.6.1 STANDARD LICENSES AND STANDARD LICENSE CONDITIONS

For consistency, the reviewer should use the sample licenses from the appropriate NUREG volume as a standard when creating a license for an applicant. In some cases, the reviewer may need to customize a license. An applicant may request authorization to use licensed materials in more than one program type. In this case, the reviewer would need to review the sample licenses in more than one NUREG volume and combine the pertinent license conditions into a single license, if appropriate. In some cases (i.e., waste broker activities), it may be best to issue separate licenses. The reviewer should also refer to Inspection Manual Chapter 2800 to identify the program code with the highest priority for inspection. This program code should be identified as the primary program code in the LTS and will dictate the inspection frequency for this license.

In other cases, an applicant may request authorization to conduct special activities in a program that is non-routine and not included in the sample license. The reviewer should refer to the approved list of standard license conditions in Appendix E. The standard conditions are organized in categories of authorization. Use of standard license conditions should not substitute for obtaining information from applicants and licensees. Reviewers should try to obtain commitments that will be captured by the tie-down condition rather than creating new conditions.

4.6.2 NON-STANDARD LICENSE CONDITIONS

When reviewing applications, if there are simple issues that the licensee did not address, even after being asked to provide the information in a deficiency request, the reviewer should use custom license conditions to achieve closure rather than protracted negotiations with the applicant. Simple issues are the requests for information identified in NUREG-1556 or existing technical guidance provided by TARs. The reviewer should use standard license conditions to the extent possible, however custom conditions may be used when necessary. The reviewer should write the custom license condition to state the requirement clearly and simply. Custom conditions should be approved by the appropriate branch chief. This strategy is intended to streamline the licensing process to be more responsive to stakeholders, to empower staff, and to reduce management reviews.

However, issues not currently addressed in the NUREG series and thought to be critical to a particular licensing action should continue to be coordinated with Headquarters. If the Region believes that a special condition is appropriate, this should also be coordinated through Headquarters before use. In addition, license reviewers should coordinate these conditions with inspection staff and licensees to ensure that all parties have the same understanding of all license conditions, especially those unique to a particular licensee. It is expected that license reviewers will call the licensee before issuing a license with non-standard license conditions.

4.6.3 ESTABLISHING LICENSE EXPIRATION DATES

The Commission approved the extension of the terms set by policy for licenses issued under 10 CFR Parts 30 (except Part 35), 40, and 70 from 5 to 10 years in 1997. In 1998, final rulemaking was published to set the license term limit for medical use (Part 35) licenses to 10 years. Now all of these materials licenses have the same license term limit. The Commission's actions approved the use of license terms shorter than 10 years on a case-specific basis.

Any license issued or renewed after July 10, 1998 (when the medical use license term limit was changed to 10 years) should have a 10-year term limit, unless management determines, on a case-by-case basis, that a license should be issued for fewer than 10 years. Some examples of conditions that may result in licenses issued for fewer than 10 years are:

New Technology: The license authorizes a new high-risk technology that the industry, the particular licensee, or NRC has not had extensive experience in using or regulating; or

Enforcement History: The licensee, in the last inspection or five years (which ever is longer), had a Severity Level I, II, or III violation; or

Possession-Only: The license authorizes possession and storage only. When no other activities are authorized, there is no principal activity for the licensee to cease. Therefore, the requirements to notify NRC and undertake decommissioning do not apply. These licenses will be renewed every 2 years and the decommissioning issues will be addressed at that time.

Other: Other situations that would warrant increased attention, on a case-specific basis.

Use the checklist in Appendix C entitled "New & Renewal - License Terms of Less Than 10 Years," to document the license term, the basis for the decision, and the basis for an exemption, if appropriate. This checklist is an OAR because it is the basis of a decision not documented elsewhere. If the reviewer recommends that the license term should be shorter than 10 years, a term of five years is typically used. Other terms may be approved on a case-specific basis. NRC management must approve all license terms shorter than 10 years.

4.6.4 ISSUANCE OF FINAL LICENSING ACTION

1. For all completed licensing actions, the license reviewer should send the licensee a cover letter with two copies of the license, the original signed license, and a copy.
2. The cover letter may be a form letter or individual letter, depending on the individual case and the practice of the Region. A sample cover letter is provided in Appendix D.
3. Many licensing actions require specific information to be included in the cover letter related to the individual case. All information may be combined into a single cover letter, or use attachments.
4. For licenses which are amended frequently, it is acceptable to include the standard information with every licensing action. However, if deemed appropriate by the Region, the information may be deleted if it was provided in a recent previous communication.
5. Cover letters are official Agency records and will be maintained in ADAMS.
6. Appendix D also contains a sample cover letter for terminating a license.

4.7 GUIDANCE FOR MULTI-SITE LICENSES

NRC has received applications for new licenses, amendments, and renewals ("applications") requesting authorization for use of NRC licensed material at multiple sites under one license. Many of these applications represent categories of licensees where multiple locations of use have not been routinely authorized. The purpose of this section is to ensure that applications

requesting authorization for multiple sites of use under one license (including amendment requests that expand a licensed program to multi-site) are identified and have radiation safety programs that are adequate, both in scope and in depth, to oversee safe use of licensed material at each facility. However, this section does not apply to certain categories of licenses that, by condition of the license, routinely authorize multiple locations of use (i.e., broad-scope, mobile medical service, and master material licenses) or licenses authorizing temporary job sites.

Furthermore, this section highlights general radiation safety management concerns specific to multi-site licenses, and does not attempt to define necessary radiation safety management structures for every type of licensed activity. The license reviewer will need to tailor the review to the type of license under consideration. Information in NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," may be of assistance during review of multi-site license applications.

Focus of Review

During the review of the licensee's radiation safety program and management oversight, the reviewer should pay particular attention to delegation of responsibility and established, reciprocal lines of communication between users and management. Regardless of the number of sites authorized under one license or the geographic distance between sites, the adequacy of the overall radiation safety management structure must be reviewed to ensure safe operations at each site.

Description of Multi-Site

A multi-site license is one that includes two or more locations of use that are identified on the license. Such locations will typically include: (1) stand-alone facilities that would otherwise be licensed individually; or (2) satellite facilities that are not located within the principal job site and for which NRC licensed material use is ongoing (excluding temporary job sites, broad scope licensees, or mobile nuclear medicine services). A multi-site facility may also include those licensees for which the addresses of use are geographically separated and may each be under the direction of the same or different RSOs.

Furthermore, the nature of licensed material use and operations (e.g., medical versus industrial) should be the same at each site. Licensed material uses currently licensed separately should continue to be licensed separately (e.g., teletherapy).

Multi-Site Examples:

1. Radiopharmacy licensees with multiple pharmacy locations on one license;
2. Radiographers or moisture density gauge users with multiple permanent work sites on one license (e.g., branch offices);

3. Medical licensees with facilities at more than one geographic location;
4. Large manufacturers with facilities at more than one geographic location; and
5. Well-loggers with multiple permanent work sites on one license.

Number of Sites

A specific limit to the number of sites permitted on a multi-site license is not practical for generic application to all licensees; rather, the reviewer should assess applications on a case-by-case basis. The basis for determining the appropriate number of sites for a specific licensee should include the following considerations: (1) past inspection history; and (2) adequacy of licensee management structure for the type, scope, and geographic distribution of the program. All sites approved for use of byproduct materials should be identified on the license when issued.

Communication

In those cases where there are multiple oversight levels, the licensee should clearly address communication and accountability systems including:

1. Delegation of clear and appropriate levels of authority, indicating sufficient organizational freedom and management prerogative to communicate with and direct personnel regarding NRC regulations and/or license provisions;
2. Descriptions of program review and reporting on a regular basis;
3. Mechanisms for addressing urgent situations;
4. Mechanisms for informing all personnel of program changes;
5. Provisions to make personnel aware of the appropriate representatives to contact at each level of authority;
6. Assurance that each level of oversight is available to interact with other levels, authorized users, and supervised workers, both as needed and on a regular basis.

Records

As provided for in 10 CFR 30.52, each licensee is to make its records available for NRC review, on reasonable notice. The license applicant should indicate point-of-contact information for NRC notification and inquiry about records. The licensee may also choose to identify locations where the records will be maintained for NRC review.

Additional Program Areas for Review

The licensee should provide specific information, including the following areas:

1. Transportation of licensed material (including radioactive waste) between sites;
2. Applicability of decommissioning requirements;
3. Sharing of safety equipment; and
4. Coordination among sites for inventory control of licensed material with the intended focus of continually monitoring types and quantities of material, thereby ensuring that regulatory possession limits are not exceeded.

4.8 OPPORTUNITY FOR AN INFORMAL HEARING – MATERIALS LICENSING

The purpose of this section is to provide basic information relevant to hearing rights associated with materials licensing. An aggrieved member of the public has the right to request a hearing on any materials licensing action. The Atomic Energy Act does not, however, require that formal notice (in the *Federal Register*) be given for materials licensing actions or that hearings held on materials licensing actions be of a formal nature.

Accordingly, the Commission has provided informal procedures for materials licensing actions and any hearings held on such actions, which are set forth in Subpart L of 10 CFR Part 2. Reviewers should be familiar with this Subpart. In particular, reviewers should be aware that in many materials licensing actions notice is not published in the *Federal Register*. In such cases, a member of the public may request a hearing on the action within (1) thirty days of receiving actual notice of a pending application, or (2) within 180 days after NRC action granting an action in whole or part (10 CFR 2.1205(d)(2)). Although the Commission is under no requirement to publish a *Federal Register* notice of a materials licensing action in most cases, such a notice is required whenever the staff makes an environmental assessment (see Section 04.10 of this NUREG). Any draft or final finding of no significant impact with respect to a proposed action must be published in the *Federal Register* (See 10 CFR 51.33 and 51.35(a)). The *Federal Register* notice should include a reference to Subpart L and the opportunity for a hearing.

Reviewers should also be aware that there have been occasions in which members of the public have filed a request for a hearing on the staff (EDO), in conformance with 10 CFR 2.1205(f)(2), but have failed to comply with 10 CFR 2.1203, which requires that the hearing request also be filed with (submitted to) the Secretary of the Commission. When a reviewer becomes aware of a hearing request filed on the staff, he should determine whether the request has also been filed on the Secretary. If not, he should discuss the matter with the Office of the Secretary and the Office of the General Counsel.

4.9 LICENSING SITE VISITS

Licensing visits should be conducted for all new byproduct material applications involving large programs or significant technical issues. More specific guidance is provided below.

Purpose of Licensing Visits

Licensing visits are conducted in order to accomplish one or more of the following objectives:

1. Evaluation of applicant's ability to conduct safe operations and comply with requirements;
2. Evaluation of safety and technical issues that are not easily understood through correspondence or telephone conversations;
3. Expedited resolution of issues and concerns through discussions with the applicant;
4. Verification of statements and commitments in the license application; and
5. First-hand review of applicant's staff, site, and facilities.

Licensing Visits for New License Applications

Licensing visits should be conducted for the following types of new license applications:

1. Type A licenses of broad scope;
2. Panoramic irradiators greater than 10,000 curies;
3. Manufacturers using unsealed radioactive material or significant quantities of sealed material;
4. Radioactive waste brokers;
5. Radioactive waste incinerators;
6. Commercial nuclear laundries; and
7. Any other application that, in the judgement of the Regional staff, involves complex technical issues complex safety questions, or unprecedented issues that warrant a site visit.

Licensing Visits for Amendments

Licensing visits should be conducted for any license amendment requesting a new authorization for the types of operations listed above. Licensing visits are also encouraged for amendments involving significant modification to the types of operations listed above.

Licensing Visit for Renewals

Licensing visits are encouraged for renewals involving the types of activities listed above. However, in many cases, resource limitations may make this difficult. For each significant renewal, an evaluation of licensee program changes and inspection history should be performed. If the Regional staff concludes that there are not significant program changes or unresolved licensing issues, and that a licensing visit would not be cost-effective, then a licensing visit need not be performed.

4.10 CATEGORICAL EXCLUSIONS FOR MATERIALS LICENSING ACTIONS

4.10.1 INTRODUCTION

10 CFR Part 51 contains NRC's regulations that implement the Guidelines of the Council on Environmental Quality requiring the preparation of environmental impact statements pursuant to the National Environmental Policy Act of 1969 (NEPA). The basic policy on environmental assessments, environmental statements, and findings of no significant impact for most materials licensing actions are covered by "categorical exclusions" in §51.22 (c) (10) and (14) and therefore do not require environmental analyses. A categorical exclusion means a category of actions "which do not individually or cumulatively have a significant effect on the human environment and which the Commission has found to have no such effect in accordance with procedures set out in §51.22, and for which neither an environmental assessment nor an environmental impact statement is required."

In the next two subsections, we will provide guidance on determining when materials license actions qualify for categorical exclusion in accordance with Part 51 and specifically identify examples of licensing actions that are not covered by categorical exclusion.

4.10.2 LICENSING ACTIONS ELIGIBLE FOR CATEGORICAL EXCLUSION

License Actions That Qualify for Categorical Exclusion Under §§51.22(c)(14)(i) Through (xv)

License actions that clearly qualify for categorical exclusion - Such license actions, except for license termination actions, do not need an Environmental Assessment (EA) or documentation in the license file with regard to the issue of an EA. Such license actions do not need to be coordinated with NMSS with regard to whether an EA is needed.

License actions that qualify for categorical exclusion based on additional technical and/or license-based justifications - Such license actions do not need an EA, nor do such license actions need to be coordinated with NMSS with regard to whether an EA is needed. Unless otherwise stated below, the licensing staff needs to place in the license file, written justification to support the determination that an EA is not needed. Examples of license actions that will need either documentation or justification are discussed below.

1. ALL LICENSE TERMINATION ACTIONS

- When licensed activities clearly qualify for categorical exclusion, the close out survey and the submitted Form NRC-314, which certifies the proper disposition of the licensee's radioactive materials, are sufficient documentation.
- When licensed activities qualify for categorical exclusion based on additional technical and/or license-based justification, the close out survey and the submitted Form NRC-314 are sufficient documentation. However, if the proper justification was not documented, the reviewer will need to prepare written justification to support a determination that an EA is not needed.
- The need for additional documentation for more complex license termination actions will be determined by the Regions on a case-by-case basis. Only complex license termination actions, such as a license action that requires the submittal of a decommissioning plan (e.g., 10 CFR 30.36(c)(2)(i)), will require documentation of the justification to support why an EA is not needed. In many cases, such license actions need to be coordinated with the Division of Waste Management (DWM) of NMSS. DWM is responsible for providing the justification for any license termination action the Regions have coordinated with DWM. DWM will coordinate with IMNS for the determination on whether an EA is needed, on those actions that have been referred to them. Unless otherwise noted, the Regions can use DWM's responses to them concerning decommissioning activities as the Region's justification to support a determination that an EA is not needed.

2. FIELD STUDIES IN WHICH LICENSED MATERIAL ORIGINATING ONSITE IS RELEASED INTO THE ENVIRONMENT

If a research and development or academic institution application proposes to release to the environment radioactive materials that originated onsite (i.e., within the controlled property of the licensee), an EA is normally not needed and is covered under categorical exclusion §51.22(c)(14)(v) provided:

- All releases, originating onsite, to the environment, such as air and liquid effluents, direct radiation from deposition of radioactive materials from the release (e.g., groundshine), comply with as low as reasonably achievable (ALARA) and Part 20 requirements.
- To assist in demonstrating compliance with the requirements of 10 CFR Part 20, the licensee should set ALARA goals for air effluents at a modest fraction of the values in

Appendix B, Table 2, Columns 1 and 2, to §§20.1001-20.2401. Experience indicates that values of about 10 millirems per year from all of the licensee's radioactive air effluents should be practicable for almost all materials facility licensees (see Regulatory Guide 8.37); therefore, as a first step toward demonstrating compliance with ALARA for radioactive air effluents, the licensee demonstrates that the nearest member of the general public receives no more than 10 millirems per year from all of the licensee's radioactive air effluents (i.e., licensee demonstrates it meets the requirements of 20.1101(d)).

- All releases onsite comply with all applicable decommissioning requirements (e.g., decommissioning record keeping requirements pursuant to 10 CFR 30.35(g)) and current decommissioning policies.

Documentation that supports the licensee's application as meeting the above criteria is sufficient to support why an EA is not needed.

For license actions that cannot meet the above criteria, the Regions should coordinate with IMNS to determine whether an EA is needed. For example, an EA would be required for discrete sources released to the environment, which originated onsite, and which may not be recovered at the conclusion of the study or decommissioning.

License Actions That Qualify for Categorical Exclusion Under 10 CFR 51.22 (c) (14) (xvi)

License actions not specifically listed in Category 14 of §51.22 will require a TAR to IMNS. To expedite the processing of the TAR, the Regions should perform an initial technical assessment, to be enclosed with the TAR, to justify why the licensing action qualifies for categorical exclusion under §51.22(c)(14)(xvi). The Commission indicated in SECY-83-286 that there should be careful documentation in cases where these categorical exclusions are applied. Appendix I provides examples of the type of information that should be submitted to Headquarters to assist in preparing this documentation. IMNS will review the documentation and determine if the action qualifies for a categorical exclusion, then provide a memorandum documenting the results to the Region to be included in the official license file.

Generic Application of Previous License Actions That Qualified Under Categorical Exclusion

If a previous technical and/or license-based analysis had been performed that bounded the environmental radiological hazards to the public for the specific generic issue, and the Region believes its specific license action is within the safety envelope of the previous generic analysis, the Region can cite the previous generic analysis. The Region should document its rationale for making this assessment, and file copies of the previous analysis and its rationale in the license file. No coordination with NMSS is necessary. If the previous analysis referenced categorical

exclusion §51.22(c)(14)(xvi), the documentation shall include the original memorandum from the Director, IMNS, or his delegate.

4.10.3 LICENSING ACTIONS NOT ELIGIBLE FOR CATEGORICAL EXCLUSION

Licensing actions for the following activities are *not* covered by categorical exclusions:

1. Use of radioactive tracers in field flood studies involving secondary and tertiary oil and gas recovery.
2. Performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study. (The use of tracers in well logging is specifically covered by the categorical exclusion in §51.22 (c)(14)(xi)).
3. Processing of source material for extraction of rare earth and other metals (currently licensed in Headquarters only).
4. Waste brokers who are authorized to store waste more than 180 days or to possess more than 50 curies of radioactive material.
5. Any commercial waste disposal (currently licensed in Headquarters only).

Any application not covered by a categorical exclusion should be coordinated with Headquarters as soon as possible, so that specific guidance can be provided. Any application involving an activity not covered by a categorical exclusion will require the staff to develop an EA, in accordance with §51.21. Headquarters staff should refer to NMSS Policy and Procedures Letter 1-48, "Procedures for Preparing Environmental Assessments." If the EA demonstrates that the proposed activity will not have an adverse impact on the environment, the staff will document this finding through a finding of no significant impact (FONSI). If the EA indicates that the proposed licensing action may have an adverse impact on the environment, the staff will prepare an environmental impact statement (EIS) in accordance with §51.20. Headquarters staff should refer to NMSS Policy and Procedures Letter 1-50, "Environmental Justice in NEPA Documents."

Note: NMSS Policy and Procedures Letters are office letters maintained by the Program Management, Policy Development and Analysis Staff in NMSS.

4.11 CRITERIA FOR DENYING APPLICATIONS – MATERIAL LICENSES

General Guidance

Applications for material licenses should be denied pursuant to 10 CFR Section 2.103(b) if the staff cannot make the findings required by the regulations (e.g., 10 CFR Section 30.33, 40.32, or 70.23, as appropriate) because either:

1. The applicant does not satisfy the substantive requirements, even after providing information on which the staff can make a decision, OR
2. The applicant has not submitted adequate information (see 10 CFR Section 2.108). Denial pursuant to 10 CFR Section 2.108 presupposes that:
   a. The staff has requested the additional information needed to make the required findings;
   b. The applicant has had at least 30 days in which to provide the needed information; and
   c. The applicant has failed to respond or the response is not adequate.

To ensure that denials, where appropriate, are issued in a timely manner, it is important for the staff to perform follow-up on oral and written communications with applicants. In special situations, grant extensions for replies and prepare denial correspondence in accordance with this NUREG. Reviewers should note that applicants have the right to request a hearing concerning the denial pursuant to 10 CFR Part 2 (see Section 04.08 of this NUREG). Sample denial letters informing applicants of this right and providing other information are provided in Appendix J.

Guidance for Unusual Cases

As early in the review process as possible, identify and coordinate with NMSS, any application:

1. In which the staff has any question about the applicant's suitability; integrity (e.g., lack of candor or submission of inaccurate or misleading information); or ability or commitment to comply with the NRC regulations (e.g., financial instability or past inspection and enforcement history); OR
2. Containing an unusual request; OR
3. Raising novel legal or technical issues.

Early identification and coordination with Headquarters staff are needed to ensure that the staff promptly prepares a letter of denial, if appropriate, or that Regional and Headquarters staff agree on an appropriate strategy for handling the application. The low frequency of issuance of denials, especially in unusual cases, necessitates case-by-case consideration.

4.12 SIGNIFICANT LICENSING ACTIONS THAT WARRANT ONSITE INSPECTION

The Incident Investigation Team, who investigated the 1992 therapy misadministration that occurred in Indiana, Pennsylvania, recommended that the staff conduct inspections of licensees whose programs have significantly changed or expanded since the last routine inspection. As a result, both short- and long-term action items were implemented to address this issue.

A checklist is provided in Appendix C for determining when a significant licensing action has taken place that may warrant a near-term onsite inspection. The selection criteria should not be considered all inclusive, in that there may be unique indicators that a licensed program has changed significantly. Significant licensing actions identified by the license reviewer should be brought to the attention of management so that appropriate action is taken. A sample memorandum is provided in Appendix C.

All license reviewers should complete this checklist with each license amendment or renewal. The checklist need not be retained as part of the record if no inspection is recommended. However, if an inspection is recommended, the checklist should become an Official Agency Record.

4.13 PROCESSING OF EXEMPTIONS FOR MATERIAL LICENSEES

This section provides guidance to the Regions for processing requests for exemptions. Material licensees may be granted exemptions from NRC regulations pursuant to 10 CFR 30.11, 40.14, and 70.14. Applicants must provide sufficient information for the reviewer to determine that the exemption is authorized by law and will not endanger life, property, or the common defense and security, and is otherwise in the public interest. Appendix K provides additional guidance on routine exemptions to sections of the regulation. Some exemptions may be granted on a temporary basis, as explained below.

Note: Headquarters staff should refer to NMSS Policy and Procedures Letter 1-58, "Processing of Exemptions for Material Licensees and Certificate Holders." NMSS Policy and Procedures Letters are office letters maintained by the Program Management, Policy Development and Analysis Staff in NMSS.

General Guidance

Exemptions

The exemptions contained in Appendix K may be granted by the Regions without coordination with Headquarters. All requests for an exemption to the regulations must not present an undue risk to public health and safety and must be consistent with the common defense and security.

The request must be accompanied by:

- A description of the exemption needed and the reason why it is needed;
- A description of compensatory safety measures that will provide a level of protection equivalent to the regulation for which the exemption is being requested; and
- A discussion of how reasonable alternatives have been considered.

Each Appendix K section describes the specific part of the regulation that may be considered for exemption, any other commitment or additional information that the licensee must submit prior to issuance of the exemption, and the license condition to be issued upon review and determination that the exemption should be granted.

Temporary Exemptions for Humanitarian or Emergency Reasons

The Regions may grant a temporary exemption to NRC regulations or license conditions, on a case-by-case basis, without referral to the Director, IMNS, NMSS, in certain circumstances in which:

- A normal license amendment is not appropriate because of the non-recurring, short duration (normally 7 days or less) nature of the exemption; and
- The non-compliance would normally result in a Severity Level IV violation per NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

A temporary exemption should be granted only after a determination has been made that the circumstances surrounding the request are urgent, temporary, and that an exemption will not endanger life, property, or the common defense and security, and is otherwise in the public interest. Such exemptions should not be exercised repeatedly for the same set of circumstances for the same licensee.

All licensee requests for a temporary exemption to the regulation must be accompanied by:

- A discussion of the requirements for which an exemption is requested and identification of the specific regulation or license condition involved;
- A discussion of circumstances surrounding the situation, including the need for prompt action, a description of why the situation could not be avoided, and the probable consequences were the request not granted;
- A preliminary evaluation of the safety significance and potential consequence(s) of granting the proposed request; and
- A discussion that justifies the duration of the exemption.

The licensee's request should normally be faxed to the Director, DNMS within the appropriate NRC Region. The Director, DNMS at each NRC Region is authorized to grant the exemption request per Management Directive 9.29, "Organization and Function: Regional Offices." However, if circumstances do not permit time for the fax, the licensee may make the request orally and read or describe the above information to the NRC staff. The oral request must be followed (within 24 hours) by written documentation of the above information. The follow-up written request must confirm the information submitted orally and upon which the NRC relied in granting the exemption.

The exemption may be granted orally by the Director, DNMS. Following the granting of the request, the Director, DNMS shall promptly send a letter to the licensee, using the standard format provided in Appendix D, documenting the circumstances surrounding the request, the exemption granted, and the duration of the exemption. The letter will normally be issued within three working days of the receipt of the licensee's written request. The license should then be amended to incorporate the temporary exemption and commitments made by the licensee and an entry made to the Licensing Tracking System (LTS). Copies of the letter sent to the licensee should be provided to the Office of Enforcement, and the Director, IMNS, NMSS.

Exemptions Requiring Coordination with NMSS

All requests for exemptions not described above should be considered as non-routine and should be forwarded to the appropriate NMSS Division Director. The Regions should follow the guidance contained in Section 4.16 for technical assistance requests and submission of exemption requests for consideration of approval. All exemption requests should be entered into the LTS upon receipt. Examples of exemptions that require coordination with NMSS before processing by the Region, which also should be recorded in the LTS, are provided below. In addition, when an exemption is being considered, the Region should submit its evaluation of the merits of the exemption from a technical standpoint as well as any generic implications, such as a need for rulemaking.

Examples of Exemptions Requiring Coordination with NMSS

- Relief from any of the provisions of 10 CFR Part 20.
- Requests for relaxation of, or exemptions from, the training and experience requirements of 10 CFR Part 35 for physicians, teletherapy physicists, nuclear pharmacists, and RSOs. These requests are coordinated with the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI).
- Request for relief from 35.400(d) and (g) for authorization of gold-198 and iodine-125 seeds for intracavitary and topical applications.

Administrative Procedures for Issuing Exemptions

When granting exemptions to a licensee, the reviewer should describe the specific exemption in the cover letter accompanying the amendment authorizing the exemption. This discussion should include any special provisions or conditions associated with this exemption. In addition, the reviewer should record the exemption on the LTS worksheet and identify the section of the regulation to which the exemption was granted. Refer to Appendix F for specific guidance about the LTS.

4.14 TECHNICAL ASSISTANCE REQUEST – MATERIAL LICENSEES

Purpose

To provide procedures for the preparation and processing of TARs related to material, including sealed source and device evaluations; and issues involving the storage and disposal of radioactive material.

Scope

This directive pertains to all TARs submitted by the Regions to the NMSS, including those for sealed source and device design evaluations.

Regional Preparation of TARs

The Regional Division Director will submit all assistance requests, except those for sealed source and device design evaluations, to IMNS using the TAR form provided in Appendix B. The request should be submitted electronically with any needed attachments. TARs should be considered non-public, but placed in ADAMS. Electronically submitted versions of the TAR should be sent to the Director, IMNS with a copy to the IMNS secretary. For information that may not be electronically available (e.g. medical consultant's report), indicate in the electronically submitted version those attachments to the TAR that could not be sent electronically and that they will be sent with the hard copy of the TAR. Information should be placed in ADAMS whenever practicable. The TAR will:

- Concisely state the problem or major issue requiring technical assistance from Headquarters;
- Specifically state the action that is requested from Headquarters;
- Identify any alternative actions for the problem/major issue and recommend one of these alternatives, if appropriate;
- Provide the appropriate background information for the request (e.g., copy of application, current license, inspection report);

- Identify a date when a response to the TAR is required by the Region; and
- Identify TARs that have addressed similar issues, by subject and date created.

When submitting a TAR as part of the licensing process, the Region shall change the milestone in the LTS to 19 and change the reviewer code to A2 for IMNS. When the Region receives a final response to the TAR from Headquarters, the Region shall change the milestone in LTS to 20 and the reviewer code to the Regional reviewer code.

Sealed source and device design evaluation TARs should be submitted on NRC Form 567 (see Appendix B). This form is available in the InForms application on the NRC computer system. The instruction block located at the top of the form should be followed for the specific details on how and what to submit.

Headquarters Processing of TARs

When the hard copy is received, the Director, IMNS will assign the TAR to an IMNS branch or will transfer the TAR to the appropriate NMSS division for resolution. The TAR will be entered into the IMNS Division Ticket Tracking Program (DRAT) as having been received and will be assigned a DRAT number with a due date of ten working days. The responding branch will perform a completeness review of the TAR with a goal of within five working days, but not to exceed ten working days from its assignment to a Headquarters reviewer. The purpose of the review is to ensure that all the information is included that will be needed by the Headquarters reviewer to prepare a response. TARs that were deemed complete through the completeness review will be assigned a completion due date in DRAT by the appropriate IMNS Section Leader. For those TARs transferred to another division, that division will provide a due date to the IMNS secretary to be entered into DRAT after the completeness review. If the TAR package is incomplete, the Region will be notified that additional information is needed to respond to the TAR. If Headquarters does not receive the remaining information within ten working days (goal of within five working days, not to exceed ten working days), the TAR package will be returned to the Region for completion of the package, and the action will be closed in DRAT.

Typically, the goal to complete TAR responses is within 60 working days from the time all necessary information is received in Headquarters. The lead branch will coordinate the TAR response with other NMSS divisions and other offices (OGC, OE, etc.) as appropriate. For TARs that involve enforcement-related issues, the Director, OE should be on concurrence. Responses may be issued by the Headquarters Branch Chief if they do not involve exemptions or generic issues; otherwise, responses will be issued by the appropriate NMSS Division Director. A sample TAR response is provided in Appendix B. The appropriate regional identifying numbers, including the license number, docket number, and control number, will be indicated on the response. In addition, those TAR responses that are directly related to an event or incident will include the Nuclear Materials Events Database (NMED) number. A list reflecting the status of open TARs in DRAT will be transmitted to the Regions and the other NMSS Divisions each

week from IMNS, including the title of the TAR, the Control Number, the due date, and the current Headquarters contact.

Before management signature, the Headquarters reviewer will e-mail the draft response to the Regional reviewer and management (Regional Branch Chief at a minimum) identified on the TAR to confirm that additional clarification is not needed and the Region has no specific concerns on the response. This e-mailing will occur after all technical concurrences have been obtained but before OGC's legal review. If OGC fundamentally alters the TAR response, the revised draft response will be e-mailed to the Region before IMNS management signature. The concurrence page of the TAR response will reflect the date of Regional coordination. This effort is for informal coordination only and not for obtaining formal Regional concurrence. The Region should respond to the cognizant Headquarters staff with comments, including no comment, within two working days from the Headquarters e-mail date. If the Region has not responded within two working days, the response will be finalized and issued. The purpose of this policy is to avoid unnecessary delays. In cases where the Regional reviewer is away from the Regional office, it is the responsibility of Regional management to either review the draft response and provide comments or to contact the Headquarters reviewer (or the reviewer's management) to negotiate an appropriate response date.

Sealed source and device evaluation TARs will be handled by the sealed source safety staff (SSSS) in IMNS. SSSS will deal directly with the device or sealed source applicant to resolve any deficiencies in the application. Upon completion of the review, SSSS will send a letter, with a copy of the registration certificate, to the license reviewer and the applicant. The Regions will receive a monthly report on the status of all sealed source and device pending cases, independent of the weekly DRAT report on open TARs.

Distribution of TAR Responses

The TAR response with all incoming documents normally will be distributed electronically to a single point of contact in RI, RII, RIII, RIV, STP, TTC, and the Regulatory Product Development Center (RPDC). The point of contact for the Regions shall be the Director, DNMS, unless otherwise indicated. Further distribution will be made by the receiving offices.

If a division other than IMNS issues the response, the IMNS division secretary should be copied to close the action in DRAT. The DRAT ticket number should be identified on the distribution page to ensure accurate tracking and closure. If the response grants an exemption or establishes a new policy for generic use, the chair of the IMNS Generic Assessment Panel (GAP) will be placed on hard copy distribution. The chair of GAP is the IMNS Deputy Director.

TAR Responses for Generic Use

If the TAR response establishes a new policy that other reviewers are authorized to implement without further Headquarters review, the memo transmitting the response is signed by the Director, IMNS, and the term "GENERIC USE" will be inserted as a header on each page of the memo. Responses for generic use will typically include a statement that Regional staff may implement the policy without further coordination with Headquarters. These responses will be reviewed by GAP to determine the need for additional action (e.g., rulemaking, generic communication, etc.).

4.15 PROCESSING PROPRIETARY INFORMATION

Final NRC records and documents, including correspondence to and from NRC regarding licensing actions, are available to the general public, except under certain circumstances, as specified in 10 CFR 2.790. A reviewer may receive information from an applicant or licensee that is marked as "proprietary," "confidential," "restricted," or "is the express property of Company X." The reviewer will need to determine whether the information is necessary to the licensing action. If the information is not necessary, it should be returned to the applicant.

If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request, in accordance with §2.790, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements in §2.790 (Appendix C includes a checklist for requests for withholding information from public disclosure). If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information. Sample letters are provided in Appendix D.

Any part of the application that the reviewer has determined should be withheld form public disclosure should be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the applicant should be notified in writing that the NRC plans to honor the request. However, the notification needs to inform the applicant that the NRC may have cause to review the determination in the future, for example, if the scope of a Freedom of Information Act request includes the information.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned, to inspect the documents. If the need arises, the NRC may send copies of this information to NRC consultants working in that area. The NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information. In all review situations, if the NRC needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

4.16 LICENSE TERMINATION

NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," contains a listing of the regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance.[1] NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," provides an acceptable method for conducting a final radiation status survey for buildings and soil before terminating a license. The reviewer should refer to the appropriate guidance when reviewing requests for termination of a license. After verifying the disposition of licensed material and ensuring that a satisfactory closeout inspection and confirmatory survey were performed, if required, the reviewer should prepare a letter informing the licensee that the license has been terminated. NUREG/BR-0241 contains a sample letter that may be used by the staff to inform the licensee that their license has been terminated. In addition, the reviewer should prepare a termination license to be enclosed with the letter. As a final step in terminating the license, the reviewer should complete the "Materials License Termination/Retirement Form" contained in NUREG/BR-0241. Copies of the letter, terminated license, and retirement form should be maintained as official Agency records.

[1] Staff should note that the Handbook was issued in late 1996. In mid-1997, NRC promulgated the License Termination Rule (LTR) which established a dose-based criteria for terminating licenses, as well as criteria for terminating licenses with restrictions on future land use. In addition, in mid-1998, the Commission instructed the staff to develop a Standard Review Plan (SRP) to assist the staff in reviewing information developed by licensees to support decommissioning. NRC staff are currently developing this SRP and will be updating the Handbook in the near future to incorporate the requirements of the LTR and the guidance in the SRP. Staff is scheduled to complete the SRP by mid-2000 and expects to issue the revised Handbook in early 2001. Until these efforts are completed, staff should contact the Decommissioning Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, with questions concerning the termination of licenses.

5 FEES

5.1 INTRODUCTION

Effective August 9, 1991, significant changes occurred to the regulations (10 CFR Parts 170 and 171) governing the licensing, inspection, and annual fees charged to applicants, licensees, and holders of certificates of compliance, registrations of sealed sources and devices, approvals of quality assurance programs, and other approvals. The revised regulations implemented the requirements of the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, which mandated that NRC recover approximately 100 percent of its budget.

NRC's current fee schedule is found in 10 CFR 170 ("Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended") and Part 171 ("Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses. . .")

For the majority of small materials license applications, there are flat application fees. These fees must accompany the application. The NRC no longer charges fees for amendments, renewals, or inspections for materials licenses except for the "full cost" categories specified in the 10 CFR 170. Fees for "full cost" categories will be calculated using the applicable professional staff-hour rates identified in Section 170.20 for licensing and inspection and will be billed on a quarterly basis for accumulated costs.

The majority of small materials licensees pay an annual fee. The basis for these charges are discussed in Section 171.16(b). Annual fees will be pro-rated for new licenses, terminations, or requests for possession-only licenses on the basis of when NRC issues the license, as specified in Section 171.17. Further, annual fees for materials licenses that are downgraded will be prorated. The appropriate annual fee will be based on when the application for downgrade was received.

The annual fees for most materials licenses are billed on the anniversary date of the license (licensees whose annual fees are $100,000 or more are assessed quarterly). The annual fee assessed will be the fee in effect on the license anniversary date. The anniversary date of the materials license is considered to be the first day of the month in which the original materials license was issued. For example, if the original materials license was issued on June 17, then for annual fee purposes, the anniversary date of the material license is June 1 and the licensee will continue to be billed in June of each year for the annual fee in effect on June 1.

Procedures for processing fees have been developed in order to make the appropriate decisions regarding the licensees' liabilities for the fees and to assure that licensees receive the invoices for annual fees before the due date.

5.1.1 PROCEDURES FOR PROCESSING FEES

General Guidelines

1. In the interest of providing accurate, uniform and legally correct information relating to fee policy, procedures and requirements, and in order to minimize confusion, requests for specific annual or license fee information should be directed to OCFO.
2. When you receive applications with checks, you should enter the action into the LTS. You should make a copy of the check and application to be retained in the Region. Endorse the original check and send it with a copy of the incoming correspondence and the postmark dated envelope (the postmark date will be used to determine if requests are timely filed) to the Mercantile Bank of St. Louis, Government Lockbox - NRC Lockbox #4514, P.O. Box 954514, St. Louis, MO 63195. The Bank will deposit the check and forward the correspondence to OCFO.
3. Applications received directly by OCFO will be promptly forwarded to the appropriate licensing staff by transmittal memorandum.
4. In order to have the most up-to-date data on which to base the annual fee billings, you should take necessary steps to complete termination, possession only, and downgrade requests as soon as possible.

Undeliverable Mail

1. The OCFO staff will make every effort to obtain valid addresses for invoices returned as undeliverable. In those instances where the file searches and telephone directory assistance are unsuccessful, OCFO will forward a copy of the invoices to the appropriate licensing staff for follow-up. The Licensing staff should promptly advise OCFO of the correct address or other pertinent information (e.g., licensee out of business, license to be terminated, etc.).
2. OCFO will notify the licensing staff of any requests for address changes submitted as a result of the annual fee invoices, and addresses obtained through other means for undelivered invoices. It is hoped that, through these measures, documents returned as undeliverable mail will be minimized in future NMSS and OCFO mailings.

"Misclassification" of Licenses

Assertions that licenses are misclassified in fee category will be handled by OCFO to the extent possible. However, there will be instances where verification or clarification from the licensing staff is required. In such cases, OCFO will send a copy of the correspondence to the appropriate licensing staff with a transmittal memorandum requesting assistance. Since the clarification or verification will be essential in determining the appropriate annual fee, the licensing staff should

make every effort to respond by the due date given in the memorandum. OCFO will prepare the responses to the licensees and will assure that appropriate concurrences are obtained.

Processing Licensing Actions Prior to Fees Approval

It is current Agency policy not to delay the initial technical review process of materials license application, up to the point of issuance, pending the receipt of a fee; therefore, an application will be processed up to the point of issuance pending notification that the fee is paid.

Processing Reciprocity Applications (NRC Form 241)

See Section 3.2.10 for information regarding fees for Agreement State licensees requesting authorization to work in NRC jurisdiction.

5.1.2 OCFO CONTACTS

For Questions Relating to Fees For:	OCFO Contact:
Power reactors and non-power reactors	Ellen Poteat (301) 415-6392
Facility Inspection Fees	Ellen Potent (301) 415-6392
Facility amendments, Topical Reports, Standard Plants, reactor operating licenses under review, reactor operator licensing exams	Ellen Poteat (301) 415-6392
Fuel Cycle, Low Level Waste, Transportation, Uranium Recovery, Topical Reports, Export/Import, Reciprocity licenses and applications, and all materials and fuel cycle inspections	Maurice Messier (301) 415-6087
Region I (CT, DC, DE, MA, MD, ME, NH, NJ, PA, RI, VT, Canada, Export, Inport, Small Entity Certifications)	Brenda Brown (301) 415-6055

Region II (AL, FL, GA, KY, MS, NC, PR, SC, TN, TN, VA, VI, WV, Reciprocity, Small Entity Certifications)	Shirley Crutchfield (301) 415-6097
Region III (IA, IL, IN, MI, MO, MN, OH, WI, Reciprocity, Small Entity Certifications)	Shirley Crutchfield (301) 415-6097
Region IV (AK, AR, AZ, CA, CO, HI, ID, KS, LA, MT, NE, ND, NM, NV, OK, OR, SD, TX, UT, WA, WY, Reciprocity, Small Entity Certifications)	Shirley Crutchfield (301) 415-6097
Fee Policy and Development	Glenda Jackson (301) 415-6057

All other inquiries relating to fees should be referred to Doug Weiss, (301) 415-7348. In addition, please add Ms. Jackson for concurrence on all correspondence containing references to the fee requirements or providing fee information.

5.2 FOLLOW-UP ACTIONS FOR ORDERS SUSPENDING AND REVOKING LICENSES FOR NONPAYMENT

The purpose of this section is to provide guidance concerning procedures for coordinating with the Office of the Chief Financial Officer (OCFO) on orders suspending and revoking licenses for nonpayment of fees and subsequent actions when licenses are suspended for nonpayment of fees. An example of the Order, now entitled "ORDER REVOKING LICENSE FOLLOWING IMMEDIATELY EFFECTIVE 30-DAY SUSPENSION" is provided in Appendix D. The precise wording may vary depending on the circumstances of individual cases. These procedures apply to quality assurance approvals, and sealed source and device registrations, but actions for these authorizations may deviate from these procedures. Separate orders are available for quality assurance approvals, sealed source and device registrations, and exempt distribution licenses.

Guidance

1. Once a licensee has failed to respond to notices of payment due, the OCFO will prepare the Order and send it electronically to the Office of General Counsel (OGC) and to the responsible Division Director for concurrence. The Region will attempt to locate the licensee by telephone or other means to determine if it has received the notices of payment. For licenses issued by Headquarters (HQ), these and other communications will go to the Director of IMNS, DWM, the Spent Fuel Project Office (SFPO), or the Division of Fuel

Cycle Safety and Safeguards (FCSS), as appropriate. The Division Director for HQ or the Region will respond within two weeks with any comments and/or concurrence. OCFO will issue the Order, sending it to the licensee by certified mail, and signed copies of the Order will be sent to the Director of the Division of Nuclear Materials Safety (for the Region) or the Chief of either the Materials Safety and Inspection Branch (MSIB/IMNS), the Decommissioning Projects Branch (DCB/DWM), the Licensing and International Safeguards Branch (FLIB/FCSS), or the Licensing and Inspection Directorate (SLID/SFPO). Copies of draft and final orders will be sent by OCFO to the responsible Branch Chief and Licensing Assistant in the Region or HQ by electronic mail. OCFO will provide copies of any additional material upon request.

2. Upon issuance of the Order, the OCFO will enter the "refusal to pay" flag in the License Tracking System (LTS) for materials licensees to preclude any licensing actions being taken without consultation with the OCFO, and enter a "Status 6" indicating that the license is suspended.

   Under the terms of the Order,

   a) Licensees must immediately:

      i) Restrict activity involving licensed material to decommissioning and safe, secure storage or transfer of material;

      ii) Continue to control entry into restricted areas until the licensee has determined and NRC has confirmed that such areas are suitable for release in accordance with NRC requirements.

   b) If the licensee does not pay the debts due NRC within 30 days of the date of the Order, the license is revoked and the licensee must, within 30 days of the date of the Order:

      i) Arrange for disposal of any licensed material, either by return to the manufacturer or transfer to an authorized recipient. Such disposal must take place within 60 days of the date of this Order. The licensee must notify the Regional Division Director or affected Headquarters Division Director, in writing, within five days of such disposal;

      ii) Any licensee who is a manufacturer, distributor, or provider of services to other licensees must notify each customer or client in writing that authorization to provide any support has been revoked and that customers and clients may need to amend their licenses to be in compliance with NRC requirements;

      iii) Conduct an adequate termination survey of the premises, as described in 10 CFR 30.36(j), 40.42(j), or 70.38(j), and report results of the survey in writing to the Regional Division Director or affected Headquarters Division Director;

      iv) Submit a written report to the Regional Division Director or affected Headquarters Division Director on the status of materials.

Upon the Regional Administrator's determination that the steps above have been satisfactorily completed, as necessary, the license will be terminated at a date specified by the Regional Administrator. If the licensee still owes fees, OCFO will continue to take action.

Under the terms of the Order, any request for relaxation will be directed to the Chief Financial Officer (CFO). The CFO will coordinate action on the requests with the Regional Administrator or Headquarters Division Director and make a determination on any such request with the concurrence of the Regional Administrator or Headquarters Division Director.

3. Thirty days after issuance of the Order, the OCFO will send a "Final Action" memorandum stating whether the license was revoked for nonpayment of fees or whether the licensee paid the invoice in full within the 30-day period, and therefore the Order is rescinded; the licensee submitted "good cause" for an extension of time or for relaxation or rescission; the licensee requested a hearing; or other basis that would stay the effectiveness of the Order, such as the Order was not delivered.

4. If the Final Action is the revocation of the license, the OCFO will update the LTS by entering a "Status 5" indicating that the license is revoked. OCFO is working on a tracking system to identify delinquent debtors that have been previously written off as bad debt so that incoming applications can be matched to these debtors.

5. The Region or Headquarters should contact the licensee 6-10 days after issuance of the Order to determine the status of the licensee's program, receipt of the Order, and its intentions relative to the Order. Depending on the licensee's response, the Region or Headquarters may need to schedule inspections and confirmatory surveys, as appropriate.

6. Upon receipt of the Final Action memorandum from the OCFO indicating the debt has not been paid and the license is revoked for nonpayment of the fee, the Region should contact the licensee by phone promptly to determine the licensee's status and intentions with respect to compliance. If the licensee does not respond in writing within seven days of the phone call, the Region should arrange to conduct an inspection of the facility within 30 days.

7. Licensees whose licenses have been revoked, and who subsequently pay the debt owed after the 30-day period provided in the Order, and who want to resume operation, should be advised that they must apply for a new license and pay the appropriate application fee. Unless these licensees apply for and are granted relaxation or rescission of the Order for good cause, such as evidence that there is some error of fact or law in the Order, the licensee must apply for a new license and pay any other outstanding debts to NRC. Licensees that choose not to decommission must pay delinquent debt and apply for a new license promptly to avoid enforcement action. The revoked license will be terminated simultaneously with the issuance of the new license.

Appendix A

List of Documents Considered in Development of this Draft NUREG

This draft report incorporates and updates the guidance previously found in the Policy and Guidance Directives (PG) listed in Table A.1. When this draft report is issued in final form, the documents in Table A.1 will be considered superseded and should not be used. These directives are superceded for the IMNS program area only. Other references were also used in this draft report and are listed below.

Table A.1 Policy and Guidance Directives

Document Identification	Title	Date
PG 0-02 (formerly FC 83-25)	Standardization of License Information in the Material Licensing Master File	8/1984
PG 0-03 (formerly FC 84-02)	Follow-up on Mail Returned from Licensees	6/1984
PG 0-04 (formerly FC 84-10)	Processing of Misdirected Materials Licensing Applications	4/1986
PG 0-05 (formerly FC 84-13)	Certification of Application Review for Materials Licenses	8/1984
PG 0-06 (formerly FC 84-19)	Preparation and Distribution of Material Licensing Documents	12/1984
PG 0-07 (formerly FC 85-15)	Availability, Security, and Integrity of Material License Files	9/1985
PG 0-09 (formerly FC 86-08)	LMS Possession Limit Database User's Guide	5/1986
PG 0-11 (formerly FC 95-05)	Updated Program Code Descriptions	10/1992
PG 0-12 (formerly FC 93-01)	Follow-up Actions for Orders Suspending Licenses for Nonpayment of Fees	11/1997
PG 0-13 (formerly FC 94-03)	Guidance to the Technical Staff on Responding to Inquiries from the Licensee Fee and Debt Collection Branch	4/1994
PG 0-14 (formerly FC 94-06)	Procedures for the Technical Review Process of Materials License Applications Prior to Fee Verification	11/1994
PG 1-01 (formerly FC 83-02)	Renewal of Materials Licenses	12/1999
PG 1-02 (formerly FC 83-10)	Follow-up on Expired Material Licenses	12/1983

Document Identification	Title	Date
PG 1-03 (formerly FC 83-11)	Deficiency Letters and Telephone Calls to Material License Applicants	8/1985
PG 1-04 (formerly FC 83-12)	Consideration of Allegations and Other Pending Matters in Licensing Actions	5/1983
PG 1-05 (formerly FC 83-15)	Responsibility for Review of License Applications	9/1983
PG 1-07 (formerly FC 83-20)	Standard License Conditions	3/1994
PG 1-08 (formerly FC 84-06)	Cover Letters for Material Licensing Actions	11/1992
PG 1-09 (formerly FC 84-09)	Licensing Visits for Byproduct Material Licensees	2/1989
PG 1-12 (formerly FC 84-20)	Impact of Revision of 10 CFR Part 51 on Material Licensing Actions (including supplement)	3/1994
PG 1-14 (formerly FC 89-03)	Criteria for Denying Applications for Material Licenses	6/1989
PG 1-15 (formerly FC 89-04)	Opportunity for an Informal Hearing on Any Materials Licensing Decision	7/1989
PG 1-16 (formerly FC 90-05)	Specific License Conditions for Reporting Requirements	9/1990
PG 1-17 (formerly FC 91-03)	Implementation of Final Revisions to 10 CFR Parts 170 and 171 on License, Inspection and Annual Fees	8/1991
PG 1-19 (formerly FC 94-01)	Issuance of "Deemed Timely" Letters for Materials Licensees	1/1994
PG 1-20 (formerly FC 94-04)	Identification of Licenses Where Significant Licensing Action Warrants an Onsite Inspection	6/1994
PG 1-22	Policy and Criteria for Initial Processing of Incoming Licensing Actions	4/1997
PG 1-23	Guidance for Multi-Site Licenses	4/1996
PG 1-24	Guidance for Oversight of Consolidated License for Syncor International Corporation	7/1996

Document Identification	Title	Date
PG 1-26 (formerly FC 84-12)	Processing of Exemptions for Material Licensees	7/1997
PG 9-01 (formerly FC 83-05)	Listing of State Health Official Contacts	4/1991
PG 9-02 (formerly FC 83-06)	Materials Safety Conference Calls	12/1985
PG 9-03 (formerly FC 83-07)	Material Licensing Workshops	6/1985
PG 9-07 (formerly FC 85-13)	Use of Coordinators for Certain Federal Organizations	8/1999
PG 9-11 (formerly FC 93-02)	Technical Assistance Requests Related to Material Licensees	7/1997

Additionally, the following documents were considered during the preparation of this guidance:

1. Memorandum from Donald A. Cool to A. Randolph Blough, et.al., dated July 10, 1997, withdrawing PG 1-18 (formerly FC 92-04), "Issuance of New Licenses for Material Use Programs."
2. Memorandum from Donald A. Cool to A. Randolph Blough, et.al., dated November 24, 1997, regarding the addition of exemption request data fields to the Licensing Tracking System (transmittal memo for PG 1-22).
3. Information Notice 94-47, "Accuracy of Information Provided to NRC During the Licensing Process," issued June 21, 1994.
4. Memorandum from Donald A. Cool to Charles W. Hehl, et. al., dated May 26, 1995, regarding the distribution of NRC licenses to Agreement States.
5. NMSS Policy and Procedures Letter 1-30, "Availability, Security, and Integrity of Material License Files," September 1999.
6. NMSS Policy and Procedures Letter 1-48, "Procedures for Preparing Environmental Assessments," May 1995
7. NMSS Policy and Procedures Letter 1-50, Rev. 2, "Environmental Justice in NEPA Documents," September 1999.
8. NMSS Policy and Procedures Letter 1-55, Rev. 1, "Policy and Criteria for Initial Processing of Incoming Licensing Actions," April 1997.

9. NMSS Policy and Procedures Letter 1-58, "Processing of Exemptions for Material Licensees and Certificate Holders," August 1997.

10. Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," issued September 8, 1997.

Appendix B

Forms

B.1 Materials License Form

NRC FORM 374 (1-1998) U.S. NUCLEAR REGULATORY COMMISSION PAGE _____ OF _____ PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1.	3. License Number
2.	4. Expiration Date
	5. Docket or Reference No.

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License

NRC FORM 374 (1-1998) PRINTED ON RECYCLED PAPER This form was designed using InForms

APPENDIX B

NRC FORM 374A (1-1998) U.S. NUCLEAR REGULATORY COMMISSION

PAGE OF PAGES

License Number

Docket or Reference Number

MATERIALS LICENSE
SUPPLEMENTARY SHEET

NRC FORM 374A (1-1998) PRINTED ON RECYCLED PAPER This form was designed using InForms

B.2 Registration Certificate for In Vitro Testing

NRC FORM 483 (7-1999) — U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0038 EXPIRES: 07/31/2002

Estimated burden per response to comply with this mandatory collection request: 7 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. Send comments regarding burden estimate to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

REGISTRATION CERTIFICATE -- *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.

1. NAME AND ADDRESS OF APPLICANT *(See Instruction 3.B. below)*

TELEPHONE NUMBER (Include Area Code):

2. APPLICATION *(Check one box only)*

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☐ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine.

INSRUCTIONS

A. Submit this form in duplicate to:

Materials Safety Branch (T-8 F5)
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.

4. REGISTRATION

REGISTRATION NUMBER:

(If this an initial registration, leave this space blank -- number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)

If place of use is different from address listed above, give complete address.

6. CERTIFICATION

I hereby certify that:

A. All information in this registration certificate is true and complete.

B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change.

D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.

PRINTED OR TYPED NAME AND TITLE OF APPLICANT	SIGNATURE	DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

NRC FORM 483 (7-1999) PRINTED ON RECYCLED PAPER

B.3 Regional Technical Assistance Request Form

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: _____

Mail and E-Mail to: _____, Director
Division of Industrial and Medical Nuclear Safety, NMSS

For E-mail, cc:
IMNS Secretary

From: _____, Director
Division of Nuclear Materials Safety, R_

Licensee: _____

License Number: _____ Docket Number: _____

Control Number: _____ (if applicable)

Letter dated: _____ (if applicable)

Enforcement Action being held in abeyance: ( ) Yes ( ) No

Suggested change in licensing procedure (enclosed):

Problem/Issue:

Action Requested:

Recommended Action and Alternatives: ( ) Approve or ( ) Reject

TARs addressing similar issues (subject and date):

Background documents (identify those not sent electronically):

Remarks:

Headquarters Reviewer: _____
Regional Reviewer: _____
Reviewer Code: _____
Reviewer Phone Number: _____ Fax Number: _____
Request Needed by: _____

B.4 Technical Assistance Request Transfer Form

TECHNICAL ASSISTANCE REQUEST TRANSFER FORM

Date of Transfer _____ DRAT Number _____

Receiving Division Director* _____

Date of TAR _____

Subject of TAR:

IMNS Division Secretary: _____
Mail Stop: T-8F5
Phone Number: _____
E-mail: _____

* Provide the IMNS division secretary with the targeted response completion date. Include the IMNS division secretary on the distribution list of the TAR response.

B.5 Sample Technical Assistance Request Response

GENERIC USE (if applicable)

(date)

MEMORANDUM TO: _____, Director
Division of Nuclear Materials Safety, R__

FROM: _____, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

(IMNS Director signs if response is for generic use.)

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST
DATED _____, XYZ LICENSEE, ANYTOWN, ANYSTATE

I am responding to your technical assistance request (TAR) dated _____ (attached).

Issue:

Action Approved:

Background:

Discussion:

Attachment: TAR dtd _____

License No. 12-34567-89
Docket No. 030-00000
Control No. _____
NMED No. _____ (if TAR is event-related)

Contact: _____, IMNS/NMSS
301-415-____

B.6 Request for a Sealed Source or Device Evaluation

NRC FORM 567
(1-1999)

U.S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER		REGION/LOCATION: ☐ I ☐ II ☐ III ☐ IV ☐ HQ ☐ LFARB
TELEPHONE NUMBER	DATE	
NAME OF APPLICANT		TYPE OF ACTION REQUESTED *(Check as appropriate)*
MAIL CONTROL NUMBER(S)		☐ SOURCE REVIEW ☐ AMENDMENT OF REGISTRATION SHEET NUMBER(S)
LETTER/APPLICATION DATE	LICENSE NUMBER(S)	☐ DEVICE REVIEW ☐ CUSTOM REVIEW

COMMENTS:

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS	NUMBER ASSIGNED
DATE RECEIVED	DATE ASSIGNED	DATE TO FEES

TYPE OF ACTION *(Indicate the number of each type)*

☐ COMMERCIAL DISTRIBUTION (FORMAL)

SOURCE (9C)	DEVICE (9A)
☐ NEW	☐ NEW
☐ AMENDMENT	☐ AMENDMENT

☐ USE BY A SINGLE APPLICANT (CUSTOM)

SOURCE (9D)	DEVICE (9B)
☐ NEW	☐ NEW
☐ AMENDMENT	☐ AMENDMENT

☐ NO SAFETY EVALUATION REQUIRED
NO FEES REQUIRED

☐ LICENSING ACTION REQUIRED (IF KNOWN) ☐ YES ☐ NO

☐ OTHER *(Specify)*

		NOTES
	TOTAL NUMBER OF REVIEW HOURS	
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR FEE USE ONLY

TYPE OF FEE		FEE CATEGORY ☐ 9A ☐ 9B ☐ 9C ☐ 9D	
AMOUNT RECEIVED	CHECK NUMBER	DATE OF CHECK	LOG
APPROVED BY			DATE OF RETURN

COMMENTS

NRC FORM 567 (1-1999) PRINTED ON RECYCLED PAPER This form was designed using InForms

Appendix C

Checklists

C.1 Renewal – Documentation of Performance Evaluation

PERFORMANCE EVALUATION OF RENEWAL APPLICATIONS
Official Agency Record

Licensee: _____

License or Docket No: _____

Control No: _____

The following performance indicators were reviewed:

Performance Indicator	Conclusion	If YES, explain:
Enforcement History	Yes__ No__	
Loss of Material	Yes__ No__	
Unauthorized Disposal or Release of Material	Yes__ No__	
Overexposure	Yes__ No__	

If any of the above items are checked "YES", perform a Comprehensive Review using the applicable guidance contained in NUREG-1556. If all boxes are checked "NO," perform a Limited Review. An exception must be approved by a supervisor, documented on this form, or a copy of the documentation must be attached to this document for placement in the docket file.

Additional Information or Explanation of Exception

_____

_____

_____

_____

Comprehensive Review _____
Limited Review _____

_____ _____
Reviewer / Date Supervisor / Date

C.2 Renewal – Limited Review Checklist

RENEWAL - LIMITED REVIEW CHECKLIST

Use either a check mark to designate a satisfactory response, "NA" to designate not applicable or "D" to designate deficiency as appropriate.

Licensee:	License No._____ Docket No_____ Control No_____

_____ NRC-313 or appropriate equivalent signed and dated by senior licensee representative.

_____ Check the possession limits and confirm that decommissioning financial assurance requirements have not changed.

_____ Place of use is a physical location (i.e., not P.O. Box, etc.)

_____ RSO and key personnel are appropriately qualified.

_____ Facilities and equipment are adequate.

_____ All uses qualify for a categorical exclusion in 10 CFR Part 51.

_____ Organizational structure conforms with applicable regulations and NUREG-1556 guidance. Reviewers are reminded licensees have the flexibility to provide information equivalent to that requested in NUREG-1556. (Appropriate individuals are present and are assigned necessary authority & responsibility.)

_____ The audit program structure conforms with applicable regulations and NUREG-1556 guidance.

_____ New authorizations requested by the licensee and any major program elements that require change as a result of the new authorization structure conform with applicable regulations and NUREG-1556 guidance.

CONTINUED NEXT PAGE

RENEWAL - LIMITED REVIEW CHECKLIST
(continued)

Major program changes, new high risk technology programs, and changes in control (ownership) normally require only a focused review of the specific changes. If these changes are so extensive that a Comprehensive Review of the entire application is needed, obtain Branch Chief approval before proceeding. Each of the following three items must be marked with NA or a check and the change briefly identified.

_____ *Major program change conforms with applicable regulations and NUREG-1556 guidance.*

_____ *New high risk technology program conforms with regulations for similar technologies, guidance provided for similar technologies in NUREG-1556 guidance, and specific licensing conditions for the new technology.*

_____ *Change in Control (Ownership) conforms with applicable regulations and NUREG-1556 guidance. NOTE: Financial assurance documents can be affected by change of ownership.*

_____ A brief overview of the remainder of the application found that the major areas discussed in the guidance on the contents of the application from the appropriate NUREG-1556 series are present.

_____ An obvious failure or a deficiency in a significant area resulted in a thorough review of that area.

_____ A Comprehensive Review was conducted and the reason for changing from a Limited Review to a Comprehensive Review is documented on the "Performance and Limited Review Check List."

_____ Appropriate additional information was requested
(circle as appropriate: phone log / e-mail / fax / letter/ _____)

C.3 New and Renewal – License Terms of Less Than 10 Years

LICENSE TERMS OF LESS THAN 10 YEARS
Official Agency Record

Licensee:	License:_____ Docket No:_____ Control No:_____

The following conditions were reviewed:

Criteria	YES	NO	Basis for YES
New high risk technology without extensive use or regulation experience by industry, or licensee, or NRC;			
Enforcement History - Severity Level I, II, or III violation due to serious programmatic deficiencies and not singular events, in preceding 3-years;			
Possession-Only - License authorizes no activities other than possession and storage of licensed material (2-year term);			
Renewal received a Comprehensive Review;			
Other, specify:			

If any of the above items are checked "YES", describe the basis above, determine the license term (usually 5 years) and document the determination below. All exceptions must be approved by a supervisor and documented with a copy of that documentation attached to this document for placement in the docket.

Assigned License Term: _____ years

Additional Information or Explanation of Exception

_____

_____

_____

_____

_____ _____

Reviewer / Date Supervisor / Date

C.4 Requests to Withhold Information from Public Disclosure

CHECKLIST FOR REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC DISCLOSURE	
In order to request that the NRC withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 10 CFR 2.790. The applicant should submit all of the following:	
[ ]	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
[ ]	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary
[ ]	An affidavit that:
[ ]	Is notarized.
[ ]	Clearly identifies (such as by name or title and date) the document to be withheld.
[ ]	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.
[ ]	States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
[ ]	Provides a rational basis for holding the information in confidence.
[ ]	Fully addresses the following issues:
[ ]	Is the information submitted to, and received by, the NRC in confidence? Provide details.
[ ]	To the best of applicant's knowledge, is the information currently available in public sources?
[ ]	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
[ ]	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

C.5 Identifying Significant Licensing Actions that Require an Onsite Inspection

CHECKLIST FOR DETERMINING WHEN SIGNIFICANT LICENSING ACTION HAS TAKEN PLACE THAT MAY REQUIRE AN ADDITIONAL ONSITE INSPECTION

If recent licensing actions have resulted in one of the following, regional management should determine the need for performing an onsite inspection prior to the next routine inspection:

1. Does the licensing action result in increased authorization for types and quantities of radioactive material that could result in a significant potential for increased radiation exposure to the public and occupational workers?

   ( ) No
   ( ) Yes *(Describe)*

   Note: This can be identified by a change to a higher priority, i.e, from a Priority 2 to a Priority 1 license. Another "rule-of-thumb" for identifying a significant change in this area would be an increase in the authorized quantity from a millicurie amount to a curie amount.

2. Does the licensing action authorize a physical move of a facility or authorize use at a temporary job site(s)?

   ( ) No
   ( ) Yes

3. Does the licensing action authorize satellite facilities where material will be used or stored?

   ( ) No
   ( ) Yes

4. Does the licensing action increase the types of uses or disposal (incineration) of radioactive materials?

   ( ) No
   ( ) Yes

5. Does the licensing action significantly increase the number of authorized users?

   ( ) No
   ( ) Yes

SAMPLE MEMO TO INSPECTION STAFF
IDENTIFICATION OF SIGNIFICANT LICENSING ACTION

License No:

Licensee:

Note to: *(Regional Inspection Supervisor)*

From: (Regional Licensing Reviewer or management)

Re: POSSIBLE NEED FOR ONSITE INSPECTION PRIOR TO ROUTINE INSPECTION

An onsite inspection of the licensee identified above should be considered due to a recent significant licensing action involving one or more of the criteria described below. Additional information is attached.

Circle all that apply:

1 - Increased types and uses

2 - Physical move or temporary job site

3 - Authorization of satellite facilities

4 - Increased disposal authorization

5 - Significant increase in number of authorized users

License Reviewer:

Date:

Change date of next inspection?

No ( )
Yes ( ) New inspection date:

Supervisor:

Date:

Appendix D

Sample Letters

D.1 Administrative Correspondence

D.1.1 Letter for Follow-Up on Returned Mail

[INSERT DATE]

[INSERT NAME & ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

This letter concerns your NRC Material License listed below. Correspondence sent to the address on your license has been returned to us unopened. We have found through telephone contacts or other sources that you can be reached at the above address.

Please be advised that you must notify us of changes in your mailing address and/or location of licensed radioactive material. We would appreciate it if you would review your current license and confirm whether it correctly reflects your mailing address and locations of radioactive material. If there are changes, you should immediately submit an amendment request to: **[INSERT APPROPRIATE NRC OFFICE ADDRESS]**.

If we do not hear from you within 30 days, we plan to turn your files over to our Inspection Branch for appropriate review.

Thank you for your cooperation.

Sincerely,

[WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**

D.1.2 Acceptance Review – Sample Acknowledgment Letter/Postcard

Mail Control No. _____
License No. _____

Name: _____
Address: _____

SUBJECT: ACKNOWLEDGMENT OF REQUEST FOR LICENSING ACTION

REF: [ ] Letter [ ] Application [ ] Dated [ ] Received __/__/__

Dear Sir or Madam:

1. We have completed the initial processing, which is an acceptance review, of your application for a(n):

   [ ] new [ ] amendment [ ] renewal [ ] termination

   [ ] registration [ ] certification licensing action.

   REVIEWER NOTE: For renewals, insert the following statement:

   Your application is deemed timely filed and, accordingly, the license will not expire until final action has been taken by this office.

2. During the initial processing, [ ] no [ ] some omissions/deficiencies were identified. These deficiencies include _____ _____. The identified information should be provided within 30 days of the date of this letter, so that your request can be forwarded for technical review. Please note that the complete technical review may identify additional omissions in the submitted information or technical issues that require additional information.

3. **REVIEWER NOTE: Insert one of the following statements regarding the estimated time for completion of the licensing action:**

   - ***New and amendment*** *actions are normally processed within 90 days, unless the technical review identifies major deficiencies, or policy issues requiring input and coordination with other offices.*
   - ***Renewal*** *actions are normally processed within 180 days. However, under timely filing (before expiration) your license will not expire until final action has been taken by this office.*
   - ***Termination*** *actions are normally processed within 90 days, unless confirmatory surveys after decontamination/decommissioning activities are involved.*

   REVIEWER NOTE: In addition, the letter should acknowledge any request for an *expedited* review for safety-significant concerns or business reasons.

4. **REVIEWER NOTE: Insert the following statement for new applicants or requests requiring full-fee recovery.**

   A copy of your correspondence has been forwarded to the NRC Office of the Chief Financial Officer, who will contact you separately if the appropriate license fee has not been submitted for your request, or for billing if your request is subject to full-cost fee recovery.

Any correspondence about this application should reference the control number.

Sincerely,

[WRITER'S IDENTIFICATION]

(OPTIONAL NRC FORM 532 - Use for new applications and amendments only.)

_____
DATE

This is to acknowledge the receipt of your letter/application dated _____, and to inform you that the initial processing, which includes an acceptance review, has been performed.

☐ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:
_____

The action you requested is normally processed in _____days.

☐ A copy of your action has been forwarded to the NRC Office of the Chief Financial Officer, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** _____.
When call to inquire about this action, please refer to this mail control number.
You may call me at _____.

Sincerely,

Licensing Assistant

D.1.3 Acknowledgment Letter for NRC Form 483 Requests

[Licensee]
ATTN: [Contact]
[Street Address]
[City, State, Zip]

SUBJECT: NRC FORM 483 REQUEST

Dear [Contact]:

[Use the following for new Form 483s:]
Enclosed is your validated NRC Form 483, "Registration Certificate-In Vitro Testing With Byproduct Material Under General License," dated [date]. Please note the registration number, [XXXX], as this is the number by which you should reference your Registration Certificate on 10 CFR 31.11 for future revisions.

[Use the following for revised Form 483s:]
Enclosed is your validated NRC Form 483, "Registration Certificate-In Vitro Testing With Byproduct Material Under General License," dated [date], reflecting the requested change [brief description of change]. Note that you have retained the previously assigned registration number, [XXXX].

Please be advised that a general license is valid indefinitely; therefore, there is no renewal process. However, the regulations under 10 CFR 31.11 require that any change in the information provided by a registrant on the initial registration certificate be reported to the Director of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change. I have enclosed a blank NRC Form 483 for your use in reporting any future changes.

Please contact me a (XXX) XXX-XXXX if I can be of any further assistance.

Sincerely,

[Reviewer]

Enclosures: 1. Certificate [XXXX]
2. NRC Form 483

D.2 Deficiency Correspondence

D.2.1 Sample Deficiency Letter

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

We have reviewed your letter dated **[INSERT DATE OF SUBMITTAL]**. Before we can take further action, we will need the following additional information.

1. **[DESCRIBE THE DEFICIENCY AND INCLUDE A CLEAR STATEMENT SPECIFYING THE INFORMATION NEEDED]**

To continue review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate and refer to the license, docket, and control number specified below. If you have questions or require clarification on any of the information stated above, we encourage you to contact us at **[INSERT THE APPROPRIATE PHONE NUMBER]**

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

Enclosure:
As stated

D.2.2 Confirmation of Deficiency Telephone Call for New Application and License Amendment

[INSERT DATE]

[INSERT NAME & ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

This is to confirm our telephone conversation on **[INSERT DATE]** with **[INSERT NAME]**, in which we discussed the information we need to continue review of your application dated **[INSERT DATE]**. The items specified below are those we discussed:

1.
2. **(EACH ITEM SHOULD BE SIMPLE AND EXPRESSED IN ONE LINE.)**
3.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

[WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

D.2.3 Confirmation of Deficiency Telephone Call for Renewal Applications

[INSERT DATE]

[INSERT NAME & ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

This is to confirm our telephone conversation on **[INSERT DATE]** with **[INSERT NAME]**, in which we discussed the information we need to continue review of your application dated **[INSERT DATE]**.

The items specified below are those we discussed.

1.
2. **(EACH ITEM MUST BE SIMPLE AND EXPRESSED IN ONE LINE.)**
3.

If we do not receive your reply within 30 calendar days from the date of this letter, it may be necessary to deny your application for license renewal and to terminate your license. This action would require you to divest yourself of all licensed material in your possession.

Sincerely,

[WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

D.3 Final Action Correspondence

D.3.1 Materials License Cover Letter for Licensing Actions, Except Terminations

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

Please find enclosed Amendment No. **[INSERT NUMBER]** to NRC License No. **[INSERT LICENSE NUMBER]**. You should review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact the U.S. Nuclear Regulatory Commission, Region office **[NAME AND PHONE NUMBER OF REVIEWER, OPTIONAL].**

NRC expects licensees to conduct their programs with meticulous attention to detail and high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the condition of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
   a) When you decide to terminate all activities involving materials authorized under the license; or
   b) If you decide not to acquire or possess and use authorized material.
4. Request and obtain a license amendment before you:
   a) Change Radiation Safety Officers;
   b) Order byproduct material in excess of the amount, radionuclide, or form authorized on the license;
   c) Add or change the areas of use or address(es) of use identified in the license application or on the license; or
   d) Change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

Thank you for your cooperation.

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

Enclosure: As stated

D.3.2 Temporary Exemption from NRC Regulation or License Condition

DOCKET NO.
LICENSE NO.

[Name of Licensee]
[Address]

SUBJECT: TEMPORARY EXEMPTION TO NRC [REGULATION OR LIST THE LICENSE CONDITION]

Pursuant to the written request dated [date of request] for temporary exemption(s) from the requirements of [NRC regulation or license condition] by [name and position of requestor representing the licensee], the following temporary exemption(s) is (are) granted for the specified period of time:

[Each temporary exemption granted should be listed separately with documentation of the circumstances surrounding the request and the duration of time for which the exemption is granted.]

If your understanding of the above temporary exemption differs from that set forth above, you are to notify [contact] immediately, at [telephone number].

_____, Director
Division of Nuclear Materials Safety

D.4 Enforcement Correspondence

D.4.1 "Warning" of Denial for Applications for Renewal

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

This refers to our letter dated **[INSERT DATE]**, a copy of which is enclosed, which requested information about your application dated **[INSERT DATE]**, for renewal of License No. **[INSERT NUMBER]**. As of this date, we have not received a reply from you. If we do not receive your reply within thirty (30) calendar days from the date of this, our second letter, it may be necessary to deny your application for license renewal and to terminate your license. This action would require you to divest yourself of all licensed material in your possession.

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

Enclosure: As stated

D.4.2 Letter Denying Application for Renewal

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]

This refers to our letters dated **[INSERT DATE]** and **[INSERT DATE]**, concerning your application dated **[INSERT DATE]** for renewal of License No. **[INSERT NUMBER]**. We have not received a reply from you; therefore, pursuant to 10 CFR 2.108, the NRC staff intends to deny your application for renewal of the License No. **[INSERT NUMBER]** for failure to supply information. Attached is a Notice of Proposed Denial of Application.

If you do not request a hearing within 30 days of the date of the enclosed order, your renewal application is denied. In such event, you must divest yourself of licensed material presently possessed and follow the attached order which requires you to comply with 10 CFR 30.36(d) and (e).

Enclosed are the NRC guidelines for decontamination of your facility and equipment. Upon completion of your facility decontamination survey and transfer of materials, the NRC may conduct inspections and independent surveys of your facility to verify compliance with 10 CFR 30.36(d) and (e).

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Docket: **[INSERT NUMBER]**
License: **[INSERT NUMBER]**
Control: **[INSERT NUMBER]**

Enclosure: As stated

D.4.3 Order Denying an Application for License Renewal

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. **[INSERT NUMBER]**
[LICENSEE]	)	
[City, State]	)	License No. **[INSERT NUMBER]**

NOTICE OF PROPOSED DENIAL OF APPLICATION
AND ORDER MODIFYING LICENSE

I.

[NAME OF LICENSEE] (Licensee) is holder of Materials License No. **[INSERT NUMBER]** issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part___. The license authorizes possession of certain material **[HERE DISCUSS MORE FULLY THE NATURE OF THE LICENSE AND LICENSEE'S ACTIVITIES]**. The license, originally issued on (date), was due to expire by its terms on **[INSERT DATE]**. On **[INSERT DATE]**, the Licensee submitted a timely renewal application. The effect of the renewal application was to extend the term of License No. **[INSERT NUMBER]** pursuant to 10 CFR 2.109 until the Nuclear Regulatory Commission (NRC) made a final determination with respect to the renewal application.

II.

[This section should provide a description of relevant events, facts, violations, technical or legal reasons that provide the substantive basis for issuing the Order. The following example is provided as a sample discussion for this section.]

[In reviewing the renewal application, the NRC staff determined that additional information was necessary, and consequently, on **[INSERT DATE OF LETTER]** and **[INSERT DATE OF SECOND LETTER]**, the NRC staff requested additional information from the Licensee. The Licensee has not replied to those requests.]

III.

[This section should provide the justification for issuing the Order, in light of the facts described in Section II. This section should also describe how the violation or careless disregard adversely affects public health and safety.]

Consequently, pursuant to 10 CFR 2.108, I intend to deny the Licensee's renewal application for failure to supply information.

IV.

Accordingly, pursuant to sections **[INSERT 53, 63, OR 81]** 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part____, IT IS HEREBY ORDERED THAT:

A. Authorization under License No. **[INSERT NUMBER]** to receive, possess and use licensed material, except as indicated below, is terminated.

B. Within 30 days of the effective date of this order, the Licensee shall

1. remove radioactive contamination to the extent practicable

2. transfer all licensed material to an authorized recipient or otherwise properly dispose of byproduct material

3. submit a completed Form NRC-314

4. submit a radiation survey report in accordance with 10 CFR 30.36(j)(2)

5. submit records required by 10 CFR 30.51(d) and (f).

The Regional Administrator, Region____, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Regional Administrator, NRC Region___, **[INSERT ADDRESS]**, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, the person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for a hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be effective and final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

FOR THE NUCLEAR REGULATORY COMMISSION

_____

Deputy Executive Director
for Regulatory Effectiveness

Dated this ___ day of _____ 2000

D.4.4 Order Revoking License for Nonpayment of Fees

[DATE]

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. **[NUMBER]**
[LICENSEE NAME]	)	License No.**[NUMBER]**
[LICENSEE ADDRESS]	)	

ORDER REVOKING LICENSE FOLLOWING
IMMEDIATELY EFFECTIVE 30-DAY SUSPENSION

I

[LICENSEE NAME] [Licensee] is the holder of Materials License No. **[NUMBER]**, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to the Atomic Energy Act of 1954, as amended, that authorizes the activities stated therein. The license has an expiration date of **[DATE]**.

II

Pursuant to 10 CFR 171.16, the Licensee is required to pay an annual fee for this license. The Licensee's annual fee for License No. **[NUMBER]** for Fiscal Year **[YEAR]**, as set forth in fee category **[CATEGORY]** of 10 CFR 171.16(d), is $ **[ANNUAL FEE]**. In accordance with 10 CFR Part 15, the Licensee was sent an original invoice dated **[DATE]**, a second notice dated **[DATE]**, and a final notice dated **[DATE]**, requesting payment. The final notice of payment due specifically informed the Licensee that nonpayment of the fee may result in the suspension or revocation of the license in accordance with the enforcement provisions of the Commission's regulations, namely, 10 CFR 171.23. To date, the annual fees(s) have not been paid as required by 10 CFR Part 171. This Order suspends License No. **[NUMBER]**, as explained below. If the fee and any other delinquent debts to NRC are paid within 30 days of the date of issuance of this Order, this Order will be withdrawn and the Licensee will be permitted to resume operations under License No. **[NUMBER]**, if all other requirements are met. If the Licensee does not pay all debts within 30 days of the date of issuance of this Order, the license will be revoked by the terms of this Order and the Licensee will, in the future, not be able to operate under License No. **[NUMBER]**. If the former Licensee wants to resume operations after revocation of the license, the former Licensee will have to pay all debts to NRC and apply for and be issued a new license.

III

I have concluded that the Licensee has willfully violated NRC requirements. In addition, prior notice of the violation and an opportunity to achieve compliance was provided. Therefore, pursuant to 10 CFR 2.202, I find that the violation requires that this Order be immediately effective. In view of the foregoing and pursuant to Sections **[INSERT 53, 63, OR 81]**, 161b, 161c, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 170.41, 171.23, and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

A. License No. **[NUMBER]** is suspended for 30 days from the date of issuance of this Order with respect to receipt and use of licensed nuclear materials. If, within this 30-day period, the Licensee does not pay all debts due to NRC, the license will automatically be revoked, effective 30 days from the date of issuance of this Order. During the time that the license is suspended, and after license revocation, the license remains in effect, pursuant to 10 CFR [30.36; 40.42; or 70.38], with respect to the possession, transfer, and storage of licensed nuclear material remaining in the Licensee's possession, as contamination or in other forms, until the Commission notifies the Licensee in writing that the license is terminated.

B. Until notified by the Commission in writing that the license is terminated, the Licensee shall:

1. Restrict activity involving licensed nuclear material to decommissioning and safe, secure storage or transfer of material; and

2. Continue to control entry into restricted areas until the Licensee has determined and NRC has confirmed that such areas are suitable for release in accordance with NRC requirements.

C. Unless full payment is made, the Licensee shall, within 30 days from the date of this Order, arrange for disposal or transfer to an authorized recipient of any licensed nuclear material acquired or possessed under the authority of License No. **[NUMBER]** and shall take all actions required by 10 CFR [30.36: 40.42: or 70.38]. Such disposal must take place within 60 days of the date of this order.

D. Within 5 days after disposal of the material, the Licensee shall notify, in writing, the Director, Division of Nuclear Material Safety, for NRC Region **[NUMBER]**, at **[ADDRESS]**, of the disposition of all licensed nuclear material acquired or possessed under the authority of License No. **[NUMBER]**, including in the written notice details as to how, where, and when disposition of the material took place.

E. Within 30 days from the date of this Order, if the Licensee manufactures, distributes, or provides services to other licensees, the Licensee must notify, in writing, each customer or client that authorization to provide any of these services has been suspended. Furthermore, the Licensee must notify its customers and clients that they may need to amend their licenses to be in compliance with NRC requirements if their license specifically states reliance on the service of the Licensee. The Licensee must provide the Director, Division of Nuclear Material Safety, for NRC Region **[NUMBER]** at **[ADDRESS]** evidence of the notification and a list of customers or clients notified.

F. Within 65 days of the date of this Order, the Licensee shall conduct an adequate final radiation survey of the premises where the licensed activities were carried out, pursuant to 30.36(j), 40.42(j), or 70.38(j), and submit a written report of the results of this survey to the Director, Division of Nuclear Material Safety, for NRC Region **[NUMBER]**, **[ADDRESS]**.

G. Within 30 days of the date of this Order, the Licensee shall submit a written report to the Director, Division of Nuclear Material Safety, for NRC Region **[NUMBER]** at **[ADDRESS]** that includes: (1) a listing of all materials disposed of, transferred, or still in the possession of the Licensee; (2) a

description of the conditions of storage of retained material and actions being taken to control access to the material; and (3) for any material not disposed of or transferred, a description of the actions taken to attempt to dispose of or transfer the material and why those actions were unsuccessful.

H. The License shall be terminated upon satisfaction of the requirements of 10 CFR [30.36; 40.42: or 70.38].

I. After the license is revoked, the former Licensee may not resume previously-licensed operations until:

1. The former Licensee has applied for and been issued a new license under 10 CFR [30; 40; 70]: and

2. All debts to NRC, including the fee for the new license, have been paid in full.

The Chief Financial Officer may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause. A request for modification of the above conditions shall be submitted to the Chief Financial Officer, with a copy to the Director, Division of Nuclear Material Safety, NRC Region **[NUMBER]**, in writing and under oath or affirmation, and must be received within 30 days from the date of issuance of this Order.

IV

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order. This answer must be received by the Office of the Chief Financial Officer within 30 days of the date of this Order.

Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Chief Financial Officer and include a statement of good cause for the extension.

The answer shall be in writing and under oath or affirmation, and it shall specifically admit or deny each allegation or charge made in this Order. The answer shall set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer or request for hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies shall also be sent to the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Assistant General Counsel for Hearings and Enforcement at the same address; the Regional Administrator, NRC Region **[NUMBER]**, **[ADDRESS]**; and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If the Licensee or a person whose interest is adversely affected requests a hearing, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee, or any other person adversely affected by this Order may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The motion must state with particularity the reasons why the order is not based on adequate evidence and must be accompanied by affidavits or other evidence relied on.

V

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, this Order shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Part III shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

VI

In lieu of filing an answer to the Order, the Licensee may pay the total amount specified below. This amount must be received by the Office of the Chief Financial Officer within 30 days of the date of this Order. This Order is withdrawn if, within 30 days of the date of this Order, the Office of the Chief Financial receives the total amount specified below:

Amounts Due

Calculated Through:

	Invoice Date	Invoice Number	Amount Billed	Late Charges Due	Amount Due
1.					
2.					
3.					
				Total Amount	$_____

The total amount listed above is a delinquent debt to the United States. Failure to pay the total amount within 30 days of the date of this Order may, pursuant to 10 CFR Part 15, result in referral of the delinquent debt to a collection agency, referral to the U.S. General Accounting Office or the U.S. Department of Justice for collection, or other action deemed appropriate. Pursuant to 10 CFR 15.29, the

Commission may not consider an application for a license from the Licensee unless all previous delinquent debts of the Licensee to the NRC, including the delinquent debt(s) identified in this Order, have been paid in full. In addition, failure to meet the requirements of this Order may subject the Licensee and its agents to civil penalties and criminal sanctions.

FOR THE NUCLEAR REGULATORY COMMISSION

_____

Chief Financial Officer

Dated at Rockville, Maryland

this _____day of _____, 2000

D.5 Reciprocity Correspondence

D.5.1 Reciprocity Procedures Letter

[Date]

[Licensee's Name]
ATTN: [Contact Person]
[Title]
[Licensee's Address]
[City, State, Zip]

Dear [Contact Person]:

Agreement State licensees [licensees] seeking to conduct activities under reciprocity in areas of exclusive Federal jurisdiction, non-Agreement States, or in offshore waters (reciprocity activities), for the first time in a calendar year, must submit the following:

- NRC Form 241, "Report of Proposed Activities in Areas of Exclusive Federal Jurisdiction, Non-Agreement States, and Offshore Waters" (see Enclosure 1); One copy of the Agreement State specific license; and
- The fee, either check or credit card application, specified in fee Category 16, 10 CFR 170.31 (see Enclosure 2).
- NRC must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by 10 CFR 150.20 (provided on NRC Form 241 for convenience). Licensees cannot perform work in areas of exclusive Federal jurisdiction without either (a) filing NRC Form 241 for reciprocity in accordance with 10 CFR 150.20(b) or (b) applying for a specific NRC license.

This general license authorizes persons holding a specific license from an Agreement State to conduct the same activity in areas of exclusive Federal jurisdiction, non-Agreement States, or in offshore waters, if the specific license issued by the Agreement State does not limit the authorized activity to specified locations or facilities. Under the general license, licensees conducting reciprocity activities, including storage (usage), are limited to a total of 180 days in any calendar year. Reciprocity activities conducted in offshore waters are not subject to the 180-day limit. NRC tracks reciprocity usage on the basis of approved usage days and will not approve any activity, under the general license, that causes the total usage days to exceed 180 days. It is important that licensees track the days of use and clarify or delete dates of work when applicable.

NUREG-1556, Vol. 19, "Guidance for Agreement State Licensees about Reporting Activities in Areas of Exclusive Federal Jurisdiction, Non-Agreement States, and Offshore Waters," contains guidelines to follow in filing NRC Form 241. It also contains important information to help licensees ensure that they are complying with NRC regulations before conducting activities under reciprocity. This document is available at the following Internet address:

<http://www.nrc.gov/NRC/NUREGS/SR1556/V19/index.html>.

APPENDIX D

Agreement State licensees operating under reciprocity in areas of NRC jurisdiction must conduct activities involving radioactive materials in accordance with the conditions specified in the licensee's Agreement State license, representations made in NRC Form 241, and other rules, regulations, and orders of NRC, now or hereafter in effect. NRC will perform inspections of activities by Agreement State licensees operating under a general license pursuant to 10 CFR 150.20. These inspections may occur at the listed work site location(s) or at the home office address. Failure to comply with these regulations or to conduct your radiation safety program in compliance with NRC regulations before operating under reciprocity may result in NRC enforcement action(s) against the licensee. Such actions could include the issuance of a notice of violation, the proposed imposition of a civil penalty, or an order suspending, modifying, or revoking the license as specified in NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions." This document is available at the following Internet address:

<http://www.nrc.gov/OE/rpr/oe_4.htm>.

For your information and use in filing for reciprocity, I have enclosed a copy of NRC Form 3 (see Enclosure 3). [Any other regulations, information notices, or other information being enclosed should be described here.] NRC's regulations, such as 10 CFR Parts 19, 20, 30, 34, 35, 39, 50, 71, are available on NRC's Homepage at www.nrc.gov. If you do not have access to the Internet and require a copy of an NRC document, please contact our office at [Address].

If you have any questions about the regulations or the application process, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,

[Reviewing Official]

Enclosures:
1. NRC Form 241
2. 10 CFR Part 170
3. NRC Form 3

D.5.2 Acknowledgment Letter for Form 241 Submittals

[Date]

[Licensee's Name]
ATTN: [Contact Person]
[Title]
[Licensee's Address]
[City, State, Zip]

SUBJECT: NRC FORM 241

Dear [Contact Person]:

Enclosed is the NRC signature copy, signifying our review, of your NRC Form 241 dated [date] to report [proposed/revised/clarified] licensed activities in NRC jurisdiction under the authority of the general license pursuant to 10 CFR 150.20 (reciprocity).

Changes to the initial NRC Form 241 for additional work locations or clients, or for changes to the radioactive material, or work activities different from the information submitted on the initial NRC Form 241 are considered revisions and do require a [amount] fee. Changes or deletions to the initial NRC Form 241 of specific locations or work sites, work site contacts, or dates of work are considered clarifications, not revisions, and do not require a fee.

A Location Reference Number has been entered on your NRC Form 241 and should be used for reference on subsequent revisions or clarifications.

[For radiography licensees, add the following:]

Please be advised that, as an Agreement State licensee authorized by general license to perform licensed activities in areas of NRC jurisdiction, you must conduct your reciprocity activities in accordance with the representations specified in your NRC Form 241 and other rules, regulations, and orders of the U.S. NRC Commission, now or hereafter in effect. [For radiography licensees, add the following:] Specifically, you must comply with 10 CFR Part 34, "LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS." 10 CFR Part 34 was revised, effective June 27, 1997, to make the requirements more understandable to licensees. Additionally, several major changes were made in the regulations to improve both the quality and the safety of industrial radiography. These changes include (but are not limited to):

1. The NRC has adopted mandatory certification requirements for industrial radiographers. Radiographers are now required to be certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of 10 CFR Part 34. This requirement becomes effective June 27, 1999. The NRC recognizes the American Society for Nondestructive Testing, Inc. (ASNT) as a Certifying Entity. The following Agreement States also administer certification programs as Certifying Entities: Georgia, Illinois, Iowa, Louisiana, Nevada, North Dakota, and Texas.

2. Survey meter calibration frequency changed from 3 months to 6 months. (***Note:*** If your Agreement State License is more restrictive, you must comply with your Agreement State License.)

3. Leak testing devices containing depleted uranium (DU) for DU contamination is required at 12-month intervals.

4. An additional qualified individual, who is at least an assistant radiographer and who must observe the activities, is required when performing radiography operations.

5. A job performance inspection program is required where each individual is evaluated at 6-month intervals.

6. After each exposure, a performance-based survey is required when approaching the device or guide tube to ensure that the source is shielded.

In addition, please note that as of January 10, 1996, all radiographic exposure devices and associated equipment must comply with 10 CFR 34.20.

[Type in any other additional paragraphs as necessary.]

If you have questions concerning this action or other aspects of working in NRC jurisdiction under reciprocity, please contact me at XXX-XXX-XXXX.

Sincerely,

[Name of reviewer, Title]
Nuclear Materials Licensing Branch
[Division]
[Office]

Enclosure(s): As stated

D.6 Withholding Correspondence

D.6.1 Agreement with Request to Withhold Information from Pubic Disclosure

[Date]

[Licensee's Name]
ATTN: [Contact Name]
[City, State Zip]

Dear [Contact]:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON [APPLICATION, LETTER, FORM] FROM PUBLIC DISCLOSURE

By [Application, Letter, Form] from [Licensee's Name] dated [date], and affidavit dated [date], you submitted [proprietary, confidential] material consisting of [brief description, e.g., personal, or client information] and requested that it be withheld from public disclosure pursuant to 10 CFR 2.790. This letter is our response to your request.

You stated that the submitted information should be considered exempt from public disclosure for the following reasons:

1.

2.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that the submitted information sought to be withheld does contain [proprietary, confidential] information. Therefore, the [brief description of information to be withheld] contained in [Application, Letter, Form], marked as [proprietary, confidential] will be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by Region (X) indefinitely.

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

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the U.S. Nuclear Regulatory Commission. You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your information). In all review situations, if NRC makes a determination adverse to the decision above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,

[Regional Branch Chief]

D.6.2 Disagreement with Request to Withhold Information from Public Disclosure

[Date]

[Licensee's Name]
ATTN: [Contact Name]
[City, State Zip]

Dear [Contact]:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON [APPLICATION, LETTER OR FORM]

By [Application, Letter, Form] from (Licensee's Name) dated [date], and affidavit dated [date], you submitted [proprietary, confidential] material consisting of [brief description, e.g., personal or client information] and requested that it be withheld from public disclosure pursuant to 10 CFR 2.790. This is our response to your request.

We have reviewed your [application, letter, form] and the material in accordance with the requirements of 10 CFR 2.790 and, for the following reasons, have determined that the submitted information, in whole or in part, sought to be withheld, does not contain proprietary information.

1.

2.

Therefore, we have determined that the material, specifically [brief description] should be released for public disclosure. In accordance with 10 CFR 2.790(c), this information is being forwarded to you as notice that the information will be placed [in the PDR thirty (30) days from the date of this letter]. If within thirty (30) days of this letter, you request withdrawal of these documents in accordance with 10 CFR 2.790(c), or provide additional reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

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

If the basis for withholding this information from public disclosure should change in the future such that the information could then be made available for public inspection, you should promptly notify NRC. You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your withheld information). In all review situations, if NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,

[Regional Branch Chief]

D.6.3 Partial Agreement with Request to Withhold Information from Public Disclosure

[Date]

[Licensee's Name]
ATTN: [Contact Name]
[City, State Zip]

Dear [Contact]:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON [APPLICATION, LETTER, FORM]

By [application, letter, form] from [Licensee's Name] dated [date], and affidavit dated [date], you submitted [proprietary, confidential] material consisting of [brief description, e.g., personal or client information] and requested that it be withheld from public disclosure pursuant to 10 CFR 2.790. This is our response to your request.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that only certain information contained in [application, letter, form] is [proprietary, confidential].

The [brief description] information contained in [application, letter, form], marked as [proprietary, confidential] does contain [proprietary, confidential] information and will, therefore, be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by Region (X) indefinitely.

We have also determined that, for the following reason(s), the information contained in [application, letter, form] does not contain proprietary information.

1.

2.

Therefore, the [brief description] contained in [application, letter, form] should be released for public disclosure. In accordance with 10 CFR 2.790(c), this information is being forwarded to you as notice that the information will be placed [in the PDR thirty (30) days from the date of this letter]. If within thirty (30) days of this letter, you request withdrawal of these documents in accordance with 10 CFR 2.790(c), or provide additional reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

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

If the basis for withholding this information from public disclosure should change in the future such that the information could then be made available for public inspection, you should promptly notify NRC. You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your withheld information). In all review situations, if NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,

[Regional Branch Chief]

Appendix E

Standard License Conditions

GENERAL INFORMATION

The record keeping requirements of certain license conditions must receive clearance from the Office of Management and Budget (OMB) prior to use. Licensing staff should not use the record keeping portion of conditions no. 22, 23, 132, 133, 164, or 165.I until notified that OMB clearance has been obtained.

In order to maintain consistency throughout the NRC, reviewers should use standard conditions to the maximum extent possible. Proposed revisions to standard conditions or proposed special conditions should be coordinated with NMSS before use.

In addition, before issuing a license with non-standard conditions, reviewers should coordinate with the inspection staff and licensees to ensure that all parties have the same understanding of all license conditions, especially any conditions unique to a particular licensee. The cover letter accompanying the licensing package should identify and bring to the licensee's attention any unique conditions on the license.

E.1 LOCATION OF USE

1. Licensed material shall be used or stored only at the licensee's facilities located at **[insert address]**.

2. Licensed material shall be used or stored at the licensee's facilities located at **[insert address]** and at temporary job sites of the licensee anywhere in the United States.

   [Reviewer Note: This condition should only be used for Federal Agencies.]

3. Licensed material shall be used or stored at the licensee's facilities located at **[insert address]** and shall be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. Licensed activities within Agreement States are not authorized without *prior* specific approval from the Agreement State.

   [Reviewer Note: This condition does NOT allow storage at temporary job sites.]

4. Licensed material shall be used or stored **[incident to mobile nuclear medicine activities]** at the licensee's facilities located at **[insert address]** and may be used or stored at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. Licensed activities within Agreement States are not authorized without *prior* specific approval from the Agreement State.

   [Reviewer Note: This condition allows storage at temporary job sites - provided the licensee has submitted acceptable procedures for storage at temporary job sites. If used on a mobile nuclear medicine license, include first bracketed phrase.]

5. Licensed material shall be used only at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. Licensed activities within Agreement States are not authorized without *prior* specific approval from the Agreement State.

   [Reviewer Note: This condition is used when permanent storage is not authorized on the license, i.e., permanent storage is in an Agreement State.]

6. Radioactive material shall be used only at the following:

   A. LOCATION(S) OF USE:

   B. FIELD STATIONS(S):

   C. PERMANENT RADIOGRAPHIC INSTALLATIONS(S):

   D. TEMPORARY JOB SITES: Anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating licensed material, including areas of exclusive Federal jurisdiction within Agreement States. Licensed activities within Agreement States, but outside of areas of exclusive Federal jurisdiction, are not authorized without *prior* specific approval from the Agreement State.

   If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal Agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate regulatory Agency.

   [Reviewer Note: For use only on radiography licenses.]

E.2 GENERAL – NEW LICENSE

7. (RESERVED)

E.3 SUPERVISION – GENERAL

8. Licensed material shall be used by, or under the supervision of, **[insert name(s)]**.

9. Licensed material shall be used by, or under the supervision and in the physical presence of, **[insert name(s)]**.

10. Licensed material shall be used only by **[insert name(s)]**.

11. (RESERVED)

12. (RESERVED)

13. (RESERVED)

E.4 SUPERVISION – LIMITED MEDICAL

14. A. Licensed material is only authorized for use by, or under the supervision of the following individuals for the materials and uses indicated:

Authorized Users	Material and Use

B. Licensed material shall be used by, or under the supervision of: **[insert name]**.

C. Authorized nuclear pharmacist: **[insert name]**.

[Reviewer Note: Use the appropriate paragraph(s) for the license. Delete the ones that are not applicable.]

E.5 SUPERVISION – BROAD – MEDICAL

15. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.

16. Individuals designated to work as authorized users **[or authorized nuclear pharmacists]**, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.

[Reviewer Note: Conditions 15 and 16 are used together.]

17. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee.

[Reviewer Note: This condition should only be used for Type A broad scope <u>medical</u> licenses.]

18. Individuals designated to work as medical physicists for **[teletherapy or HDR brachytherapy]** shall meet the training and experience criteria established in 10 CFR 35.961 **[(substituting similar experience in HDR brachytherapy-specific tasks for those listed in 10 CFR 35.961(c))]**; or be named on a current U. S. Nuclear Regulatory Commission or Agreement State license, or a permit issued under a broad scope license as an HDR medical physicist; and shall be designated, in writing, by the Radiation Safety Committee. In addition, the physicist must meet the recentness of training requirement in 10 CFR 35.972, and have recent, device-specific training and experience for each make and model of **[teletherapy or HDR]** device used by the licensee.

[Reviewer Note: Delete teletherapy or HDR references as appropriate.]

19. (RESERVED)

E.6 SUPERVISION – PACEMAKER

20. The physicians responsible for implantation, follow-up, explanation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are **[insert name(s)]**.

    [Reviewer Note: If the renewal application does not include plans for new implants, the word "implantation" may be deleted from this condition.]

E.7 SUPERVISION – NUCLEAR PHARMACY

21. Licensed material shall be used by, or under the supervision of:

    A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and 32. 72(b)(4).

    B. Authorized nuclear pharmacists: **[insert name(s)]**.

    C. Authorized User Material and Use

    [Reviewer Note: Use the appropriate paragraph(s) for the license. Delete the ones that are not applicable.]

E.8 SUPERVISION – BROAD – NON-MEDICAL

22. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

    [*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

    [Reviewer Note: Authorized user for Type A Broad License]

23. Licensed material shall be used by or under the supervision of individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

    [*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

    [Reviewer Note: Authorized user for Type B Broad License.]

24. Licensed material shall be used by or under the supervision of individuals meeting the requirements stated in 10 CFR 33.15(b)(1) and (2).

    [Reviewer Note: Authorized user for Type C Broad License.]

E.9 SUPERVISION – PORTABLE GAUGES, FIXED GAUGES, AND IRRADIATORS

25. Licensed material shall be used by, or under the supervision of individuals who have received the training described in the **[application/letter]** dated **[insert date(s)]**.

26. (RESERVED)

27. (RESERVED)

E.10 SUPERVISION – RADIOGRAPHY

28. Licensed material shall be used by, or under the supervision of individuals who have received the training described in the **[application/letter]** dated **[insert date(s)]**.

29. (RESERVED)

E.11 SUPERVISION – WELL LOGGING

30. The individuals listed below are the only persons authorized by this license to act as logging supervisors or logging assistants as defined in 10 CFR 39.2:

Logging Supervisors	Logging Assistants

31. (RESERVED)

32. (RESERVED)

33. (RESERVED)

E.12 RADIATION SAFETY OFFICER

34. The Radiation Safety Officer for this license is **[insert name].**

35. A. The Radiation Safety Officer for this license is **[insert name].**

    B. Before assuming the duties and responsibilities as Radiation Safety Officer for this license, the individual shall have successfully completed the training described in 10 CFR **[insert regulation number]**.

36. (RESERVED)

37. (RESERVED)

    (***Note:*** "Leak Test" was moved to Condition number 165.)

E.13 TIE-DOWN

38. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A.

    B. (Documents should be listed chronologically)

    C.

    [Reviewer Note: Use for all licenses except medical.]

39. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A.

    B. (Documents should be listed chronologically.)

    [Reviewer Note: This condition should only be used for medical licensees.]

40. (RESERVED)

41. (RESERVED)

E.14 GAS CHROMATOGRAPHS

42. (RESERVED)

43. Maintenance, repair, cleaning, replacement and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

44. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified in the certificate of registration issued by the NRC pursuant to10 CFR 32.210 or the equivalent regulations from an Agreement State.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

[Reviewer Note: Condition 44.B should not be used with portable field devices.]

45. (RESERVED)

46. (RESERVED)

47. (RESERVED)

E.15 FEMA

48. A. Each sealed source containing licensed material to be used outside of a shielded exposure device shall have a durable, legible, and visible tag permanently attached by a durable ring. The tag shall be at least 1 inch square, shall bear a conventional radiation symbol prescribed in 10 CFR 20.1901 (a) and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE – NOTIFY CIVIL AUTHORITIES IF FOUND.

B. Replacement of tags and rings shall be carried out by the licensee in accordance with instructions contained in procedures provided by the Federal Emergency Management Agency.

49. (RESERVED)

50. (RESERVED)

E.16 PORTABLE GAUGES

51. Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container must be locked when in transport, storage or when not under the direct surveillance of an authorized user.

52. The licensee is authorized to detach the source or source rod from **[insert manufacturer name and model no. of gauge]** gauges for the purpose of cleaning, maintenance, or repair of the gauge(s) in accordance with procedures outlined in **[insert dates]**.

[Reviewer Note: This condition is used if the licensee is authorized to perform non-routine maintenance.]

53. Any cleaning, maintenance, or repair of the gauge(s) that requires detaching the source or source rod from the gauge shall be performed only by the manufacturer or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

[Reviewer Note: This condition is used if the licensee is <u>not</u> authorized to perform non-routine maintenance.]

54. Sealed sources or source rods containing licensed material shall not be opened or sources removed or detached from source rods or gauges by the licensee, except as specifically authorized.

55. A. If the licensee uses unshielded sealed sources extended more than 3 feet below the surface, the licensee shall use a surface casing that extends from the lowest depth to 12 inches above the surface and other appropriate procedures to reduce the probability of the source or probe becoming lodged below the surface. If it is not feasible to extend the casing 12 inches above the surface, the licensee shall implement procedures to ensure that the cased hole is free of obstruction before making measurements.

B. If a sealed source or a probe containing a sealed source becomes lodged below the surface and it becomes apparent that efforts to recover the sealed source or probe may not be successful, the licensee shall notify the U.S. Nuclear Regulatory Commission and submit the reports required by 10 CFR 30.50(b)(2) and (c). The licensee shall not abandon the sealed source or probe without obtaining the Commission's *prior* written consent.

[Reviewer Note: May use this condition on portable gauge licenses if the probe can be inserted into the ground to a depth of greater than 3 feet.]

E.17 RADIOGRAPHY

56. A. No sealed source or device containing licensed material shall be stored for a period of more than 3 years without being tested for leakage and/or contamination.

B. The licensee is authorized to analyze leak test samples in accordance with the **[application/letter]** dated **[insert date]**.

C. Sealed sources authorized for a use other than radiography shall be tested for leakage in accordance with 10 CFR 34.27.

[Reviewer Note: Condition 56.C should be used only if the license authorizes the use of sources for other than radiography, e.g., a source contained in an instrument calibrator.]

57. The licensee is authorized to conduct source retrieval activities in accordance with the application/letter dated **[insert date]**.

    [Reviewer Note: This condition should only be used if the licensee meets the criteria for source retrieval activities in NUREG-1556, Vol. 2.]

58. Notwithstanding the requirements of 10 CFR 34.20(a), and pursuant to 10 CFR 34.51, radiographic equipment authorized for use in radiographic operations under this license need not comply with the torque criteria of Section 8.9.2(c) of American National Standard N432 - 1980.

    [Reviewer Note: The above condition requires coordination with NMSS. See Section 4.13.]

59. Notwithstanding the requirements of 10 CFR 34.20(a) and (c)(2), and pursuant to 10 CFR 34.51, the licensee may use its [insert Manufacturer and Model number] exposure device in accordance with procedures contained in letter/application dated [insert date].

    [Reviewer Note: The above condition requires coordination with NMSS. See Section 4.13]

E.18 WELL LOGGING

60. (RESERVED)

61. A. Notwithstanding the periodic leak test required by 10 CFR 39.35, sources that are stored and not being used, and contain less than 10 microcuries (370,000 Bqs) of alpha- or neutron-emitting radioactive material, are exempted from this periodic test. The sources exempted from this periodic test shall be tested for leakage before use or transfer to another person. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    [Reviewer Note: This condition may be used without NMSS coordination. See Section 4.13.]

    B. The licensee is authorized to analyze leak test samples in accordance with the **[application/letter]** dated **[insert date]**.

    C. Sealed sources authorized for a use other than well logging shall be tested for leakage and shall be inventoried in accordance with 10 CFR 39.35 and 39.37.

62. The licensee shall not vacate or release to unrestricted use a field office or storage location whose address is identified in Condition **[insert condition number]**, without prior NRC approval.

63. Notwithstanding the requirements of 10 CFR 39.77(c)(1), and pursuant to 10 CFR 39.91, the licensee may in the event of an immediate threat to health and safety, and to protect life and property, implement abandonment procedures, and delay notification of NRC, when it becomes apparent that efforts to recover well logging tools containing sealed sources will not be successful. However, the licensee must notify the NRC by telephone within 24 hours and describe the circumstances that caused an immediate threat to health and safety, and life and property.

    [Reviewer Note: The revision of 10 CFR Part 39, "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," supercedes and/or includes the provisions provided by this condition. This condition is deleted on the effective date of the Rule (expected in the third quarter of calendar year 2000)].

64. The opening, repair, or modification of any energy compensation source (ECS) must be performed by persons specifically approved to do so by the Commission or an Agreement State.

E.19 FIXED GAUGE

65. A. Each gauge shall be tested for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or at such longer intervals as specified in the certificate of registration issued by the NRC pursuant to 10 CFR 32.210 or the equivalent regulations of an Agreement State.

    B. Notwithstanding the periodic on-off mechanism (shutter) and indicator test, the requirement does not apply to gauges that are stored, not being used, and have the shutter lock mechanism in a locked position. The gauges exempted from this periodic test shall be tested before use.

66. The following services shall ***not*** be performed by the licensee: installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source and non-routine maintenance or repair of components related to the radiological safety of the gauge (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding). These services shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

    [Reviewer Note: Use when licensee is NOT authorized to perform any services on the gauges.]

67. A. **[Insert which services are authorized in this license, delete remaining:]** Installation, initial radiation surveys. relocation, removal from service dismantling, alignment, replacement, disposal of the sealed source and non-routine maintenance or repair of components related to the radiological safety of the gauge] shall be performed only by, **[insert name(s)]** or other individuals who have completed the training specified in **[insert application/letter date]** or by persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.

B. The following services shall ***not*** be performed by the licensee: **[Insert which services are NOT authorized in this license, delete remaining:]** Installation, initial radiation surveys. relocation, removal from service. dismantling. alignment. replacement. disposal of the sealed sources and non-routine maintenance or repair of components related to the radiological safety of the gauge]. These services shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

[Reviewer Note: Part A of this condition is used to specify which non-routine operations may be performed by a licensee. Part B of the condition is used to specify which non-routine operations a licensee is NOT authorized to perform. If the licensee may perform all listed operations, use only Part A of the condition.]

68. The licensee may initially mount a gauge, if permitted by the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State, and under the following conditions:

A. The gauge must be mounted in accordance with written instructions provided by the manufacturer.

B. The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by the Commission or an Agreement State.

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

D. The gauge must be received in good condition (i.e. the package was not damaged).

E. The gauge must not require any modification to fit in the proposed location.

Mounting does ***not*** include electrical connection, activation or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such operations.

69. Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the U.S. Nuclear Regulatory Commission or an Agreement State.

70. The licensee shall operate each device containing licensed material, within the manufacturer's specified temperature and environmental limits such that the shielding and shutter mechanism of the source holder are not compromised.

71. The licensee shall assure that the shutter mechanism, for each device containing licensed material, is locked in the closed position during periods when a portion of an individual's body may be subject to the direct radiation beam. The licensee shall review and modify, as appropriate, its "lock-out" procedures whenever a new device is obtained to incorporate the device manufacturer's recommendations.

72. A. The licensee may maintain, repair, or replace device components that are ***not*** related to the radiological safety of the device containing byproduct material and that do not result in the potential for any portion of the body to come into contact with the primary beam or in increased radiation levels in accessible areas.

    B. The licensee may <u>not</u> maintain, repair, or replace any of the following device components: the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, or shielding, or any other component related to the radiological safety of the device.

E.20 IRRADIATORS

73. Irradiation and distribution of foods for human consumption shall be in accordance with the rules and regulations of the Food and Drug Administration.

74. (RESERVED)

75. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may affect safe operation of the irradiator. These activities may be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

    [Reviewer Note: This condition is used for licensees NOT authorized to perform non-routine maintenance.]

OR

Except for the repair or maintenance operations described in **[letter/application]** dated **[insert date]**, the licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may affect safe operation of the irradiator. These activities may be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

[Reviewer Note: This condition is used for licensees authorized to perform non-routine maintenance.]

76. For each J. L. Shepherd and Associates, Mark I or Model 81-22, cesium-137 Irradiator installed and used, the licensee shall:

A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

C. Have room monitors installed that will:

(i) Operate at all times when the irradiator is in use; and

(ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and

(iii) Detect any radiation leaking from the irradiator door; and

(iv) Be visible to the irradiator user when he is next to the irradiator; or

D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:

(i) Determine the radiation level at the irradiation door when the door is closed; and

(ii) Check for any increase in radiation levels each time the irradiator door is opened.

E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Parts 20, 21 or 30.

F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

[Reviewer Note: This condition is used on all licenses authorizing possession and use of J. L. Shepherd Mark I or Model 81-22 irradiators.]

77. The procedures contained in the manufacturer's instruction manual, for the irradiator authorized by this license, shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

78. The licensee is authorized to use the following sealed sources in the pool irradiator:

Manufacturer	Model No

79. Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the **[letter/application]** dated **[insert date]**.

[Reviewer Note: This condition applies only to converted teletherapy units. Regions may use it without NMSS coordination. See Section 4.13.]

80. Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the **[letter/application]** dated **[insert date].**

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

81. Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the **[letter/application]** dated **[insert date]**.

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

82. Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having a visible and audible alarm within the treatment area, based on the commitments described in the **[letter/application]** dated **[insert date].**

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

83. Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the **[letter/application]** dated **[insert date]**.

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

84. Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from **[insert what is exempted]** based on the commitments described in the letter/application dated **[insert date]**.

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

85. Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated [insert date]. The radiation room door key shall be attached to the portable survey meter.

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

86. Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with the letter/application dated **[insert date].**

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

87. Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room that must be activated prior to irradiation that would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the letter/application dated **[insert date]**.

[Reviewer Note: Regions may use this condition for converted teletherapy units without NMSS coordination. See Section 4.13.]

E.21 MEDICAL – GENERAL

88. Notwithstanding the requirements of 10 CFR 35.20(a), the licensee is not required to develop and implement an ALARA program.

[Reviewer Note No. 1: Use this condition for licenses authorizing 35.500 only. This condition may be used without NMSS coordination.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

89. Notwithstanding the requirements of 10 CFR 35.22 the licensee is not required to establish a Radiation Safety Committee.

[Reviewer Note No. 1: Use this condition for institutional licensees that only authorize 35.500 devices. This condition requires coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

90. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35.

[Reviewer Note: Use LC for licensees with R&D programs where human use research is the only medical use authorized.]

91. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions only to the extent that the instructions are not applicable to the type of use proposed by the licensee.

[Reviewer Note No. 1: The above condition may be used without NMSS coordination. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

92. Notwithstanding the requirements of 10 CFR 35 **[insert paragraph number]**,the licensee may use the alternative method for **[record keeping or posting]** as described in the **[letter/application]** dated **[insert date]**.

[Reviewer Note: The above condition may be used without NMSS coordination. See Section 4.13.]

93. Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the letter/application dated **[insert date]**.

[Reviewer Note No. 1: The above condition may be used without NMSS coordination. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

94. Notwithstanding the requirements of 10 CFR 35.70(b) and (e), the licensee may conduct surveys for contamination and ambient exposure rates of the area where radiopharmaceutical waste is being stored, whenever waste is moved, placed into, removed from storage, or **[insert frequency]**, whichever is more frequent.

    [Reviewer Note No. 1: The above condition REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

95. Notwithstanding the requirements of 10 CFR 35.51(a)(3), the licensee may record the apparent exposure from its check source upon receipt from the calibration facility.

    [Reviewer Note No. 1: The above condition REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

96. Notwithstanding the requirements of 10 CFR 35.315(a)(7), the licensee may reassign a patient room to another radiopharmaceutical therapy patient when removable contamination is less than 2000 disintegrations per minute per 100 square centimeters, and in accordance with letter/application/facsimile dated **[insert date]**.

    [Reviewer Note No. 1: The above condition REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

97. Notwithstanding the requirements of 10 CFR 35.406(a), the licensee is exempt from the requirements to count brachytherapy sources following explanation, based on the commitments described in the letter/application/facsimile dated **[insert date]**.

    [Reviewer Note No. 1: The above condition REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

98. Notwithstanding the requirements of 10 CFR 35.415(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the **[letter/application]** dated **[insert date]**.

[Reviewer Note No. 1: The above condition may be used without NMSS coordination. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

99. Replacement-exchange of the source/source-holder combination for sources identified in 35.500 may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual.

[Reviewer Note No. 1: This condition is for licenses authorizing 10 CFR 35.500. The above condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

100. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care a patient with a temporary eye plaque implant in place, in accordance with procedures described in letter/application dated **[insert date]**.

[Reviewer Note No. 1: The above condition may be used without NMSS coordination. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

101. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every 6 months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

E.22 MEDICAL – BROAD

102. Notwithstanding the requirements of 10 CFR 35.49(a), the licensee may use any byproduct material for 10 CFR 35.400 and 35.500 uses.

[Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

103. (RESERVED)

104. (RESERVED)

105. (RESERVED)

E.23 MEDICAL – BRACHYTHERAPY REMOTE AFTERLOADERS

106. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient and returned to the fully-shielded position in the remote afterloading device. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

[Reviewer Note: The revision of 10 CFR Part 35 includes the requirements in this license condition. This condition is deleted on the effective date of the Rule.]

107. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

108. For each high dose rate remote afterloading brachytherapy unit, prior to initiation of a treatment program, and subsequent to each source exchange, the licensee shall perform the following radiation surveys:

    A. Survey the source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed **[insert appropriate number]** milliroentgen per hour.

    B. Survey all areas adjacent to the treatment room with the source in the "exposed" position. The survey shall clearly establish:

        1. That radiation levels in restricted areas are not likely to cause personal exposure in excess of the limits specified in 10 CFR 20.1201(a), 20.1207, and 20.1208.

        2. That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

    C. Records of the survey results shall be maintained for inspection by the U.S. Nuclear Regulatory Commission for 3 years.

    [Reviewer Note No. 1: As dose rates differ from unit to unit, insert the appropriate dose rate in paragraph A, for the specific HDR authorized by the license.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

109. The following shall be performed only by *manufacturer's representatives* or persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services:

    A. Installation and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.

    B. Any maintenance or repair operations on the high dose rate remote afterloading brachytherapy unit(s) and associated equipment listed in Subitem(s) of Item 9, involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

    [Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

110. The medical physicist for this license is [insert name].

111. The medical physicist(s) for this license **[is/are] [insert name(s)]** or individuals designated, in writing, by the licensee's Radiation Safety Committee, and who comply with at least one of the following criteria:

A. Meet the training and experience criteria established in 10 CFR 35.96(1)(a) or (b), and meet the recentness of training criteria established in 10 CFR 35.972; or

B. Is identified as a medical physicist on a U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of a high dose rate remote afterloading brachytherapy device; or

C. Is designated as a medical physicist by a U.S. Nuclear Regulatory Commission or Agreement State license of broad scope that authorizes the use of a high dose rate remote afterloading brachytherapy device; or

D. Is identified as teletherapy physicist on a U.S. Nuclear Regulatory Commission or Agreement State license and has completed the manufacturer's training on the use of a high dose rate remote afterloading brachytherapy device; or

E. Is designated as a teletherapy physicist by a U.S. Nuclear Regulatory Commission or Agreement State license of broad scope and has completed the manufacturer's training on the use of a high dose rate remote afterloading brachytherapy device; and, having received training for the specific make(s) and/or model(s) of remote afterloading device(s) used by the licensee.

[Reviewer Note: This condition is for use with limited Part 35 licensees who have requested authorization to appoint their own HDR physicists (medical physicists) in accordance with the criteria set forth in 10 CFR 35.961 and 10 CFR 35.972, and who commit to training the physicists for the specific make(s) and/or model(s) of remote afterloading devices(s) listed on their license.]

112. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off' control is reset at the control panel.

C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use, prior to use. Records of test results shall be maintained for inspection by the U.S. Nuclear Regulatory Commission for a period of 3 years.

D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

113. (RESERVED)

E.24 GAMMA STEREOTACTIC RADIOSURGERY UNIT CONDITIONS

114. A. Licensed material shall be used by or under the supervision of a team of at least three individuals that includes the following: A neurosurgeon, a radiation therapist, and a medical physicist, each of whom is specifically named on the license (and persons with any other speciality as deemed appropriate by the licensee).

B. Radiation therapist(s) for this license are **[fill in name]**.

C. Neurosurgeon(s) for this license are **[fill in name]**.

D. Medical physicist(s) for this license are **[fill in name]**.

[Reviewer Note: The revision of 10 CFR Part 35 does not require the names of all of these individuals. This condition is deleted on the effective date of the Rule.]

115. A. Gamma stereotactic radiosurgery unit sources shall be tested for leakage at intervals not to exceed 6 months. Records of test results shall be kept in units of microcuries or becquerels and maintained for inspection by the U.S. Nuclear Regulatory Commission. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a source received from another person shall not be used until tested for leakage.

B. The tests shall be sufficiently sensitive to detect 0.005 microcurie (185 becquerels) of contamination on the test sample.

C. The test sample shall be taken from selected accessible surfaces of the gamma stereotactic radiosurgery unit. The selected accessible surface should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used helmets. A minimum of a single wipe of the entire surface of the collimator will be taken.

D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the gamma stereotactic radiosurgery unit from use and take action to prevent spread of contamination. A report shall be filed, within 5 days of the date the leak test result is known, with the U.S. Nuclear Regulatory Commission, **[insert appropriate address for Region]**. The report shall specify the source involved, the test results, and corrective action taken.

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the requirements in this condition. This condition is deleted on the effective date of the Rule.]

116. A set of written emergency instructions shall be posted at the gamma stereotactic radiosurgery unit's control console. These instructions shall inform the operator of the procedure to be followed should he be unable to withdraw the patient from the focus beam of radiation with the controls outside the treatment room.

A. Access to the gamma stereotactic radiosurgery room shall be controlled by a door at each entrance. Such doors shall be normally closed.

B. Each entrance to the gamma stereotactic radiosurgery room shall be equipped with an electrical interlock system that will remove the patient from the focus beam of radiation upon opening of any entrance door. The interlock system shall be connected in such a manner that the patient cannot be returned to the focus beam until all entrance doors are closed and the control is reset at the control panel.

C. Electrical entrance to the gamma stereotactic radiosurgery room shall be tested for proper operation at least once every 6 months. Records of test results shall be maintained for inspection by the U.S. Nuclear Regulatory Commission. Records may be disposed of following Commission inspection.

D. In the event of malfunction of any door interlock, the gamma stereotactic radiosurgery unit control shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

117. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the gamma stereotactic radiosurgery unit that could result in increased radiation levels in areas outside the gamma stereotactic radiosurgery treatment room shall be evaluated by a radiation survey made in accordance with **[Condition 118]** and reported to the U.S. Nuclear Regulatory Commission within 30 days following completion of the change(s).

B. Relocation of the gamma stereotactic radiosurgery unit to a new facility is not permitted without prior approval of all the plans and details from the U.S. Nuclear Regulatory Commission. Following such approval and relocation, a radiation survey shall be made in accordance with **[Condition 118]**, and reported to the U.S. Nuclear Regulatory Commission within 30 days after completion of the move.

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

118. Before initiation of a treatment program, and subsequent to each set of source changes, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

1. The gamma stereotactic radiosurgery unit source housing, with the shielding door closed. The maximum and average radiation levels at 1 meter from the gamma stereotactic radiosurgery unit housing in the 'closed' position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.

2. All areas adjacent to the treatment room with the gamma stereotactic radiosurgery unit shielding door in the 'open' position. The survey shall be performed with a phantom in the focus beam of radiation and shall clearly establish:

(i) That the radiation levels in restricted areas are not likely to cause occupational doses in excess of the limits specified in 10 CFR 20.1201 or doses to members of the public in excess of the limits specified in 10 CFR 20.1301; and

(ii) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301(a)(2).

B. Tests shall be made to determine proper operation of:

1. Electrical interlocks on entrance doors to the gamma stereotactic radiosurgery unit treatment room.

2. The gamma stereotactic radiosurgery unit treatment timing device.

A report of the results of the above surveys and tests shall be sent to the U. S. Nuclear Regulatory Commission, **[insert appropriate Regional Office information]**, not more than 30 days after connection of the hydraulic system for the gamma stereotactic radiosurgery unit.

[Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

119. The following shall be performed by the manufacturer or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services:

    A. Installation, relocation, or removal of a gamma stereotactic radiosurgery unit containing sources;

    B. Source replacements;

    C. Any maintenance or repair operations on the gamma stereotactic radiosurgery unit involving a mechanism that could expose the sources, reduce the shielding around the sources, or compromise the safety of the unit and result in increased radiation levels.

    [Reviewer Note: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

120. Notwithstanding the requirements of 10 CFR 35.632(b)(2), 35.632(b)(3), 35.632(b)(6), 35.634(a)(3), and 35.634(a)(4), the licensee is not required to determine the coincidence of the radiation field and the field indicated by a light beam localizing device, the uniformity of the radiation field and its dependence on the orientation of the useful beam, and the accuracy of all distance measuring and localization devices in medical use.

    [Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

E.25 TELETHERAPY

121. Notwithstanding the requirements of 10 CFR 35.647, the licensee is authorized to extend until **[insert date]** the time interval for inspection and servicing of its teletherapy unit.

    [Reviewer Note: This condition may be used without NMSS coordination. See Section 4.13.]

122. The teletherapy physicist for this license is **[insert name]**.

123. The licensee is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

    [Reviewer Note: This condition REQUIRES coordination with NMSS. See Section 4.13.]

124. Notwithstanding the requirements of 10 CFR 35.961, **[insert name]** may perform the duties of the teletherapy physicist for those full-calibration and spot-check measurements specified in 10 CFR Part 35.

[Reviewer Note: This condition REQUIRES coordination with NMSS. See Section 4.13.]

125. (RESERVED)

126. (RESERVED)

E.26 MOBILE NUCLEAR MEDICINE

127. Notwithstanding the requirements of 10 CFR 35.29(d) and 10 CFR 35.80(b), licensed material may be delivered to **[insert licensee's name]** at client addresses in accordance with the procedures outlined in **[letter/application]** dated **[insert date]**.

[Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

128. Notwithstanding the requirements of 10 CFR 35.80(b), the licensee may perform mobile nuclear medicine studies in the imaging van in accordance with procedures in letter(s) dated **[insert date]**.

[Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

129. Notwithstanding the requirements of 10 CFR 35.80(b), the licensee may transport 99Mo/99m Tc generators in the operation of mobile medical service, in accordance with procedures described in letter/application/facsimile dated **[insert date]**.

[Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

130. Notwithstanding the requirements of 10 CFR 35.80(b), the licensee may store the material overnight at locations of use consistent with procedures and commitments proposed by the licensee in the letter(s) dated **[insert date]**.

[Reviewer Note No. 1: This condition REQUIRES coordination with NMSS. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

E.27 CARDIAC PACEMAKERS

REVIEWER NOTE: DO NOT USE THESE CONDITIONS FOR *NEW* PACEMAKER LICENSES. NEW PACEMAKER LICENSE CONDITIONS WILL *REQUIRE* COORDINATION WITH HQ.

131. The specified possession limit for nuclear-powered pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.

132. The licensee shall report to the U.S. Nuclear Regulatory Commission's Regional Office referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.

[*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

133. The licensee shall continue patient follow-up and replacement procedures for the nuclear-powered pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

[*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

134. (RESERVED)

E.28 RADIOPHARMACIES

135. Individuals designated, in writing, to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee. [*Exceptions may be made on a case-by-case basis in accordance with the procedures described in the letter(s) dated* ***[insert date].***] The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

    [Reviewer Note No. 1: The portion of the above condition in *[bracketed italics]* REQUIRES coordination with NMSS. See Section 4.13.]

    [Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes and/or includes the provisions provided by this License Condition. This condition is deleted on the effective date of the Rule.]

136. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers, limited to radiopharmacy-supplied syringes and vials and their contents.

137. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may redistribute alpha-, beta,- or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licenses pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.

    [Reviewer Note: The above condition REQUIRES coordination with NMSS. See Section 4.13.]

138. (RESERVED)

139. (RESERVED)

E.29 WASTE DISPOSAL

140. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to **[insert 65 or 120]** days for decay-in-storage before disposal in ordinary trash, provided:

    A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

[Reviewer Note: This condition may be used for radionuclides with either T½ <= 65 days or 120 days.]

141. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letter dated **[insert date]**.

[Reviewer Note: Use this condition when a waste storage plan has been submitted and reviewed against IN 90-09.]

142. Notwithstanding the requirements of 10 CFR 35.92(a), the licensee may hold any radioactive material authorized by this license with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided the licensee stores the material for decay in accordance with all other requirements of 10 CFR 35.92.

[Reviewer Note No. 1: This condition is for use on medical licenses with a non-human R&D program (generally broad scopes) where the licensee has requested DIS for radioactive waste with a half-live of ≤120 days and has agreed to abide by all other DIS requirements in 35.92. This condition may be used without NMSS coordination. See Section 4.13.]

[Reviewer Note No. 2: The revision of 10 CFR Part 35 supercedes the requirements in this License Condition. This condition is deleted on the effective date of the Rule.]

143. (RESERVED)

E.30 INCINERATION

144. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration, provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.

145. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver 108-m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.

[Reviewer Note: This condition may be used if ash concentrations allow disposal as ordinary waste (see PG 8-10 "Guidance on Disposal of Incinerator Ash as Ordinary Waste"). If the licensee requests to dispose of ash as ordinary waste and the ash does not meet the concentrations specified in PG 8-10, the request must be coordinated with NMSS.]

E.31 TRANSPORTATION

146. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

[Reviewer Note: Put this condition on ALL licenses.]

147. (RESERVED)

148. (RESERVED)

E.32 DISTRIBUTION

149. The licensee may distribute products containing licensed material from **[insert address]**.

[Reviewer Note: For use on distribution only licenses.]

150. Each device distributed pursuant to the conditions of this license shall be in accordance with the following table:

Device Model Number	Isotope	Source Model Number	Maximum Activity Per Source

151. This license does not authorize possession or use of licensed material.

[Reviewer Note: For use on G, E, and MD distribution licenses.]

152. (RESERVED)

E.33 EXEMPT DISTRIBUTION

153. Pursuant to 10 CFR 32 **[insert section number],** the licensee is authorized to distribute the **[smoke detectors or self-luminous products]** specified in Condition **[insert number]** to persons exempt from the requirements for a license pursuant to 10 CFR 30 **[insert section number]** or equivalent provisions of the regulations of any Agreement State.

154. The following **[smoke detectors or self-luminous products]** may be distributed provided the amount of **[insert isotope]** contained in the device does not exceed the amounts specified in the following table:

Device/Series Model	Maximum Quantity per Device

155. The licensee shall file periodic reports as specified in Section 32.XX of 10 CFR Part 32.

E.34 MANUFACTURERS

156. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.20, inclusive, or equivalent regulations of any Agreement State.

157. This license does not authorize commercial distribution of licensed material.

158. This license does not authorize distribution pursuant to 32.72 or 32.74; to persons exempt from licensing; or to general licensees.

[Reviewer Note: Use for Manufacturers and Distributors not authorized to distribute to medical licenses.]

E.35 MISCELLANEOUS – UNSEALED MATERIAL

159. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

160. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

161. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

162. Pursuant to 10 CFR 20.1301(c) and in reliance on statements, procedures and representations made by the licensee in the **[application/letter]** dated **[insert date]** the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level	Unrestricted Area

[Reviewer Note: The above condition requires coordination with NMSS. See Section 4.13.]

E.36 MISCELLANEOUS – SEALED SOURCES

163. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

164. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

[*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

165. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

[Reviewer Note: Paragraph "B" may be deleted if not needed.]

C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

[Reviewer Note: Paragraph "C" may be deleted if not needed.]

D. In the absence of a certificate from a transferor indicating that a leak test has been made, within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

[Reviewer Note: Paragraph "E" may be deleted if not needed.]

F. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

H. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

[Reviewer Note: This part of the condition is used for licensees NOT authorized to perform leak test analysis.]

OR

H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

[Reviewer Note: This part of the condition is used for licensees authorized to collect AND analyze leak test samples.]

I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

[*Warning*: Do not use the record keeping portion of this condition until notified that OMB clearance has been obtained.]

166. (RESERVED)

167. (RESERVED)

E.37 EMERGENCY PLANS/DECOMMISSIONING

168. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 that require consideration of the need for an emergency plan for responding to a release of licensed material.

[Reviewer Note: When requested by the licensee, use where the authorized quantity of any isotope does not require an emergency plan by itself, but where the sum of the isotopes may require an emergency plan. Use of this condition should be infrequent, and usually only where a limited number of radionuclides are in use. Otherwise, the reviewer should request information regarding the inventory or tracking system the licensee will use to verify that the overall limits will not be exceeded.]

169. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR **[30.35(d) or 40.36(b) or 70.25(d)]** for establishing decommissioning financial assurance.

[Reviewer Note: This is a general possession limit for no decommissioning financial assurance for cases where the possession limit is not explicit in license Item 8.]

170. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of **[unsealed byproduct material or readily dispersible source material]** to quantities less than **[10^4 or 10^5 of the applicable limits in Appendix B of 10 CFR Part 30, or 100 μCi]** as specified in 10 CFR **[30.35(d) or 40.36(b) or 70.25(d)]**.

[Reviewer Note: This is a general possession limit for intermediate level decommissioning financial assurance.]

171. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer Note: This condition is used to authorize the types and quantities of materials for a Type C Broad License. The possession limits for these licenses require submission of $150,000 for financial assurance for decommissioning. This condition does not address isotopes with atomic # greater than 83. To eliminate the need for FA, use LC 183 A and B. Alternately, LC 169 may be added. Please note that FA is not required if Item 6 authorizes only material with a half-life of less than 120 days. See note to LC 173 also.]

172. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer Note: This condition authorizes types and quantities of materials for a Type B Broad License. The possession limits for these licenses require submission of financial assurance and a decommissioning funding plan with a cost estimate. To eliminate the need for a DFP, use LC 184 A and B. Alternatively, LC 169 may be added and financial assurance would not be required. Please note that FA is not required if Item 6 authorizes only material with a half-life of less than 120 days. This condition does not address isotopes with atomic #s greater than 83. See also note to LC 174.]

173. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Iodine 129	10 microcuries
Any byproduct material other than alpha-emitting byproduct material not listed in 10 CFR 33.100, Schedule A	100 microcuries

[Reviewer Note: This condition limits the possession limit for a Type C Broad License to eliminate the need for financial assurance for decommissioning. This condition may also be modified to add isotopes not listed in Part 30, Appendix B, that have T½ < 120 days (i.e. phosphorus-33). When these isotopes are added, the reviewer needs to be alert to specify sufficient activity of the isotope to ensure that the allowable percentage is not exceeded. This condition does not address isotopes with atomic numbers greater than 83. For atomic numbers 84-93, see LC 175.]

174. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Notwithstanding 10 CFR 33. 100, Schedule A, Column I, the applicable quantities, for the purpose of performing the unity calculation as provided in Section A of this condition, for the following radionuclides are:

Carbon 14	10 curies
Krypton 85	10 curies
Iodine 129	1 millicurie
Any byproduct material other than alpha-emitting byproduct material not listed in 10 CFR 33. 100, Schedule A	10 millicuries

[Reviewer Note: This condition limits the possession limit for a Type B Broad License to quantities requiring $750,000 financial assurance but below those quantities requiring a decommissioning funding plan. If the license contains this condition and has a Radiation Safety Committee, it is considered to be a Type A Broad Scope. This condition may also be modified to add isotopes not listed in Part 30, Appendix B that have T ½ < 120 days (i.e. phosphorus-33). When these isotopes are added, the reviewer needs to be alert to specify sufficient activity of the isotope to ensure that the allowable percentage is not exceeded. This condition does not address isotopes with atomic numbers greater than 83. See LC 176.]

175. A. **[Same as Part A of LC 173.]**

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II:

(i) the applicable quantities for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Iodine 129	100 microcuries
Any byproduct material other than alpha-emitting byproduct material not listed in 10 CFR 33.100, Schedule A	100 microcuries

(ii) the following nuclides are added:

Any byproduct material with atomic number 84 through 98	10 microcuries

[Reviewer Note: See note for LC 173. This condition can be used only in conjunction with part A of LC 173 to address isotopes with atomic numbers greater than 83. Use of this condition with part A of LC 173 limits the possession limit for a Type C Broad License to quantities below those requiring financial assurance for decommissioning.]

176. A. **[Same as Part A of LC 174.]**

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column I:

(i) the applicable quantities for the following radionuclides are reduced to:

Carbon 14	10 curies
Krypton 85	10 curies
Iodine 129	10 millicuries
Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	10 millicuries

(ii) the following nuclides are added:

Any byproduct material with atomic number 84 through 98	1 millicurie

[Reviewer Note: See note for LC 174. This condition can be used only in conjunction with part A of LC 174 to address isotopes with atomic numbers greater than 83. Use of this condition with part A of LC 174 limits the possession limit for a Type B Broad License to quantities requiring $750,000 financial assurance but below those quantities requiring a decommissioning funding plan.]

177. The license is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

[Reviewer Note: This condition REQUIRES coordination with NMSS. See Section 4.13.]

E.38 POSSESSION ONLY

178. The licensee will take all actions that are within its ability to dispose of its material, and notify NRC within 30 days if disposal is achieved.

Appendix F

Additional Guidance for LTS Users

The following is additional guidance for users of the Licensing Tracking System (LTS) that is not covered in the LTS User's Guide:

F.1 Exemption Data Fields

A requirement to identify, document, and track exemption requests in licensing actions was established by a staff requirements memorandum (SRM) dated January 30, 1997, responding to SECY-96-249, "Staff Response to SRM on SECY-96-147 Regarding Reducing Need for Exemptions and Consistency of the Exemption Process." The LTS worksheet contains exemption data fields that should be annotated to identify the section of the regulation to which the exemption was granted, requested and denied. For example, if an exemption is granted to allow relief from 10 CFR §35.647 (to extend the time for servicing and inspection of a teletherapy unit), then the entry should be 35.647. **Do not use abbreviations or entries other than the specific section of the regulation.** If an exemption is not effective after a specific date, then the date should be entered in LTS in parentheses following the section, i.e., 35.647 (8/31/98).

The exemption field names and synonyms are:

EXEMP_GRANTED	/ EXGRANTD	(55 characters)
EXEMP_REQSTD	/ EXREQSTD	(55 characters)
EXEMP_DENIED	/ EXDENIED	(55 characters)

F.2 Standard LTS Input Abbreviations

Original Entry	**Changed (Mandatory) Entry**
Administration (other than Veterans)	Adm.
and	&
Associated, Associates, or Association	Assoc.
Center	Ctr.
Company	Co.
Corporation	Corp.
County	Cty.
Fort	Ft.
Government	Govt.
Incorporated	Inc.
Industries, Industry	Ind.
Institute, Institution	Inst.
Laboratories	Labs.
Laboratory	Lab.
Limited	Ltd.
Manufacturing	Mfg.
M.D.	MD.
Metropolitan	Metro.

Mount	Mt.
Saint	St.
System, Systems	Sys.
United States	U. S.
Veterans Affairs	V. A.

F.3 Examples of Standard LTS Inputs

Original Entry	**Changed (Mandatory) Entry**
General Services Administration	General Services Adm.
General Tire and Rubber Company	General Tire & Rubber Co.
Geo-Tech Associates	Geo-Tech Assoc.
Saint Luke's Medical Center	St. Luke's Medical Ctr.
Oil Recovery Company Incorporated	Oil Recovery Co., Inc.
Ohio Valley Paving Corporation	Ohio Valley Paving Corp.
Smyth County Community Hospital	Smyth Cty. Community Hospital
Fort Howard Paper Company	Ft. Howard Paper Co.
Government of District of Columbia	District of Columbia, Gov't of
Ford, Bacon and Davis Incorporated	Ford, Bacon, & Davis, Inc.
Electromagnetic Industries	Electromagnetic Ind.
Gateway Technical Institute	Gateway Technical Inst.
Gamma Diagnostic Laboratories, Incorporated	Gamma Diagnostic Labs., Inc.
Immuno-Diagnostic Laboratory, Incorporated	Immuno-Diagnostic Lab., Inc.
Trutom Limited	Trutom Ltd.
Vulcan Manufacturing Company	Vulcan Mfg. Co.
Mabee, M.D., Judson 0.	Mabee MD., Judson 0.
Madison Metropolitan Sewerage District	Madison Metro. Sewerage District
Mount Carmel Medical Center	Mt. Carmel Medical Ctr.
Institute for Cancer Research	Inst. for Cancer Research
Saint Joseph's Hospital	St. Joseph's Hospital
Midwest Inspection Service Limited	Midwest Inspection Service Ltd.
Advanced Medical Systems Incorporated	Advanced Medical Sys., Inc.
United States Postal Service	U. S. Postal Service
Department of Veterans Affairs	V. A., Dept. of

F.4 LTS Input Notes

- One space in between initials (e.g., J. B. Thomas Hospital).
- A comma in between a word and Incorporated (e.g., Moorehead Electric Co., Inc.).
- A period at the end of abbreviations (e.g., Mt. Desert Island Biological Lab.).

- An apostrophe followed by an "s" for names (e.g., St. Peter's Medical Ctr.).
- No spaces in between hyphenated words (e.g., Stablex-Ruetter, Inc.).
- List the city or state before "Department of" or "Government of" (e.g., Indiana, Department of Highways or District of Columbia, Gov't. of). Should be alphabetized under the city or state name and not "Department" or "Govt."
- List university name before "University of" (e.g., Virginia, University of). Should be alphabetized under university name and not "University."
- All names should be alphabetized by their last name, followed by either Jr., MD., etc., with a comma separating the last from the first name, followed by a middle initial (e.g., Deluca Jr., Ph.D., Paul M.).
- Use the two letter state abbreviations at the end of the line (e.g., Atec Assoc. of MD, Inc.).
- You are limited to 35 spaces per licensee name. Use all the abbreviations you can; if the name appears over 35 spaces, the computer will automatically cut the name off.

Appendix G

LTS Program Code Descriptions

PROGRAM CODES USED IN MATERIALS AND FUEL LICENSING AND INSPECTION PROGRAMS

A five-digit program code number is assigned by the NRC to each license to designate the major activity or principal use authorized in the license. Table 1 contains a listing of the program codes used in this document. The regulations applicable to the various activities and uses of byproduct, source and special nuclear materials are contained in Parts 30, 40 and 70, respectively, of Title 10 of the Code of Federal Regulations. A basic understanding of these regulations is a necessary prerequisite to the proper assignment of a program code to a particular activity or use. NRC uses about 100 program codes to classify the thousands of active licenses. (See Table 2 for general information on license numbers.) Some of these program codes narrowly define an activity, such as radiography, while other program codes have a more extensive scope. More than one code may apply to a given license. However, the primary code indicates the licensee's principal use of material. Secondary code or codes may be used to indicate other significant uses.

"**BROAD**" licenses are issued to large facilities having a more comprehensive radiological protection program. These licenses authorize possession of a wide variety of radioactive materials without having each radionuclide and authorization listed on the license. There are three types of broad licenses--Type A, Type B and Type C. It should be noted that broad licensees can be authorized to use up to 100,000 curies in sealed sources for irradiation of materials (see 10 CFR 33.17). Most broad licenses are Type A. (For a clear understanding of these three types, see 10 CFR Part 33.)

Broad-Type A licenses are issued pursuant to 10 CFR 33.13 and typically authorize possession of any byproduct material with an atomic number between 1 and 83, in any chemical or physical form. The maximum possession limit is usually specified both for the individual radionuclide and for the total activity of all radionuclides. These licensees must have a radiological safety officer and a committee that acts in the place of the NRC to make day-to-day decisions about the program.

Broad-Type B licenses are issued pursuant to 10 CFR 33.14 and authorize possession of a variety of radionuclides. The maximum possession limit is specified in 10 CFR 33.100, Schedule A, Column I. Broad-Type B licensees must have a radiological safety officer and adequate administrative controls.

Broad-Type C licenses are issued pursuant to 10 CFR 33.15 and authorize possession of a variety of radionuclides. The maximum possession limit is specified in 10 CFR 33.100, Schedule A, Column II. Broad-Type C licensees must have training and experience as specified in the regulations and the licensee must have adequate administrative controls.

"**OTHER**" licenses are usually issued to smaller organizations requiring a more restrictive license. These licenses are usually more specific in identifying each radionuclide, the chemical and physical form, and the authorized activities and users.

Materials licensing and inspection fee categories are described in 10 CFR Parts 170.31 and 171.16. Multiple fee categories may apply for different activities performed under a single license. The Omnibus Budget Reconciliation Act of 1990, as amended, requires that the Commission recover 100 percent of its budget authority, less appropriations from the Nuclear Waste Fund, by assessing license and annual fees. The fee categories listed in the following pages are a guide to which fee categories are most likely to occur for the program code. In order to determine if a fee exemption may apply, one must refer to 10 CFR 170.11 and 171.11. For multiple categories, they are arranged in order of decreasing likelihood. The Office of the Chief Financial Officer (OCFO) determines fee categories and fee exemption requests on a case-by-case basis, using the licensed material and the authorized use description included in the license. Questions regarding fee issues must be referred to OCFO.

The fuel cycle facility inspection program is described in NRC Inspection Manual, Chapter 2600 (MC 2600). The inspection frequency for the various procedures at these facilities is described in Table 1 of MC 2600.

Inspection priorities for materials licenses are described in detail in NRC Inspection Manual Chapter 2800 (MC 2800) and noted at the end of each program code description in this list.

Inspections are generally conducted as follows:

Initial inspection of licenses in categories with priorities 1 through 5 are conducted within 6 months after material is received and operations under the license have begun. Initial inspections of licenses in categories with priorities 6 and 7 are conducted within one year.

Routine periodic inspections are normally conducted at intervals in years corresponding to the inspection priority for that category:

Priority 1 - yearly,
Priority 2 - every two years,
Priority 3 - every three years,
Priority 4 - every four years and
Priority 5 - every five years.
Priority 6 or 7 are inspected initially and thereafter normally only for resolution of problems.
Priority W - for walk-in or pool type irradiators under construction (MC 2815).

Historically, inspection program categories were used when all licensing was managed at NRC Headquarters. At that time, the Regions used program codes to denote types of licensees, which served the same function as the Headquarters' inspection program categories. After regionalization, when almost all licensing was transferred to the Regions, both designations continued to be used. The following were the meanings of the inspection program categories codes:

Category	Examples
A-Source Material	Unsealed PU (22110) & U 235 (22111)
B-Process and Distribution	Medical Products (02511, 02512, 02513)
C-Radiography	Radiography Fixed (03310) & Field (03320) [C1]
D-Waste Brokers	Waste Disposal Prepackaged (03232) [D1] & Incineration (03233)
E-Industrial	R&D Type A (03610) [E1A], Well Logging (03110-03113), Critical Mass Material (21310, 21320) [E1C]
F-Academic	Academic Broad (01100, 01110, 01120) [F1A-F1C]
G-Medical	Teletherapy (02125) [G3], HDRs (02230, 02231) [G2]
K-Various	Fixed Gauges (03120), Civil Defense (03710)
UFF-Uranium Fuel Fabrication	Hot Cell Operations (21130)

Although inspection program categories are not routinely used, they periodically appear in documents and are denoted here only for historical systems.

Table 1

Program Code	Title
01100	Academic Type A Broad
01110	Academic Type B Broad
01120	Academic Type C Broad
02110	Medical Institution Broad
02120	Medical Institution - QMP required
02121	Medical Institution - QMP not required
02200	Medical Private Practice - QMP required
02201	Medical Private Practice - QMP not required
02210	Eye Applicators Strontium-90
02220	Mobile Nuclear Medicine Service
02230	High Dose Rate Remote Afterloader
02231	Mobile High Dose Rate Remote Afterloader
02240	Mobile Therapy
02300	Teletherapy
02310	Stereotactic Radiosurgery - Gamma Knife
02400	Veterinary Non-Human
02410	In Vitro Testing Laboratories
02500	Nuclear Pharmacies
02511	Medical Product Distribution - 32.72 - Prepared Radiopharmaceuticals
02513	Medical Product Distribution - 32.74 - Sources and Devices
03110	Well Logging Byproduct and/or SNM Tracer and Sealed Sources
03111	Well Logging Byproduct and/or SNM Sealed Sources Only
03112	Well Logging Byproduct Only - Tracers Only
03113	Field Flooding Studies
03120	Measuring Systems Fixed Gauges

Program Code	Title
03121	Measuring Systems Portable Gauges
03122	Measuring Systems Analytical Instruments
03123	Measuring Systems Gas Chromatographs
03124	Measuring Systems Other
03211	Manufacturing and Distribution Type A Broad
03212	Manufacturing and Distribution Type B Broad
03213	Manufacturing and Distribution Type C Broad
03214	Manufacturing and Distribution Other
03218	Nuclear Laundry
03219	Decontamination Services
03220	Leak Test Service Only
03221	Instrument Calibration Service Only - Source Less Than 100 Curies
03222	Instrument Calibration Service Only - Source Greater Than 100 Curies
03225	Other Services
03231	Waste Disposal (Burial)
03232	Waste Disposal Service Prepackaged Only
03233	Waste Disposal Service Incineration
03234	Waste Disposal Service Processing and/or Repackaging
03235	Incineration - Noncommercial (Secondary Code)
03236	Waste Treatment Service (other than compaction)
03240	General License Distribution - 32.51
03241	General License Distribution - 32.53
03242	General License Distribution - 32.57
03243	General License Distribution - 32.61
03244	General License Distribution - 32.71
03250	Exempt Distribution - 32.11 - Exempt Concentrations and Items

Program Code	**Title**
03251	Exempt Distribution - 32.14 - Certain Items
03252	Exempt Distribution - 32.17 - Resins
03253	Exempt Distribution - 32.18 - Small Quantities
03254	Exempt Distribution - 32.22 - Self Luminous Products
03255	Exempt Distribution - 32.26 - Smoke Detectors
03256	Exempt Distribution - 32.21 - C14 Urea Capsules
03310	Industrial Radiography Fixed Location
03320	Industrial Radiography Temporary Job Sites
03510	Irradiators Self Shielded Less Than 10000 Curies
03511	Irradiators Other Less Than 10000 Curies
03520	Irradiators Self Shielded Greater Than 10000 Curies
03521	Irradiators Other Greater Than 10000 Curies
03610	Research and Development Type A Broad
03611	Research and Development Type B Broad
03612	Research and Development Type C Broad
03613	R & D Broad - Multisite-Multiregional
03620	Research and Development Other
03710	Civil Defense
03800	Byproduct Material Possession Only - Permanent Shutdown
03810	Byproduct Material Standby - No Operations
03900	Decommissioning of Byproduct Material Facilities
06100	Low Level Waste Storage at Reactor Sites
06101	Low Level Waste Storage - Other (Secondary Code)
11100	Mills
11200	Source Material Other Less Than 150 Kilograms
11210	Source Material Shielding

Program Code	Title
11220	Source Material Military Munitions - Indoor Testing
11221	Source Material Military Munitions - Outdoor Testing
11230	Source Material General License Distribution - 40.34
11300	Source Material Other Greater Than 150 Kilograms
11400	Uranium Hexafluoride (UF_6) Production Plants
11500	Solution Mining (R & D and Commercial Facilities)
11600	Heap Leach, Ore Buying Stations and Byproduct Recovery
11700	Rare Earth Extraction and Processing
11800	Source Material Possession Only - Permanent Shutdown
11810	Source Material Standby - No Operations
11900	Decommissioning of Source Material Facilities
21130	Hot Cell Operations
21135	Decommissioning of Advanced Fuel R & D and Pilot Plants
21200	Uranium Enrichment Plants
21210	Uranium Fuel Processing Plants
21215	Decommissioning of Uranium Fuel Processing Plants
21240	Uranium Fuel R & D and Pilot Plants
21310	Critical Mass Material - Universities
21320	Critical Mass Material - Other Than Universities
21325	Decommissioning of Critical Mass - Other Than Fuel Fabrication
22110	SNM Plutonium - Unsealed Less Than a Critical Mass
22111	SNM U-235 and/or U-233 Unsealed Less Than a Critical Mass
22120	SNM Plutonium - Neutron Sources Less Than 200 Grams
22130	Power Sources With Byproduct and/or Special Nuclear Material
22140	SNM Plutonium - Sealed Sources in Devices
22150	SNM Plutonium - Sealed Sources Less Than a Critical Mass

Program Code	Title
22151	SNM U-235 and/or U-233 Sealed Sources Less Than a Critical Mass
22160	Pacemaker Byproduct and/or SNM - Medical Institution
22161	Pacemaker Byproduct and/or SNM - Individual
22162	Pacemaker Byproduct and/or SNM - Manufacturing and Distribution
22170	SNM General License Distribution (70.39)
22200	Decommissioning of Other SNM Facilities – Less Than Critical Mass
23100	Fresh Fuel Storage at Reactor Sites
23200	Interim Spent Fuel Storage
23300	SNM Possession Only (Non-Fuel) – Permanent Shutdown
23310	SNM Standby (Non-Fuel) – No Operations
25110	Transport - Private Carriage

Table 2

Part 30 Licenses

A Part 30 license number has the following format: xx-xxxxx-xx.

The first two digits are the state code. The middle five digits are the institutional code, which is the same for each physical location. The last two digits are an identification number. There will be a different identification number for each license held by the same institution.

In addition, a license suffix follows certain license types.

License Suffixes

xx-xxxxx-xxG	General (Distribution)
xx-xxxxx-xxE	Exempt (Distribution)
xx-xxxxx-xxMD	Medical Distribution
xx-xxxxx-xxMA	Medical Approval (no longer used)

Part 40 Licenses

The license number for a Part 40 license is composed of three letters followed by a number.

The first letter is always 'S'.
The second letter can be U, T, or M:
- U - Uranium Only
- T - Thorium Only
- M - Both Uranium and Thorium

The third letter can be A, C, D, E, or B:
- A - Manufacture/Possession of Ore
- C - Storage Only
- D - Sub Critical Assembly
- E - Export
- B - Everything Else

The identification number that follows the three letter code is assigned chronologically.

For example, SMC - xxx is a Part 40 license that covers both uranium and thorium storage.

Part 70 Licenses

All Part 70 Licenses are composed of the same three letter code 'SNM' followed by an identification number, which is assigned chronologically.

BYPRODUCT MATERIAL PROGRAM CODES

Byproduct materials are man-made radioactive materials (except special nuclear material) produced or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials such as in a nuclear reactor. Byproduct material does include activation products from nuclear reactors and from plutonium-beryllium neutron sources, but it does not include activation products from other neutron sources such as californium-252 or accelerators. (See 10 CFR 30.4 and 40.4 for a definition of byproduct material.)

Academic Broad and Academic Other Licenses

Academic Broad and Academic Other licenses are issued to educational institutions for the possession and use of radionuclides for teaching, training and some research purposes, such as carbon-14 dating, equipment calibration, tracer studies and the identification of substances in compounds.

Academic Broad-Type A — Program Code 01100

Academic Broad-Type A licenses are issued to larger institutions where there is a diversity in the utilization of various radionuclides. The kinds and uses of radionuclides may change frequently, even within the same institution. Quantities are usually in the multicurie range. The "Authorized Use" condition on these licenses may permit teaching and training of students, research and development (as defined in 10 CFR 30.4 or laboratory research, including animal studies. If the "Authorized Use" includes medical research, diagnosis and/or therapy, the license should be listed under program code 02110 (Medical Institution Broad), with this program code as a secondary code. (See Regulatory Guides 10.5 and 10.8 for further explanation.)

10 CFR Citation: Part 33.13

Inspection Program Category: F1A
Priority: 2

Fee Category: Applicable to the Licensed Activity

10 CFR 170.31 License Fee (exemption in §170.11 may apply)
10 CFR 171.16 Annual Fee (exemption in §171.11 may apply)

Academic Broad-Type B — Program Code 01110

Academic Broad-Type B licenses are issued for the possession and use of fewer radionuclides and in smaller quantities than Type A licenses. (See Part 33.100, Schedule A, Column I.)

10 CFR Citation: Part 33.14

Inspection Program Category: F1B
Priority: 3

Fee Category: Applicable to the Licensed Activity

10 CFR 170.31 License Fee (exemption in §170.11 may apply)
10 CFR 171.11 Annual Fee (exemption in §171.11 may apply)

Academic Broad-Type C **Program Code 01120**

Academic Broad-Type C licenses are issued for the possession and use of a limited number of radionuclides and in smaller quantities than Type B licenses. (See Part 33.100, Schedule A, Column II.)

10 CFR Citation: Part 33.1

Inspection Program Category: F1C
Priority: 5

Fee Category: Applicable to the Licensed Activity

10 CFR 170.31 License Fee (exemption in §170.11 may apply)
10 CFR 171.11 Annual Fee (exemption in §171.11 may apply)

Medical Institutions

A medical institution is defined in 10 CFR 35.2 to be an organization in which several medical disciplines are practiced. It typically provides 24 hour per day medical, surgical or psychiatric treatment, nursing, food, lodging, etc., to ill or injured patients. Medical Institution Broad and Medical Institution Limited licenses are issued to organizations for the application of byproduct material, or its radiation, to humans. Radioactive material administered to patients is considered to be an *in-vivo* procedure. (Use of radioactive material in test tubes in the laboratory is considered to be an *in vitro* procedure and these licensees are in program code 02410.) Separate licenses are issued to authorize HDR's, teletherapy, and gamma knives. These licensees are listed under program codes 02230, 02300, and 02310.

Medical Institution Broad **Program Code 02110**

Medical Institution Broad licenses are issued to larger medical institutions for the possession and use of a wide range of radionuclides in medical research, diagnosis and therapy. These licensees have Radiation Safety Committees and these committees are allowed to authorize their own users. Some medical institutions have "hybrid broad" licenses. These licenses authorize routine clinical procedures using the Group medical licensing system and include a Broad-Type A, Broad-Type B or Broad-Type C authorization for research. These licenses should be assigned program code 02120 for the primary code and 03610, 03611 or 03612, as appropriate, for the secondary code.

10 CFR Citation: Parts 33.13-15 and 35

Inspection Program Category: G1
Priority: 1

Fee Category: 7B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Institution - QMP Required **Program Code 02120**

Medical Institution - QMP Required licenses are issued to medical institutions required to have a quality management program pursuant to 10 CFR 35.32. This applies to licenses that authorize (1) any teletherapy, (2) any gamma stereotactic radiosurgery, (3) any brachytherapy, (4) any administration of either sodium iodide I-125 or I-131 in quantities greater than 30 microcuries, or (5) any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131. In general, this code should be used as the primary program code only for nuclear medicine and emerging technologies. When licenses satisfy the description of other, more specific program codes (i.e., teletherapy, gamma knife, etc.), the more specific program code should be used as the primary code.

10 CFR Citation: Part 35.32

Inspection Program Category: N/A
Priority: 3

Fee Category: 7B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Institution - QMP Not Required **Program Code 02121**

Medical Institution - QMP Not Required licenses are issued to medical institutions *not* required to have a quality management program pursuant to 10 CFR 35.32 (See Program Code 02120). In general, this code should be used as the primary program code *only* for nuclear medicine and emerging technologies. When licenses satisfy the description of other, more specific program codes (i.e., teletherapy, gamma knife, etc.), the more specific program code should be used as the primary code.

10 CFR Citation: Part 35.32

Inspection Program Category: N/A
Priority: 5

Fee Category: 7B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Private Practice Licenses

Medical Private Practice licenses are issued, pursuant to 10 CFR 35.12, to a physician or physicians for the possession and use of radionuclides in well-established diagnostic and therapeutic procedures usually in their offices outside a medical institution. Separate licenses are issued to authorize HDR's, teletherapy, and gamma knives. These licensees are listed under program codes 02230, 02300, and 02310.

Medical Private Practice - QMP Required — Program Code 02200

Medical Private Practice - QMP Required licenses are issued to a physician or physicians required to have a quality management program pursuant to 10 CFR 35.32. This applies to licenses that authorize (1) any teletherapy, (2) any gamma stereotactic radiosurgery, (3) any brachytherapy, (4) any administration of either sodium iodide I-125 or I-1ĺ1 in quantities greater than 30 microcuries, or (5) any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131. In general, this code should be used as the primary program code *only* for nuclear medicine and emerging technologies. When licenses satisfy the description of other, more specific program codes (teletherapy, gamma knife, etc.), the more specific program code should be used as the primary code.

10 CFR Citation: Part 35.32

Inspection Program Category: N/A
Priority: 3

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Private Practice - QMP Not Required — Program Code 02201

Medical Private Practice - QMP Not Required licenses are issued to a physician or physicians *not* required to have a quality management program pursuant to 10 CFR 35.32 (see Program Code 02200). In general, this code should be used as the primary program code *only* for nuclear medicine and emerging technologies. When licenses satisfy the description of other, more specific program codes (i.e., teletherapy, gamma knife, etc.), the more specific program code should be used as the primary code.

10 CFR Citation: Part 35.32

Inspection Program Category: N/A
Priority: 5

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Eye Applicators Sr-90 **Program Code 02210**

Eye Applicator licenses are issued to a physician or physicians for the possession and use of a device containing a strontium-90 source to treat superficial eye diseases.

10 CFR Citation: Parts 35.11 and 35.12

Inspection Program Category: G2
Priority: 3

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Mobile Nuclear Medicine Service **Program Code 02220**

Mobile Nuclear Medicine Service licenses are issued to a physician or physicians for the receipt of radioactive material at a central facility and preparation of patient doses to be administered at outlying small hospitals, nursing homes, etc., where clinical studies are conducted. (If a medical institution conducts a mobile nuclear medicine service, in addition to performing routine diagnostic and therapeutic procedures at its own location, the license should be assigned a primary program code of 02120 and a secondary program code of 02220.)

10 CFR Citation: Part 35.11 and 35.29

Inspection Program Category: G
Priority: 2

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

High Dose Rate Remote Afterloader **Program Code 02230**

High Dose Rate (HDR) Remote Afterloader licenses authorize the use of large activity byproduct material sealed sources, typically ten curies of iridium-192, for cancer brachytherapy. These sources are connected to a wire and contained in a shielded device that feeds the source into the patient via a catheter. (If a medical institution or private practice performs HDR procedures in addition to performing diagnostic and therapeutic procedures referenced in 35.100, 35.200, 35.300, 35.400, and 35.500, the license should be assigned a primary program code of 02230 and a secondary program code of 02120, 02121, 02200, 02201, or 02500.)

10 CFR Citation: Part 35.400

Inspection Program Category: G2
Priority: 1

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Mobile High Dose Rate Remote Afterloader **Program Code 02231**

Mobile High Dose Rate Remote Afterloader licenses authorize the use of large activity byproduct material sealed sources, typically ten curies of iridium-192, which is transported to outlying small hospitals, nursing homes, etc. for cancer brachytherapy. These sources are connected to a wire and contained in a shielded device that feeds the source into the patient via a catheter. (If a medical institution conducts brachytherapy at outlying locations using a mobile high dose rate remote afterloader in addition to performing the routine diagnostic and therapeutic procedures referenced in 35.100, 35.200, 35.300, 35.400, and 35.500 at the permanent site, the license should be assigned a primary program code of 02231 and a secondary program code of 02120, 2121, or 02500.)

10 CFR Citation: Part 35.400

Inspection Program Category: G2
Priority: 1

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Mobile Therapy **Program Code 02240**

Mobile Therapy licenses authorize the use of byproduct material for cancer therapy *other than* mobile HDR (see Program Code 02231). Equipment for these treatments is transported to outlying small hospitals, nursing homes, etc.

10 CFR Citation: Part 35

Inspection Program Category: N/A
Priority: 2

Fee Category: Applicable to the Licensed Activity

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Teletherapy **Program Code 02300**

Teletherapy licenses authorize the use of cobalt-60 or cesium-137 for external beam cancer therapy. Many of the teletherapy licensees also have a medical institution license (see program codes 02110, 02120, and 02121). Most of the licensees in this group also possess x-ray machines and linear accelerators that are outside NRC jurisdiction.

10 CFR Citation: Part 35.13

Inspection Program Category: G3
Priority: 3

Fee Category: 7A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Stereotactic Radiosurgery-Gamma Knife **Program Code 02310**

Stereotactic Radiosurgery-Gamma Knife licenses are issued for the use and possession of a gamma knife, a radiation therapy unit containing cobalt-60 that is located in a hemispherical shield with collimator ports directed to a single three-dimensional focus inside the unit. These units are used for the treatment of intracranial anomalies.

10 CFR Citation: Part 30.33

Inspection Program Category: G2
Priority: 1

Fee Category: 7A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Veterinary Non-Human **Program Code 02400**

Veterinary licenses are issued to veterinarians for the possession and use of radionuclides in medical diagnosis or therapy procedures on animals. This category does not include any animal research or any of the activities described above in program codes 02110 and 02120.

10 CFR Citation: Part 30

Inspection Program Category: G2
Priority: 5

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

In-Vitro Testing Laboratories **Program Code 02410**

In-Vitro Testing Laboratory licenses are issued to individuals or facilities for the possession and use of radionuclides for performing In-Vitro analyses and are not included in larger programs covered by program codes 02110 and 02120.

10 CFR Citation: Part 30

Inspection Program Category: G2
Priority: 5

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Nuclear Pharmacies **Program Code 02500**

Nuclear Pharmacy licenses are issued to nuclear pharmacies for the possession and distribution of radiopharmaceuticals and other items to hospitals and physicians. These licensees usually purchase various radioactive materials in bulk from larger firms and prepare and distribute patient dosages. Note that most customers are medical use licensees.

10 CFR Citation: Part 32.72

Inspection Program Category: G1
Priority: 1

Fee Category: 3C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Product Distribution-32.72 Prepared Radiopharmaceuticals **Program Code 02511**

Medical Product Distribution licenses are issued to individuals or organizations for the distribution of prepared radiopharmaceuticals containing byproduct material to persons who have been issued a specific license under Part 35.11 for the possession and medical use of byproduct material specified in Section 35.100, 35.200, or 35.300.

10 CFR Citation: Part 32.72

Inspection Program Category: B
Priority: 3

Fee Category: 3D (not involving processing of byproduct material)
3C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Medical Product Distribution-32.74 Sources and Devices **Program Code 02513**

Medical Product Distribution licenses are issued to individuals or organizations for the distribution of sources and devices containing byproduct material to persons who have been issued a specific license under Part 35.11 to use a calibration or reference source or for the possession and medical use of byproduct material specified in 10 CFR Parts 35.400 or 35.500.

10 CFR Citation: Part 32.74

Inspection Program Category: B
Priority: 3

Fee Category: 3D (not involving processing of byproduct material)
3C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Well Logging Licenses

Well logging licenses are issued to firms for the possession and use of radionuclides for subsurface surveying to obtain geological information. These testing procedures are primarily used in oil, gas and mineral exploration to identify subsurface geologic formations.

Well Logging Byproduct and/or SNM Tracer and Sealed Sources — Program Code 03110

Well Logging Byproduct and/or Special Nuclear Material Tracer and Sealed Sources licenses are issued for the possession and use of both sealed and unsealed sources in connection with the exploration for oil, gas or minerals in wells.

10 CFR Citation: Parts 39.11 and 39.13

Inspection Program Category: E
Priority: 3

Fee Category: 5A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Well Logging Byproduct and/or SNM Sealed Sources Only — Program Code 03111

Well Logging Byproduct and/or Special Nuclear Material Sealed Sources Only licenses are issued for the possession and use of only sealed sources to be used in connection with the exploration for oil, gas or minerals in wells. Occasionally, licenses are also issued for the study of subsurface potable aquifers.

10 CFR Citation: Parts 39.11 and 39.13

Inspection Program Category: E
Priority: 3

Fee Category: 5A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Well Logging Byproduct Only-Tracers Only — Program Code 03112

Well Logging Byproduct Only-Tracers Only licenses are issued for the possession and use of only unsealed byproduct material to be used in connection with the exploration for oil, gas or minerals in wells.

10 CFR Citation: Parts 39.11 and 39.13

Inspection Program Category: E
Priority: 3

Fee Category: 5A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Field Flooding Studies **Program Code 03113**

Field Flooding Study licenses are issued for the injection of unsealed byproduct material into large areas for tracing oil and gas reservoirs.

10 CFR Citation: Parts 39.11 and 39.13

Inspection Program Category: E
Priority: 3

Fee Category: 5B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Measuring Systems

Measuring System licenses are issued for the possession and use of measuring devices such as gauges and gas chromatographs containing radionuclides. Frequently, the equipment is serviced and leak tested by the manufacturer or lessor of the equipment.

Measuring Systems Fixed Gauges **Program Code 03120**

Measuring System Fixed Gauge licenses are issued for the possession and use of nonportable gauging devices, i.e., gauges mounted in fixed locations that are designed for measurement or control of material density, flow, level, thickness or weight, etc. The gauges contain sealed sources that radiate through the substance being measured to a readout or controlling device.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 5

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Measuring Systems Portable Gauges **Program Code 03121**

Measuring System Portable Gauge licenses are issued for the possession and use of a portable gauging device, such as a moisture density gauge used at field locations. These gauges contain a gamma-emitting sealed source, usually cesium-137, and/or a sealed neutron source, usually americium-241 and beryllium.

10 CFR Citation: Part 30.33

Inspection Program Category: E1
Priority: 5

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Measuring Systems Analytical Instruments **Program Code 03122**

Measuring System Analytical Instrument licenses are issued for the possession and use of analytical systems such as x-ray fluorescence analyzers that do not fit any of the other measuring system category descriptions.

10 CFR Citation: Part 30.33

Inspection Program Category: E2
Priority: 7

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Measuring Systems Gas Chromatographs **Program Code 03123**

Measuring System Gas Chromatograph licenses are issued for the possession and use of gas chromatographs to be used for quality control testing in industrial processes.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 7

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Measuring Systems Other **Program Code 03124**

Measuring System Other licenses are issued for the possession and use of instrument calibrators, krypton leak detectors, and other measuring systems that do not fit the category descriptions for the measuring system categories (program codes 03120-03123). ***Note:*** Although program code was previously used for "storage-only" of byproduct, source and special nuclear material, program codes 3800, 3810, 11800, 11810, 23300, and 23310 should be used for "storage-only."

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 7

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Manufacturing and Distribution

Manufacturing and Distribution Broad and Manufacturing and Distribution Other licenses are issued for the manufacture and distribution of products containing byproduct material in various forms for a number of diverse purposes. The products are distributed usually to persons specifically licensed by NRC or an Agreement State. Licensees include medical suppliers that process, package and distribute products such as diagnostic test kits, radioactive surgical implants, and tagged radiochemicals for use in medical, academic and industrial research, and for diagnosis and therapy. Licensees are also suppliers who, after purchasing bulk quantities of byproduct material, process, encapsulate, package and distribute these sealed sources for use in gamma radiography, cobalt irradiation, well logging, etc. Major products include gamma radiography sources, cobalt irradiation sources, well logging sources, sources for gauges and smoke detectors and radiochemicals for non-medical research. Firms are also involved with the manufacture, assembly and distribution of various other products that contain radionuclides. The broad licenses are issued to the larger facilities having more comprehensive radiological protection programs. It is also interesting to note that distribution is authorized under a separate license with, for example, an "E" or "G" suffix.

Manufacturing and Distribution Broad-Type A — Program Code 03211

Manufacturing and Distribution Broad-Type A licenses are issued to larger organizations where there is often quite a diversity in the utilization of various radionuclides. The kinds and uses of radionuclides may change frequently, even within the same organization. Broad-Type A licenses are used for programs run by a Radiation Safety Committee that designates the authorized users of the material. The Radiation Safety Committee also has a full- time Radiation Safety Officer (RSO). These licenses authorize the possession and use of a wide variety of radioactive material without having each radionuclide and authorization specifically listed on the license. Quantities are usually in the multicurie range. (See also the introductory remarks and Broad-Type A description in 10 CFR Part 33.)

10 CFR Citation: Part 33.13

Inspection Program Category: B
Priority: 1

Fee Category: 3A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Manufacturing and Distribution Broad-Type B **Program Code 03212**

Manufacturing and Distribution Broad-Type B licenses are issued for the possession and use of fewer radionuclides and in smaller quantities than Type A licenses. (See Part 33.100, Schedule A, Column I. See also the introductory remarks and Broad-Type B description in 10 CFR Part 33.)

10 CFR Citation: Part 33.14

Inspection Program Category: E
Priority: 3

Fee Category: 3A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Manufacturing and Distribution Broad-Type C **Program Code 03213**

Manufacturing and Distribution Broad-Type C licenses are issued for the possession and use of a limited number of radionuclides and in smaller quantities than Type B licenses. (See Part 33.100, Schedule A, Column II. See also the introductory remarks and Broad-Type C description in 10 CFR Part 33.)

10 CFR Citation: Part 33.15

Inspection Program Category: E1C
Priority: 5

Fee Category: 3A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Manufacturing and Distribution Other **Program Code 03214**

Manufacturing and Distribution Other licenses are issued to smaller firms that require a more restrictive license.

10 CFR Citation: Part 30

Inspection Program Category: E
Priority: 3

Fee Category: 3B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Nuclear Laundry **Program Code 03218**

Nuclear Laundry licenses are issued for the cleaning of protective clothing contaminated with radioactive material. Firms in this industry often provide nuclear cleaning services as part of a full line of uniform rental or health physics services.

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 2

Fee Category: 6A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Decontamination Services **Program Code 03219**

Decontamination Service licenses authorize the cleaning and release of contaminated material, usually scrap metal, for unrestricted use.

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 2

Fee Category: 3N

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Leak Test Service Only **Program Code 03220**

Leak Test Service Only licenses are issued to commercial service organizations (those that offer their services to other licensees) for the possession and use of radioactive material for leak testing sealed sources or devices containing sealed sources, analyzing leak test samples and supplying pre-registered leak test kits. Many facilities own or lease equipment, such as gauges or industrial radiographic cameras, that contain sealed sources that have to be periodically tested for removable contamination. This is usually done by wiping the potentially contaminated surfaces of the device or, in some cases, the surface of the sealed source, and analyzing the wipe for radioactive contamination.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 7

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Instrument Calibration Service Only, Source Less Than 100 Curies **Program Code 03221**

These Instrument Calibration Service Only licenses are issued to commercial service organizations (those that offer their services to other licensees) for the possession and use of sealed sources for calibration of radiation survey and monitoring instruments. Each source must have less than 100 curies (3.7 TBq) of radioactive material.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 5

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Instrument Calibration Service Only, Source Greater Than 100 Curies **Program Code 03222**

These Instrument Calibration Service Only licenses are issued to service organizations (those that offer their services to other licensees) for the possession and use of sealed sources for commercial calibration of radiation survey and monitoring instruments. One or more sources has more than 100 curies (3.7 TBq) of radioactive material.

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 3

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Other Services **Program Code 03225**

Other Service licenses are issued to service organizations (those that offer their services to other licensees) for the possession and use of radioactive material for commercial services, such as teletherapy or industrial gauge servicing, that are not covered in the descriptions for program codes 03220-03224.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 3

Fee Category: 3N

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Waste Disposal Service

Waste disposal service licenses authorize the collection, transportation and storage of radioactive wastes. These licenses authorize firms to collect packaged waste material, transport the waste, and temporarily store it before transporting the waste to an authorized burial ground. Some licenses authorize the opening of packages and treatment of the waste to reduce the volume, e.g., compaction.

Waste Disposal (Burial) **Program Code 03231**

Waste Disposal (Burial) licenses authorize the commercial disposal of radioactive wastes containing byproduct, source and special nuclear material received from other persons. It is also used as a secondary code for organizations authorized to dispose of their own waste (non-commercial).

10 CFR Citation: Parts 27, 30 and 61

Inspection Program Category: N/A
Priority: 1

Fee Category: 4A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Waste Disposal Service Prepackaged Only **Program Code 03232**

Waste Disposal Service Prepackaged Only licenses authorize the pick-up, transportation, and storage of only already packaged wastes. This license does not authorize the opening of the packages.

10 CFR Citation: Part 30.33

Inspection Program Category: D1
Priority: 2

Fee Category: 4C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Waste Disposal Service Incineration **Program Code 03233**

Waste Disposal Service Incineration licenses authorize the commercial receipt of wastes from other persons and disposal of the wastes by incineration.

10 CFR Citation: Parts 20.2004 and 30.33

Inspection Program Category: D
Priority: 1

Fee Category: 4A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Waste Disposal Service Processing and/or Repackaging **Program Code 03234**

Waste Disposal Service Processing and/or Repackaging licenses authorize the receipt of packaged wastes from other persons, opening of the packages, compacting and repackaging of wastes, and transfer to an authorized burial ground for disposal.

10 CFR Citation: Part 30.33

Inspection Program Category: D
Priority: 1

Fee Category: 4B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Incineration, Non-Commercial **Program Code 03235**
SECONDARY CODE ONLY

Incineration, Non-Commercial licenses are issued to organizations authorized to incinerate their own radioactive wastes, pursuant to 10 CFR 20.2004.

10 CFR Citation: Part 20.2004 and 30.33

Inspection Program Category: N/A
Priority: N/A

Fee Category: See Primary Code

Waste Treatment Service (Other Than Compaction) **Program Code 03236**

Waste Treatment Service (Other Than Compaction) licenses authorize both the receipt of wastes from other persons and treatment operations more complicated than compacting and repackaging of wastes, and the transfer to an authorized burial ground for disposal. Waste Treatment Service licenses authorize the physical or chemical treatment of contaminated soil, and other solid, liquid, and gaseous wastes. Such waste treatment authorizes removing radioactive materials from waste, reducing the volume of the waste, changing the form of waste, or other similar operations to allow for the transfer of the treated waste to an interim storage facility or an authorized burial ground for disposal. For contaminated soil or water, this includes activities related to site evaluation before waste treatment. This code should *not* be used for incineration. Program code 03233 or 03235 (secondary code) should be used for incineration.

10 CFR Citation: Part 30.33 and 40.32

Inspection Program Category: N/A
Priority: 1

Fee Category: 4A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

General License Distribution

General License Distribution licenses are issued for the distribution of byproduct material, usually sealed sources in devices, to general licensees. (Examples of such items are: gauges, luminous aircraft safety devices, calibration and reference sources, ice detection devices and in vitro test kits.) The requirements for a license for distribution to general licensees are specified in various sections of 10 CFR Part 32. A general licensee does not need to submit a formal application and does not receive a formal license. The conditions of a general license are contained in 10 CFR Part 31. These licenses generally do not authorize possession/use and have a "G" suffix.

General License Distribution-32.51 **Program Code 03240**

General License Distribution licenses are issued to organizations for the transfer of byproduct material in sealed sources contained in devices to persons who may be general licensees under Part 31.5. (Licenses authorizing manufacture and distribution are described in program codes 03211-03214.) General licenses under Part 31.5 are issued to commercial and industrial firms and research, educational and medical institutions for possession of material in devices designed for detecting, measuring, gauging or controlling density, thickness, radiation leakage, or chemical composition or for producing light or an ionized atmosphere.

10 CFR Citation: Part 32.51

Inspection Program Category: E
Priority: 5

Fee Category: 3J

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

General License Distribution-32.53 **Program Code 03241**

General License Distribution licenses are issued to organizations for the distribution of luminous aircraft safety devices to persons who may be general licensees under Part 31.7. General licenses under Part 31.7 are issued for possession and use of tritium or promethium-147 contained in luminous aircraft safety devices, where the device contains less than 10 curies (370GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147.

10 CFR Citation: Part 32.53

Inspection Program Category: E
Priority: 5

Fee Category: 3J

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

General License Distribution-32.57 **Program Code 03242**

General License Distribution licenses are issued to organizations for the distribution of calibration or reference sources to persons who may be general licensees under Part 31.8. General licenses under Part 31.8 are issued for possession and use of americium-241 in calibration and reference sources. A person may be a general licensee under this provision only if they already possess a specific license.

10 CFR Citation: Part 32.57

Inspection Program Category: E
Priority: 5

Fee Category: 3K

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

General License Distribution-32.61 **Program Code 03243**

General License Distribution licenses are issued to organizations for the distribution of ice detection devices to persons who may be general licensees under Part 31.10. General licenses under Part 31.10 are issued for possession and use of strontium-90 in ice detection devices.

10 CFR Citation: Part 32.61

Inspection Program Category: E
Priority: 5

Fee Category: 3J

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

General License Distribution-32.71 **Program Code 03244**

General License Distribution licenses are issued to organizations for the distribution of byproduct material to persons who may be general licensees under Part 31.11. General licenses under Part 31.11 are issued to physicians, hospitals, clinical laboratories or veterinarians in the practice of veterinary medicine for the possession of specified byproduct material in prepackaged units for use in certain *in vitro* clinical or laboratory tests.

10 CFR Citation: Part 32.71

Inspection Program Category: E
Priority: 5

Fee Category: 3K

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution

Exempt Distribution licenses are issued for the commercial distribution of byproduct material to persons who are exempt from the licensing requirements. These exemptions and their limitations, if any, are contained in 10 CFR Parts 30.14-30.20, inclusive. (Examples of exempt items are: watches, balances, locks, compasses, electron tubes, synthetic plastic resin for sand consolidation, and smoke detectors.) The requirements for a license to distribute byproduct material to persons exempt from licensing are contained in 10 CFR Part 32. These licenses generally do not authorize possession and have an "E" suffix.

Exempt Distribution-32.11: Exempt Concentrations and Items — Program Code 03250

Exempt Distribution licenses authorize: (1) the transfer of byproduct material or a product containing byproduct material owned by or in the possession of the licensee; and (2) the transfer of ownership or possession of the material or product containing the byproduct material to persons exempt from the licensing requirements of Part 30.14. The residual byproduct material in a product must be the result of use of byproduct material for another purpose, e.g., a tracer study in a refinery could result in residual contamination of the gasoline, kerosene, or heating oil being produced by the refinery.

10 CFR Citation: Part 32.11

Inspection Program Category: E2
Priority: 5

Fee Category: 3I

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.14: Certain Items — Program Code 03251

Exempt Distribution licenses authorize: (1) the transfer of certain products containing byproduct material, as specified in Part 30.15; or (2) the initial transfer for sale or distribution of products specified in Part 30.15 to persons exempt from licensing requirements.

10 CFR Citation: Part 32.14

Inspection Program Category: E
Priority: 5

Fee Category: 3I or 3H

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.17: Resins **Program Code 03252**

Exempt Distribution licenses are issued for the initial transfer for sale or distribution of synthetic plastic resins containing scandium-46 and designed for sand consolidation in oil wells to persons exempt from the licensing requirements of 10 CFR 30.16.

10 CFR Citation: Part 32.17

Inspection Program Category: E
Priority: 5

Fee Category: 3I

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.18: Small Quantities **Program Code 03253**

Exempt Distribution licenses are issued for the commercial distribution of small quantities of byproduct material to persons exempt from the licensing requirements of 10 CFR 30.18.

10 CFR Citation: Part 32.18

Inspection Program Category: E
Priority: 5

Fee Category: 3I

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.22: Self Luminous Products **Program Code 03254**

Exempt Distribution licenses are issued for the initial transfer of self-luminous products containing tritium, krypton-85 or promethium-147 to persons exempt from the licensing requirements of 10 CFR 30.19.

10 CFR Citation: Part 32.22

Inspection Program Category: E
Priority: 5

Fee Category: 3I or 3H

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.26: Smoke Detectors **Program Code 03255**

Exempt Distribution-32.26 licenses are issued for the initial transfer of gas and aerosol detectors containing byproduct material and designed to protect life or property from fire and airborne hazards to persons exempt from the licensing requirements of 10 CFR 30.20.

10 CFR Citation: Part 32.26

Inspection Program Category: E
Priority: 5

Fee Category: 3H

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Exempt Distribution-32.21: Carbon-14 Urea Capsules **Program Code 03256**

Exempt Distribution-32.21: Carbon-14 Urea Capsule licenses are issued for the commercial distribution of a radioactive drug containing one microcurie of carbon-14 to persons exempt from the licensing requirements of 10 CFR 30.21.

10 CFR Citation: Part 32.21

Inspection Program Category: E
Priority: 5

Fee Category: 3I

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Industrial Radiography

Industrial Radiography licenses are issued for the possession and use of sealed radioactive materials, usually in exposure devices or "cameras," that emit gamma rays for non-destructive examination of pipelines, weld joints, steel structures, boilers, aircraft, ship parts and other high stress alloy parts. The radioisotopes most commonly used are cobalt-60 and iridium-192. Radiography can be conducted either in a permanent facility or at a temporary job site.

Industrial Radiography Fixed Location — Program Code 03310

Industrial Radiography Fixed Location licenses are issued for the possession and use of sealed radioactive materials in exposure devices. These licenses are issued to organizations to conduct activities only at permanent facilities, usually designed and shielded for radiography. However, a "field-site" could be authorized as a place of use.

10 CFR Citation: Part 34.11

Inspection Program Category: C
Priority: 1

Fee Category: 3O

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Industrial Radiography Temporary Job Sites — Program Code 03320

Industrial Radiography Temporary Job Sites licenses are issued for the possession and use of sealed radioactive materials in exposure devices. These licenses are issued to organizations to conduct activities at multiple temporary locations.

10 CFR Citation: Part 34.11

Inspection Program Category: C1
Priority: 1

Fee Category: 3O

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Irradiators

Irradiator licenses are issued for the possession and use of high activity sealed sources of radioactive material in an irradiator constructed so that the sealed sources and the material being irradiated are contained in a shielded volume. Primary uses include non-human medical and non-medical research conducted chiefly by universities, and industrial uses, such as the sterilization of medical products and drugs, and treating of hardwoods, plastics and semi-conductor materials. The radioisotopes most commonly used in these irradiators are cobalt-60 and cesium-137. Self-shielded units are designed so that the operator cannot inadvertently place any part of his/her body in the path of the beam. Units other than self-shielded units may rely on facility alarms and interlocks to prevent accidental exposure to radiation. "Irradiators Other" include units where the source is stored and/or used under water.

Irradiators Self Shielded Less Than 10,000 Curies — Program Code 03510

These Irradiator Self Shielded licenses are issued for the possession and use of sealed sources of byproduct material in devices in which the total radioactivity is less than ten thousand curies (370 TBq). The device is constructed so that there is no external beam during use and is "usually a small cabinet type device that is not built in."

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 5

Fee Category: 3E

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Irradiators Other Less Than 10,000 Curies — Program Code 03511

These Irradiator Other licenses are issued for the possession and use of sealed sources of byproduct material in devices in which the total radioactivity is less than ten thousand curies (370 TBq). The device does not provide shielding from the radiation beam, so that additional shielding needs to be provided and special radiation protection precautions need to be taken.

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 3

Fee Category: 3F

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Irradiators Self Shielded Greater Than 10,000 Curies **Program Code 03520**

These Irradiator Self Shielded licenses are issued for the possession and use of sealed sources of byproduct material in devices in which the total radioactivity is ten thousand curies (30 TBq) or more. The device is constructed so that there is no external beam during use and is "usually a small cabinet type device that is not built in."

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 3

Fee Category: 3E

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Irradiators Other Greater Than 10,000 Curies **Program Code 03521**

These Irradiator Other licenses are issued for the possession and use of sealed sources of byproduct material in devices in which the total radioactivity is ten thousand curies (370 TBq) or more. The device does not provide shielding from the radiation beam, so that additional shielding needs to be provided and special radiation protection precautions need to be taken.

10 CFR Citation: Part 30.33

Inspection Program Category: E3
Priority: 1*

Fee Category: 3G

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

*Irradiators under construction are inspected as needed.

Research and Development

Research and Development licenses are issued to private organizations, universities and government agencies for the possession and use of radionuclides in research. Typical uses include: irradiation of materials, tracers and catalysts in chemical reactions, measurement using industrial gauges, and the identification of substances in compounds. In private industry, uses are primarily in product development. In academic institutions, research and development includes training of students in the use of radioactive materials. Broad licenses are issued to larger facilities having a more comprehensive radiation protection program where the types of research being conducted may fluctuate rapidly. Typical activities include environmental analysis, food quality studies, aerospace and engineering applications, and product development.

Research and Development Broad-Type A — Program Code 03610

Research and Development Broad-Type A licenses are issued to larger organizations where there is a diversity in the utilization of various radionuclides. The kinds and uses of radionuclides may change frequently, even within the same organization. Broad-Type A licenses are used for programs run by a Radiation Safety Committee that designates the authorized users of the material. The Radiation Safety Committee also has a full time Radiation Safety Officer (RSO). These licenses are issued for the possession and use of a wide variety of radioactive material without having each radionuclide and authorized use listed on the license. Quantities are usually in the multicurie range. (See also the introductory remarks and Broad-Type A description in 10 CFR Part 33.)

10 CFR Citation: Part 33.13

Inspection Program Category: E1A
Priority: 2

Fee Category: 3L

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Research and Development Broad-Type B — Program Code 03611

Research and Development Broad-Type B licenses are issued for the possession and use of fewer radionuclides and smaller quantities of byproduct material than Type A licenses. (See Part 33.100, Schedule A, Column I. See also the introductory remarks and Broad-Type B description in 10 CFR Part 33.)

10 CFR Citation: Part 33.14

Inspection Program Category: E1B
Priority: 3

Fee Category: 3L

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Research and Development Broad-Type C **Program Code 03612**

Research and Development Broad-Type C licenses are issued for the possession and use of a limited number of radionuclides and smaller quantities of byproduct material than Type B licenses. (See Part 33.100, Schedule A, Column II. See also the introductory remarks and Broad-Type C description in 10 CFR Part 33.)

10 CFR Citation: Part 33.15

Inspection Program Category: E1C
Priority: 5

Fee Category: 3L

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Research and Development Broad-Multisite-Multiregional **Program Code 03613**

Research and Development Broad-Multisite-Multiregional licenses are issued for the possession and use of material at fixed facilities in more than one Region, e.g., the Department of the Air Force or the Department of the Navy. (See also the introductory remarks and R&D Broad-Type A Program Code 03610 description.)

10 CFR Citation: Part 33.12

Inspection Program Category: E1A
Priority: 1

Fee Category: 3L

10 CFR 170.31 License Fee (Federal Agencies Exempt)
10 CFR 171.16 Annual Fee (Air Force and Navy Master Licenses, a.k.a. Fee Category 17 under 171.)

Research and Development Other **Program Code 03620**

Research and Development Other licenses are issued for the possession and use of specifically designated radionuclides in academic institutions, industrial facilities and medical institutions for non-human research.

10 CFR Citation: Part 30.33

Inspection Program Category: E
Priority: 5

Fee Category: 3M

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Civil Defense **Program Code 03710**

Civil Defense licenses are issued for the possession and use of sealed sources for training individuals in civil defense activities, such as calibrating and demonstrating the use of radiation survey and monitoring equipment.

10 CFR Citation: Part 30.33

Inspection Program Category: K
Priority: 5

Fee Category: 8A

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Byproduct Material Possession Only - Permanent Shutdown **Program Code 03800**

Byproduct Material Possession Only-Permanent Shutdown licenses authorize possession and/or storage of residual contamination or other byproduct material in anticipation of removal of all licensed material and eventual termination of the license. This license is for licensees that have stated in writing that they have permanently ceased operations with no intent to restart. A formal request for license termination is not required at this time. Only packaging and shipping operations necessary to remove licensed materials from the site are authorized. No decontamination or other work involving byproduct material is authorized. (This code should not be used for licenses covered by program codes 03232, 03900, or 06100. Additionally, program codes that were used previous to this one should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Part 30.32

Inspection Program Category: N/A
Priority: 2

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Byproduct Material Standby - No Operations **Program Code 03810**

Byproduct Material Standby - No Operations licenses authorize possession and/or storage of by-product material for licensees that are not conducting the principal activity for which the license was issued but have not decided to cease operations permanently yet. Only packaging and shipping operations necessary to remove licensed material from the site are authorized. No decontamination or other work involving byproduct material is authorized. (This program code should not be used for licenses covered by program codes 03232, 03900, or 06100. Additionally, program codes which were used previous to this one should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Parts 30, 170

Inspection Program Category: N/A
Priority: 2

Fee Category: 3P

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Decommissioning of Byproduct Material Facilities **Program Code 03900**

For licensees that have notified the Commission of their intent to terminate all or part of their activities involving byproduct material and are authorized to decommission the facilitie(s). A plan may have been submitted for decontaminating the property and equipment so that it may be released for unrestricted use. Includes licensees performing decontamination, decommissioning, reclamation, or site restoration in order to release a facility.

10 CFR Citation: Part 30.32

Inspection Program Category: N/A
Priority: 1

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Storage of Reactor Low-Level Waste **Program Code 06100**

Low-Level Waste Storage licenses are issued to operating power reactors to allow additional onsite storage of low-level radioactive wastes generated onsite.

10 CFR Citation: Part 30

Inspection Program Category: See 1
Priority: See 1

Fee Category: 4A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Low-Level Waste Storage - Other **Program Code 06101**
SECONDARY CODE

Low-Level Waste Storage - Other licenses are issued to allow onsite storage of low-level radioactive waste generated onsite.

10 CFR Citation: Part 30

Inspection Program Category: See 1
Priority: See 1

Fee Category: Applicable to the licensed activity

SOURCE MATERIAL PROGRAM CODES

Source materials are materials essential to the production of special nuclear materials. Source material includes: 1) uranium (and depleted uranium produced as enrichment tails) or thorium, or any combination thereof, in any physical or chemical form; or 2) ores that contain by weight 0.05% or more of uranium, thorium, or any combination thereof. (See 10 CFR 40.4 for a definition of source material.)

Source Material licenses are issued for the possession and use of refined uranium and/or thorium for fabrication, research, and manufacture of consumer products such as ceramics and glassware; manufacture of refractories; uranium shielding; analytical standards; and other uses not specifically classified. A smaller number of these licenses are issued to allow the possession of uranium and/or thorium for other uses such as distribution and storage. An even smaller number of these licenses are issued to allow the use of uranium in subcritical assemblies. Priority sections denoted as 1/0 indicate that inspections are done at least annually but that the LTS system tracks "O".

Mills **Program Code 11100**

Mill licenses are issued for the extraction of uranium from uranium ore. In milling operations, the ore is crushed, ground to a fine mesh, and chemically treated to extract the uranium and convert it to a form called yellowcake.

10 CFR Citation: Part 40

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 2A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Source Material Other Less Than 150 Kilograms **Program Code 11200**

These Source Material Other licenses are issued for the possession and use of source material for fabrication, research or manufacture of consumer products. These licenses do not allow the possession of more than one hundred and fifty kilograms of material.

10 CFR Citation: Part 40

Inspection Program Category: E
Priority: 5

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material Shielding **Program Code 11210**

Source Material Shielding licenses are issued for the possession and use of source material in shielding for protection against radiation.

10 CFR Citation: Part 40

Inspection Program Category: E
Priority: 7

Fee Category: 2B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material Military Munitions Indoor Testing **Program Code 11220**

Source Material Military Munitions Indoor Testing licenses are issued for the possession, use and testing of depleted uranium products designed for the military. The testing is done within an enclosure - the testing usually results in fragmentation of the munitions.

10 CFR Citation: Part 40

Inspection Program Category: K
Priority: 5

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material Military Munitions Outdoor Testing **Program Code 11221**

Source Material Military Munitions Outdoor Testing licenses are issued for the possession, use and testing of depleted uranium products designed for the military.

10 CFR Citation: Part 40

Inspection Program Category: K
Priority: 3

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material General License Distribution 40.34 **Program Code 11230**

Source Material General License Distribution licenses are issued either to authorize the initial transfer of industrial products and devices containing depleted uranium, or to initially transfer such products or devices to persons who have been issued a general license under Part 40.25. (A general license under Part 40.25 authorizes the receipt, acquisition, possession, use or transfer of depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.)

10 CFR Citation: Part 40.34

Inspection Program Category: E
Priority: 5

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material Other Greater Than 150 Kilograms **Program Code 11300**

These Source Material Other licenses are issued for the possession and use of source material for fabrication, research or manufacture of consumer products. These licenses authorize the possession of more than one hundred and fifty kilograms of material.

10 CFR Citation: Part 40.32

Inspection Program Category: E
Priority: 3

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Uranium Hexafluoride Production Plants **Program Code 11400**

Uranium Hexafluoride Production Plant licenses are issued for the possession and use of uranium to allow the conversion of yellowcake and/or ore concentrates to uranium hexafluoride (UF6).

10 CFR Citation: Part 40.32

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 2A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Solution Mining (R&D and Commercial Plants) **Program Code 11500**

Solution Mining licenses are issued for the extraction of uranium from uranium ores. The only mining operation licensed by the NRC is solution mining, which is leaching of ore by injection of liquid chemicals into the geologic formation. (Conventional mining is not under the NRC jurisdiction.)

10 CFR Citation: Part 40.32

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 2A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Heap Leach, Ore Buying Stations and Byproduct Recovery **Program Code 11600**

Heap Leach, Ore Buying Stations and Byproduct Recovery licenses are issued for the recovery of source material from low grade uranium ores, from old tailings piles or from a small ore body at a location distant from the mill complex. The heap leach process consists of spraying or trickling an acid solution over sections of the heap pile. Pipes or covered drains in the base of the pile collect the uranium-enriched solution after it percolates through the heap.

10 CFR Citation: Part 40.32

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 2A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Rare Earth Extraction and Processing **Program Code 11700**

Rare Earth Extraction and Processing licenses are issued for the possession and use of source material for processing activities not directly related to the nuclear fuel cycle. This category includes licenses for extraction of metals, heavy metals, and rare earths. The extraction may be accomplished by a number of different methods, with the source material generally considered to be a waste product. This program code category is not used for milling operations (program code 11100), licenses for uranium hexafluoride production (program code 11400) and licenses for processing and recovery of source material in *in-situ* or heap leaching operations (program code 11500).

10 CFR Citation: Part 40

Inspection Program Category: E
Priority: 3

Fee Category: 2A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Source Material Possession Only - Permanent Shutdown **Program Code 11800**

Source Material Possession Only-Permanent Shutdown licenses authorize possession and/or storage of residual contamination, tailings piles, slag piles, or other source material in anticipation of removal of all licensed material and eventual termination of the license. This license is for licensees that have stated in writing that they have permanently ceased operations with no intent to restart. A formal request for license termination is not required at this time. Only packaging and shipping operations necessary to remove licensed material from the site are authorized. No decontamination or other work involving the material is authorized. (Program codes that were used previous to this one should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Parts 40, 51, and 170

Inspection Program Category: UFO
Priority: 2

Fee Category: 2C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Source Material Standby - No Operations **Program Code 11810**

Source Material Standby - No Operations licenses authorize possession and/or storage of source material for licensees that are not conducting the principal activity for which the license was issued but have not decided to cease operations permanently yet. Only packaging and shipping operations necessary to remove licensed material from the site are authorized. No decontamination or other work involving source material is authorized. (Program codes which were used previous to this code should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Parts 40, 51, and 170

Inspection Program Category: N/A
Priority: 2

Fee Category: 2C

10 CFR 70.31 License Fee
10 CFR 171.16 Annual Fee

Decommissioning of Source Material Facilities **Program Code 11900**

Decommissioning of Source Material Facilities licenses are issued for facilities that have notified the Commission of their intent to terminate all or part of their activities involving source material and authorize decommissioning the facilities where the activities were performed. A plan may have been submitted for decontaminating the property and equipment so that it may be released for unrestricted use. This includes licenses which authorize decontamination, decommissioning, reclamation, or site restoration to release a facility.

10 CFR Citation: Part 40

Inspection Program Category: N/A
Priority: 1

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

SPECIAL NUCLEAR MATERIAL PROGRAM CODES

Special nuclear materials include plutonium, uranium-233, uranium enriched in the isotopes of uranium-233 or uranium-235, and any material artificially enriched in any of these materials. (See 10 CFR 40.4 and 70.4 for a definition of special nuclear material.) Priority sections denoted as "1/0" indicate inspections are done at least annually, but LTS tracks "O".

Hot Cell Operations **Program Code 21130**

Hot Cell Operation licenses are issued for the processing and fabrication of reactor fuels containing uranium and/or plutonium for experimental purposes. Some facilities also perform chemical operations to recover the uranium and plutonium from scrap and other off-specifications materials.

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0*

Fee Category: 1A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

*Typically 3 inspections per year

Decommissioning of Advanced Fuel R&D And Pilot Plants **Program Code 21135**

Decommissioning of Advanced Fuel R&D and Pilot Plants licenses are issued for a facility that has notified the Commission of its intent to terminate a portion or all of its activities involving special nuclear materials and/or has submitted to the Commission a plan and schedule for decontaminating the facilities, property, and equipment so that it may be released for unrestricted use. The program code is used only when the license authorizes the decommissioning/decontamination.

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Uranium Enrichment Plants* **Program Code 21200**

Uranium Enrichment Plant licenses are issued for the possession and use of source and special nuclear material for the purpose of enriching natural uranium in the U-235 isotope. Existing and planned plants enrich uranium in the form of uranium hexafluoride, either by gaseous diffusion or gas centrifuge methods. Future plants may use other forms of uranium and methods of enrichment. Plants whose product is for eventual use in commercial power reactors enrich uranium up to about 5 percent U-235, while plants whose product is for naval reactor propulsion enrich uranium to greater than 90 percent U-235.

10 CFR Citation: Parts 40, 70

Inspection Program Category: N/A
Priority: 1/0

Fee Category: 1E

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

*May have Resident Inspectors

Uranium Fuel Fabrication Plants* **Program Code 21210**

Uranium Fuel Fabrication Plants licenses are issued for the possession and use of special nuclear material for the purpose of fabricating uranium fuel elements. In most uranium facilities where light water reactor fuels are processed, low-enriched uranium hexafluoride is converted to uranium dioxide pellets and inserted into zirconium tubes. The tubes are fabricated into fuel assemblies, which are shipped to commercial nuclear power plants. In other facilities, high-enriched uranium is processed into naval reactor fuel and fabricated into naval reactor cores or core components. Licenses are for possession and use of five kilograms or more of uranium-235 that has been enriched to less than twenty percent.

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 1A

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

*Typically 3 inspections per year

Decommissioning of Uranium Fuel Fabrication Plants **Program Code 21215**

Decommissioning of Uranium Fuel Fabrication Plants licenses are issued for a facility that has notified the Commission of its intent to terminate a portion or all of its activities involving special nuclear materials and/or has submitted to the Commission a plan and schedule for decontaminating the facilities, property, and equipment so that it may be released for unrestricted use. This program code is used only when the license authorizes the decontamination or decommissioning.

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Uranium Fuel Research and Development and Pilot Plants **Program Code 21240**

Uranium Fuel Research and Development and Pilot Plant licenses are issued for the possession and use of enriched uranium for purposes such as academic training and in research and development activities associated with nuclear fuel other than fuel processing (program code 21210). Licenses authorize possession and use of five kilograms or more of enriched uranium-235 in unsealed form, or two kilograms or more of uranium-233 in unsealed form.

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 1A or 1D

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Critical Mass Material Licenses **Program Codes 21310 & 21320**

Critical Mass Material licenses are issued for the possession and use of special nuclear material in quantities sufficient to form a critical mass, specifically, more than 350 grams of enriched uranium-235, more than 200 grams of uranium-233, more than 200 grams of plutonium, or any combination thereof. Program code 21310 is for universities. Program code 21320 is for all licenses except those issued to universities.

10 CFR Citation: Part 70

Inspection Program Category: E1C
Priority: 5

Fee Category: 1A

10 CFR 170.11 License and Inspection Fee (exemption in §170.11 may apply to program code 21310)
10 CFR 171.11 Annual Fee (exemption in §171.16 may apply to program code 21310)

Decommissioning of Critical Mass - Other Than Fuel Fab **Program Code 21325**

Decommissioning of Critical Mass - Other Than Fuel Fab licenses are issued for a facility that has notified the Commission of its intent to terminate a portion or all of its activities involving special nuclear materials and/or has submitted to the Commission a plan and schedule for decontaminating the facilities, property, and equipment so that it may be released for unrestricted use. This program code is used only when the license authorizes the decontamination or decommissioning.

10 CFR Citation: Part 70

Inspection Program Category: E1C
Priority: 1

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material Plutonium - Unsealed, Less Than A Critical Mass **Program Code 22110**

Special Nuclear Material Plutonium-Unsealed, Less Than A Critical Mass licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total) in unsealed form for purposes such as biological and chemical testing and for calibration of instruments, etc.

10 CFR Citation: Part 70

Inspection Program Category: A
Priority: 2

Fee Category: 1D

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material, U-235 and/or U-233 - Unsealed, Less Than A Critical Mass **Program Code 22111**

Special Nuclear Material U-235 and/or U-233 - Unsealed, Less Than a Critical Mass licenses are issued for the possession and use of small quantities of uranium (less than 350 grams of U-235 and/or less than 200 grams of U-233) in unsealed form for purposes such as biological and chemical testing and for calibration of instruments, etc.

10 CFR Citation: Part 70

Inspection Program Category: A
Priority: 2

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material, Plutonium Neutron Sources, Less Than 200 Grams **Program Code 22120**

Special Nuclear Material, Plutonium Neutron Sources, Less Than 200 Grams licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total), usually combined with beryllium, as the source of neutrons for instrument calibration, teaching and demonstration purposes, and industrial applications.

10 CFR Citation: Part 70

Inspection Program Category: E2
Priority: 5

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Power Sources with Byproduct and/or Special Nuclear Material **Program Code 22130**

Power Sources with Byproduct and/or Special Nuclear Material licenses are issued for the possession and use of byproduct and/or special nuclear material to generate heat or power that will be used for remote weather stations, space satellites and other special applications.

10 CFR Citation: Parts 30 and 70

Inspection Program Category: K
Priority: 7

Fee Category: 3P, 3B or 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material Plutonium-Sealed Sources in Devices **Program Code 22140**

Special Nuclear Material Plutonium-Sealed Sources in Devices licenses are issued for the possession and use of sealed sources containing special nuclear material installed in devices such as gauges.

10 CFR Citation: Part 70

Inspection Program Category: F
Priority: 5

Fee Category: 1C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material Plutonium-Sealed Sources Less Than A Critical Mass **Program Code 22150**

Special Nuclear Material Plutonium-Sealed Sources Less Than A Critical Mass licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total) in sealed sources, for purposes such as biological and chemical testing and for calibration of instruments, etc.

10 CFR Citation: Part 70

Inspection Program Category: F
Priority: 5

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material, Uranium-235 and/or Uranium-233 Sealed Sources, Less Than A Critical Mass **Program Code 22151**

Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less Than A Critical Mass licenses are issued for the possession and use of small quantities of uranium (less than 350 grams of U-235 and/or less than 200 grams of U-233) in sealed sources for purposes such as biological and chemical testing and for calibration of instruments, etc.

10 CFR Citation: Part 70

Inspection Program Category: F
Priority: 5

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Pacemaker-Byproduct Material and/or Special Nuclear Material

Pacemaker-Byproduct Material and/or Special Nuclear Material licenses are issued to: (1) medical facilities for the surgical implantation of pacemakers that are powered by a device containing byproduct or special nuclear material; (2) manufacturers and distributors for the distribution of these pacemakers; and (3) individuals, most often Canadian citizens on holiday, with implanted nuclear pacemakers, who are visiting the United States.

Pacemaker-Byproduct and/or Special Nuclear Material - Medical Institution — Program Code 22160

Pacemaker-Byproduct and/or Special Nuclear Material-Medical Institution licenses are issued to a medical facility for the surgical implantation of nuclear powered cardiac pacemakers and follow-up, recovery and disposal of the pacemakers.

10 CFR Citation: Parts 30 and 70

Inspection Program Category: K
Priority: 7

Fee Category: 7C

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Pacemaker-Byproduct and/or Special Nuclear Material - Individual — Program Code 22161

Pacemaker-Byproduct and/or Special Nuclear Material-Individual licenses are issued to the recipient of a surgically implanted nuclear powered cardiac pacemaker. These licenses authorize the person, usually from a foreign country, to possess the pacemaker while in the United States.

10 CFR Citation: Parts 30 and 70

Inspection Program Category: K
Priority: 7

Fee Category: Not subject to 10 CFR 170 and 10 CFR 171 fees.

Pacemaker-Byproduct and/or Special Nuclear Material - Manufacturing and Distribution — Program Code 22162

Pacemaker-Byproduct and/or Special Nuclear Material-Manufacturing and Distribution licenses are issued for the manufacture of byproduct or special nuclear material powered cardiac pacemakers and the distribution of these pacemakers to licensees authorized to receive them.

10 CFR Citation: Parts 30 and 70

Inspection Program Category: B
Priority: 1

Fee Category: 1D or 3B

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Special Nuclear Material, General License Distribution (70.39) **Program Code 22170**

Special Nuclear Material, General License Distribution licenses are issued to individuals for the initial distribution of calibration or reference sources containing plutonium to persons who have been issued a general license under Part 70.19. General licenses under Part 70.19 authorize the possession and use of plutonium in calibration or reference sources. A person may be a general licensee under this provision only if the person is already a specific licensee.

10 CFR Citation: Part 70.39

Inspection Program Category: B
Priority: 5

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Decommissioning of Other SNM Facilities - Less than Critical Mass **Program Code 22200**

Decommissioning of Other SNM Facilities - Less Than Critical Mass licenses are issued for facilities not covered by other SNM program codes that have notified the Commission of their intent to terminate all or part of their activities involving special nuclear material and are authorized to decommission the facilitie(s). A plan may have been submitted for decontaminating the property and equipment so that it may be released for unrestricted use. This includes licensees performing decontamination, decommissioning, reclamation, or site restoration in order to release a facility. This program code is used only when the license specifically authorizes decommissioning or decontamination.

10 CFR Citation: Part 70

Inspection Program Category: N/A
Priority: 1

Fee Category: 14

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Fresh Fuel Storage at Reactor Sites* **Program Code 23100**

Fresh Fuel Storage at Reactor Sites licenses are issued to commercial nuclear power reactors that have been granted a Construction Permit (CP) but not an Operating License (OL). These licenses authorize the storage of new unirradiated reactor fuel elements containing special nuclear material. Once a reactor has been granted an OL, this Part 70 materials license is terminated. (The OL includes authorization for possession of the fuel.)

10 CFR Citation: Part 70

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 1D

10 CFR 170.21 License Fee
10 CFR 171.16 Annual Fee

*Resident Inspectors audit more frequently

Interim Spent Fuel Storage **Program Code 23200**

Interim Spent Fuel Storage licenses are issued under 10 CFR Part 72 for possession of power reactor spent fuel and other radioactive materials associated with spent fuel storage, in an independent spent fuel storage installation. (These licenses are issued for up to 20 years.)

10 CFR Citation: Part 72

Inspection Program Category: UFF
Priority: 1/0

Fee Category: 1B, 13A, 13B, or 13C

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

*Resident Inspectors audit more frequently

SNM Possession Only (Non-Fuel) - Permanent Shutdown **Program Code 23300**

SNM Possession Only (Non-Fuel) - Permanent Shutdown licenses authorize possession and/or storage of residual contamination or other special nuclear material in anticipation of removal of all licensed material and eventual termination of the license. This license is for licensees that have stated in writing that they have permanently ceased operations with no intent to restart. A formal request for license termination is not required at this time. Only packaging and shipping operations necessary to remove licensed materials from the site are authorized. No decontamination or other work involving the material is authorized. This category does not include storage of fresh reactor fuel or spent reactor fuel (see program codes 23100 and 23200). (Program codes that were used previous to this one should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Parts 70, 170

Inspection Program Category: N/A
Priority: 2

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

SNM Standby (Non- Fuel) - No Operations **Program Code 23310**

SNM Standby (Non-Fuel) - No Operations licenses authorize possession and/or storage of SNM for licensees that are not conducting the principal activity for which the license was issued, but have not yet decided to cease operations permanently yet. Only packaging and shipping operations necessary to remove licensed material from the site are authorized. No decontamination or other work involving the material is authorized. This category does not include storage of fresh reactor fuel or spent reactor fuel (see program codes 23100 and 23200). (Program codes that were used previous to this one should be used as secondary codes to ensure traceability of license types within LTS.)

10 CFR Citation: Parts 70, 170

Inspection Program Category: N/A
Priority: 2

Fee Category: 1D

10 CFR 170.31 License Fee
10 CFR 171.16 Annual Fee

Transport-Private Carriage **Program Code 25110**

Transport-Private Carriage licenses are issued for the possession of byproduct, source and special nuclear materials in packages authorized under Part 71, and in private carriage from a carrier's terminal to the licensee's facility, all within the United States.

10 CFR Citation: Parts 30, 40 and 70

Inspection Program Category: N/A
Priority: N/A

Fee Category: 12

10 CFR 170.31 License and Inspection Fee
10 CFR 171.16 Annual Fee

Appendix H

Coordinators for Certain Federal Organizations

1. **AIR FORCE** (Master Materials License)

Department of the Air Force
HQ AFMOA/SG02
ATTN: MAJ Kristin N. Swenson
110 Luke Avenue, Suite 400
Bolling Air Force Base
Washington, DC 20332-7050

USAF CONTACT: MAJ Kristin N. Swenson
Phone: (202) 767-4308
FAX: (202) 767-5302
Emergency Number: 1-888-506-0383
-(then put your number in)
Alternate Contact: MAJ James Hicks (202) 767-4307

Region IV NRC Contact: Tony Gaines (817) 860-8252

2. **ARMY**

a. **Corps of Engineers:** (civil works)

U.S. Army Corps of Engineers
ATTN: CESO-I (Stout)
Room 4122-C
20 Massachusetts Avenue, N.W.
Washington, DC 20314-1000

CoE Contact: Robert Stout, Manager
Industrial Hygiene Program
Phone: (202) 761-8566
FAX: (202) 761-1369
Emergency Numbers: (202) 761-0251 (duty hours)
(202) 697-0218 (non-duty hours)

b. **Surgeon General:** (all medical and teletherapy licenses)

U.S. Army Medical Command
ATTN: MCHO-CL-W (COL Eric Daxon)
2050 Worth Road
Ft. Sam Houston, TX 78234-6010

DASG Contact: COL Eric Daxon
Phone: (210) 221-6612
FAX: (210) 221-6673
Staff Duty Officer: (210) 221-8445
Emergency Number: (703) 697-0218

c. **Army Program Manager**: (worldwide industrial, R&D, test)

Commander Headquarters
U.S. Army Materiel Command
ATTN: AMCSF-P (J. Manfre)
5001 Eisenhower Avenue
Alexandria, VA 22333-0001

AMC Contact: John Manfre
Phone: (703) 617-9475
Voice Mail: (703) 617-9340
FAX: (703) 617-9469
E-mail: JMANFRE@HQAMC.ARMY.MIL
Emergency Number: (703) 617-9223
Alternate Contact: Donald Pittenger
Phone: Same as Mr. Manfre

HQ AMC Contact: COL Robert Cherry
200 Army Pentagon
Washington, DC 20310-0200
Phone: (703) 601-2413
Fax: (703) 601-2417
E-mail: GOTOBUTTON B
M_1_CHERRYRN@HQDA.ARMY.MIL

3. **NAVY** (Master Materials Licensee)

Department of the Navy
Chief, Naval Operations (N-455)
ATTN: Executive Secretary (CDR Higgins)
Navy Radiation Safety Committee
2211 S. Clark Place
Arlington, VA 22244-5108

USN Contact: CDR Garry Higgins
Phone: (703) 602-5365
FAX: (703) 602-4786
Emergency Number: (703) 602-2569 (N-45)

NRC Region II Contact: Mike Fuller (404) 562-4714

4. DEFENSE LOGISTICS AGENCY

Defense Logistics Agency
ATTN: CAAE (M. Coogen)
8725 John J. Kingman Road, Suite 2533
Ft. Belvoir, VA 22060-6221

DLA Contact: Michael Coogen
Phone: (703) 767-6231
FAX: (703) 767-6093
Emergency Number: (703) 767-6666 (M-F)
(703) 767-5200 (Weekend)

5. DEPARTMENT OF INTERIOR

Department of the Interior
Office of the Secretary
Office of Managing Risk and Public Safety
ATTN:J. Harrison Daniel
755 Parfet Street, Suite 364
P.O. Box 25007 D-115
Denver, CO 80225-0007

DOI Contact: J. Harrison Daniel
Phone: (303) 236-7128 (Ext. 229)
FAX: (303) 236-7336

Back-up: Raymond Kunicki
1849 C Street, N.W. MS 7356
Washington, DC 20246
Phone: (202) 219-0189
FAX: (202) 219-5078

6. **DEPARTMENT OF VETERANS AFFAIRS**
(formerly VETERANS ADMINISTRATION)

Department of Veterans Affairs
National Health Physics Program (115HP)
ATTN: E. Lynn McGuire
Bldg. 33, Room 102 (115-HP/NCR)
2200 Forth Roots Drive
North Little Rock, AR 72114

VA Contact: E. Lynn McGuire, Program Director
Phone: (501) 257-1571
(501) 257-1570

7. **U.S. DEPARTMENT OF AGRICULTURE**

U.S. Department of Agriculture
OP, SHAD, R.S.
ATT.: Mr. John Jensen
5601 Sunnyside Avenue
Beltsville, MD 20705

USDA Contact: Mr. John Jensen
Phone: (301) 504-2440
FAX: (301) 504-2450

NRC Region I Contact: Keith Brown, Ph. D. (610) 337-5048

Appendix I

Examples of Technical Assessments of Licensing Actions for Categorical Exclusion

DEC 08, 1993

MEMORANDUM FOR: Ronald R. Bellamy, Chief
Nuclear Materials Safety Branch, RI

FROM: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: DEPARTMENT OF THE INTERIOR, BUREAU OF MINES REQUEST TO AMEND LICENSE NO. 37-01712-11 TO USE XENON-133 IN A VENTILATION TRACER STUDY AT THE EXPERIMENTAL MINE, BRUCETON RESEARCH CENTER, PITTSBURGH, PENNSYLVANIA, AND NEED FOR AN ENVIRONMENTAL ASSESSMENT

This refers to your Technical Assistance Request dated August 7, 1992 (Enclosure 1), requesting guidance on whether the Department of the Interior, Bureau of Mines, License No. 37-01712-11, amendment request to use xenon-133 in a ventilation tracer study at the Experimental Mine, Bruceton Research Center, Pittsburgh, Pennsylvania, requires the NRC to perform an environmental assessment (EA) pursuant to 10 CFR Part 51. Based on a technical analysis and pursuant to 10 CFR 51.22(c)(14)(v) and (xvi), an EA will not be required.

During the technical review, certain radiation safety concerns associated with the use of xenon-133 gas in a mine and by a licensee authorized to use only sealed sources, foils, and sealed gap were identified and summarized in Enclosure 2. Once the radiation safety issues and other issues identified by the Region are resolved with the licensee, the Region can amend the license to authorize the requested study.

The staff determined three categorical exclusion paragraphs for licensing and regulatory actions are applicable to the Bureau of Mines' proposed amendment request to use xenon-133 gas. The "research and development" paragraph is applicable because the license is a research and development license and the amendment is for a research study. The "medical and veterinary" paragraph is applicable in combination with the "catch all" paragraph because the form and quantity of xenon-133 use is similar to that in the medical use of xenon-133.

1. 10 CFR 51.22(c)(14)(v), "Use of radioactive materials for research and development and for educational purposes'".

   The proposed study is a research and development study that involves releasing xenon-133 gas into the fresh air stream within the mine, measuring concentrations of xenon-133 at points in the mine downstream from the injection point, and releasing xenon-133 directly into the environment (i.e., in air or water leaving the mine). The purpose of the study is to develop a xenon-133 detector and determine whether xenon-133 can be used as a tracer in an underground coal mine to characterize air flow patterns for later use in characterizing underground coal fires.

   The March 12, 1984, statement of consideration for the final rule amending 10 CFR Part 51 to implement section 102(2) of the National Environmental Policy Act of 1969 (49 FR 9352) provided additional guidance on this categorical exclusion. The following statements addressing research and development situations with direct releases into the environment are in the statement of consideration. "This categorical exclusion does not encompass . . . (b) performance of field

studies in which licensed material is deliberately released into the environment for the purposes of the study. . . ."

While it initially appears the proposed study should have an environmental assessment because it is a field study (it is performed outside a laboratory in an unrestricted area that is inseparable from the environment) with all releases going directly into the environment, additional consideration must be given to the isotope used and the effect of the planned releases on the environment. The short half-life of xenon (5.24 days), the quantities released, and the chemical inertness of xenon ensure that it will have a negligible effect on the environment.

The most probable route of exposure to humans, other animals, and plants is direct contact with the radioactive xenon-133 gas. The probability and consequences of any effects will diminish with time, as the xenon-133 decays. The most significant hazard to humans is the external radiation hazard from the beta particles and x-rays associated with being submersed in the xenon-133 gas cloud. In this study, the probability of direct or prolonged contact of xenon-133 with the general public, other animals and plants is insignificant because of scheduling the study for a weekend, restricting entrance to the mine, releasing multiple small quantities of xenon-133 (12 to 48 millicuries per release) instead of one large release (300 millicuries), and environmental dispersion and dilution factors.

Internal hazards are not as significant because the metabolically inactive xenon-133 is rapidly removed from humans and other animals by exhaling. In medical studies xenon-133 is generally washed out of the lungs in one or two breaths regardless of whether the xenon-133 is administered as a inhaled gas or injected in saline suspension. (Xenon-133 in the 10 to 30 millicurie levels are physiologically inactive and gas entering the circulatory system is returned to the lungs and exhaled after a single pass through the peripheral circulation.) This gives a very low probability of internal exposure. Xenon-133 is not expected to either enter underground potable water supplies or remain in plants or animals because of its short radioactive half-life and its chemically inert properties. The short half-life precludes it from reaching underground potable water supplies before it decays away. It is unlikely xenon-133 will enter the plant or animal food chain, because the experiment will be performed in the winter and the xenon will have decayed away before the normal plant growing season.

Therefore, this study meets the criteria of a categorical exclusion for research and development under this paragraph.

2. 10 CFR 51.22(c)(14)(xvi) many use of source, byproduct, or special nuclear material not listed above, which involves quantities and forms of source, byproduct, or special nuclear material similar to those listed in paragraphs (c)(14)(i) through (xv) of this section (Category 14)."

10 CFR 51.22(c)(14)(iv), "Medical and veterinary".

The description of activities in the statements of consideration for this exclusion includes among other things "laboratory use of unsealed sources for performance of diagnostic tests or for tracer studies for research purposes. . . . releases to air and water . . . are of small quantities, or if of larger quantities, are short lived. Effluent releases . . . are estimated at less than 10 percent of the applicable limits."

The licensee proposed to release up to a maximum of 300 millicuries (the total available on site)

of xenon-133 in either 20 releases of 12 millicuries each or 5 releases of 48 millicuries. The releases will be made over a one to two day period with waiting periods between the releases. The waiting periods are to either insure the xenon-133 detector is reading background or position the detector at a new location. The xenon-133 is ultimately exhausted outside the mine. The total effluent releases, if averaged over a year, are significantly less than 10 percent of the 10 CFR Part 20 releases permitted to the unrestricted area. Further, xenon-133 is a short-lived radioisotope with a half-life of 5.24 days.

In medical institutions, xenon-133 is used in patient diagnostic lung perfusion and brain imaging tests. During the perfusion test, patients are rebreathing xenon-133 gas administered in dosages between 6 and 30 millicuries per test. Some brain imaging studies use xenon-133 gas; others use xenon-133 suspended in saline. A number of patients can be scheduled for the xenon-133 perfusion or brain imaging tests in any day. The xenon-133 in the medical institution may be either exhausted to the outside or released into a xenon-133 trap where it is held until it decays.

Therefore, the Bureau of Mines' proposed activity meets both the categorical exclusion criteria of 10 CFR 51.22(c)(14)(v) "use of radioactive materials for research and development" and the criteria of 10 CFR 51.22(c)(14)(xvi) because the quantities and form of the xenon-133 gas are similar to the quantities and form of xenon-133 used in the medical activities categorical exclusion (i.e., 10 CFR 51.22(14)(iv)), and does not need an environmental assessment.

If you have any questions, please feel free to contact Dr. Donna-Beth Howe of my staff at (301) 504-2636.

/RA/
Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:

1. TAR fm R. Bellamy dtd 8/7/92 **(NOT ENCLOSED)**

2. Summary of Radiation Safety Concerns

APPENDIX I

Occupational Concerns

There are a number of reasons why the licensee needs to place special emphasis on providing specific radiation safety and emergency procedure instruction to individuals participating in the study, restricting access to the mine area during the study, insuring adequate surveys are performed before returning the mine to unrestricted use, and informing Bruceton Research Center personnel of the study. These reasons include the following: the fact that the study involves radioactive materials and situations outside the normal radiological experiences of either the Pittsburgh Research Center or the University of Kentucky, Department of Mining Engineering personnel; the unique situation of people being able to enter and exit the mine only through the radioactive material effluent release "stack;" and the fact that normally the Experimental Mine and each worker in the mine is an unrestricted area and non-radiation worker, respectively.

All personnel involved with the experiment should be provided with instructions and written procedures on both the handling of xenon-133 in normal or emergency situations and adequate area or removable contamination survey procedures, as well as, the normal proper receipt, transportation, and disposal procedures. These instructions should include:

1. identification of the responsible individual for specific radiation protection decisions;

2. procedures to handle spill situations inside and outside the mine;

3. procedures to handle situations increasing the xenon-133 air concentration, or causing xenon-133 movement into areas outside the predicted study area (i.e., the surface buildings or other portions of the mine);

4. personnel evacuation procedures in the event of a spill, failure of the mine ventilation system, and other adverse situations;

5. guidance on the performance of area and removable contamination surveys and determination of when the mine is releasable to unrestricted use;

6. a policy on minimum weather condition requirements needed prior to starting the xenon-133 releases (i.e., conditions to insure the dispersion of the xenon outside the mine).

The licensee should be encouraged to use non-radioactive methods to determine probable areas of xenon-133 concentration in the mine due to dead spaces prior to releasing the xenon-133. This information can be used in assuring the surveys performed prior to releasing the mine to unrestricted use are adequate.

ENCLOSURE 2

November 23, 1993

NOTE TO: Files

FROM: Donna-Beth Howe, Ph.D.
Medical and Academic Section

SUBJECT: STAFF TECHNICAL REVIEW OF DEPARTMENT OF INTERIOR, BUREAU OF MINES, REQUEST TO RELEASE XENON-133 FOR VENTILATION STUDIES IN THE BUREAU OF MINES EXPERIMENTAL RESEARCH MINE AT BRUCETON RESEARCH CENTER PITTSBURGH PENNSYLVANIA

Background

By letter dated July 17, 1992, the Department of the Interior, Bureau of Mines, Pittsburgh Research Center (the licensee) requested an amendment to Byproduct Material License 37-01712-11 to perform a xenon-133 gas mine ventilation study at the Pittsburgh Research Center Experimental Mine, located at the Bruceton Research Center, Pittsburgh, Pennsylvania.

The license currently authorizes the use of byproduct material in the form of sealed sources, foils, and gas in sealed tubes for reference standards, analytical instruments, gauges, and research and development of instruments and gauges. It does not authorize the use of unsealed gases and prohibits the release of byproduct material in field studies. The proposed amendment would authorize the licensee to possess and store xenon-133 gas at the Pittsburgh Research Center (part of the Bruceton Research Center). It would also authorize the University of Kentucky, Department of Mining Engineering personnel in coordination with the licensee's personnel to use xenon-133 gas for a ventilation study in the licensee's Experimental Mine.

The xenon-133 gas study is part of a research project entitled, "Assessment of the extent of fires in abandoned mine lands using non-invasive tracer techniques." The purpose of the study is to evaluate the potential effectiveness of xenon-133 gas as a tracer to determine the ventilation characteristics of underground mines for application to underground coal mine fires. In the United States alone, there are 100 underground coal mine fires. They are a serious health, safety, and environmental hazard because of toxic fumes emissions and air quality deterioration.

The three basic methods of fighting underground mine fires, i.e., excavation, making fire barriers, and surface sealing, are usually unsuccessful, because it is difficult to locate and treat all combustion areas. Underground fire is easily spread by the migration of hot gases to discontinuous and discrete fire zones; initial information and monitoring techniques are usually inadequate; and fires presumed to be extinguished can reignite within 3 to 5 years if all the burning material was not removed or cooled.

Information gained from xenon-133 gas movement measurements made at the Experimental Mine, with its well-characterized tunnels and air ventilation system, is expected to be used later in coordination with xenon-133 releases at mines with underground fires to map inaccessible air pathways supplying oxygen to the underground fire. If the tracer can be used to identify the source of incoming air, then human intervention to control the flow of oxygen feeding the fire may reduce the extent of the combustion, decrease the probability of re-ignition, and increase the effectiveness of current and future fire fighting techniques.

The University of Kentucky researchers have experience using xenon-133 gas in laboratory situations, but they do not have experience with releasing radioactive materials in field or mine situations. They have performed tests with small scale ventilation ducts and computer models. Certain parameters such as mine void, roughness of the walls, and location of the detector, that may have significant effects on the performance and detection of the tracer in an actual mine fire, cannot be replicated in the laboratory.

Xenon, a noble gas, is chemically inert, heavier than air, and may temporarily adhere to some plastics, rubber, and dust particles or get dispersed in water. Xenon-133 has a 5.24 day half-life and decays by beta emission to stable cesium-133. The primary radiation products are a beta particle with a maximum energy of 346 kiloelectron volts (99 percent per disintegration) and cesium X-rays with an energy of 81 kiloelectron volts (36 percent per disintegration).

In this review, the term "xenon release point" will be used to refer to the initial point where the xenon-133 is released within the mine into the mine airstream, and the terms "xenon exhaust point" or "mine exhaust point" will be used to designate the final point at which xenon-133 is released from the mine into the environment. These terms should reduce the inherent confusion found when the word "release" is used in a radiological hazards review. Another point of confusion may exist because the mine layout differs *significantly from* most areas where radioactive gasses are used. In most cases, the area has at least one door for people to enter or exit the area, a vent to bring fresh air in, and a stack to exhaust volatilized radioactive effluents. In the Experimental Mine, the twin side-by-side entrance tunnels serve not only as the doorway into and out of the mine, but also the only stack to exhaust the radioactive effluents. Therefore, people entering the mine during the experiment, in effect, are walking into the effluent release stack.

Mine Description

The Experimental Mine is part of three interconnected coal mines located under the Bruceton Research Center. The Bruceton Research Center is a 0.96 square kilometer (238 acre) facility, in the Pittsburgh suburbs, where approximately 1600 people work for three different federal agencies. The Bureau of Mines Pittsburgh Research Center owns approximately 0.72 square kilometers (178 acres) and has approximately 700 employees and contractors; the Department of Energy owns approximately 0.24 square kilometers (60 acres) and has approximately 800 employees and contractors; and the Mine Safety and Health Administration occupies one building and has approximately 100 employees.

The Experimental Mine is connected to the Safety Research Coal Mine by two tunnels and two 7.6-centimeter (3-inch) holes. The two tunnels between the coal mines can be closed off by closing the explosion-proof doors in the permanent bulkheads. The tunnels connected by the two 7.6-centimeter (3-inch) holes can be isolated from the xenon-133 gas study area by closing the doors in other bulkheads. The Safety Research Coal Mine is, in turn, connected by a 5 centimeter (2-inch) hole to the third coal mine.

Both the Experimental Mine and the Safety Research Coal Mine are active research mines. For radiological purposes, these mines are considered unrestricted areas both before and after the study and the Bureau of Mines workers in the mine at these times are not radiological occupational workers. The Experimental Mine provides a dedicated mine for the testing of coal and gas explosions and for underground fire research in a full-scale multiple-entry mine.

The Experimental Mine elevation ranges from 308 to 312 meters (1009 to 1022 feet) and the overburden ranges from 1 or 2 meters to 30 meters (few feet to 100 feet). One office building (building 143), a series

of 9 side-by-side maintenance trailers (building 145), and six other smaller structures (buildings 2, 7, 12, 25, 102, and 105) are located directly over the portion of the Experimental Mine where the xenon-133 study will be performed. Another office building (building 140) is 23 meters (75 feet) above the tunnels adjacent to the xenon study area. For the most part, the workers in these structures are not radiological workers.

The normal Experimental Mine ventilation system forces outside air into the mine through a 12-meter (40-foot) shaft from the surface approximately 46 meters (150 feet) from the Experimental Mine's side-by-side walk-in entrances. The air is then pushed through the "east air course" (which includes the xenon-133 gas study area). The xenon release point is approximately 165 meters (540 feet) from the mine entrance, and the first detector measurement location is approximately 107 meters (350 feet) from the xenon release point. From the last experimental measurement Point in the east air course, the air passes through approximately 1.5 kilometers (4,800 feet) of additional tunnels before it is exhausted out of the same two side-by-side walk-in mine entrances described above. These final tunnels are actually 3 interconnecting parallel 0.4 kilometer (0.25 mile) long tunnels. The air may pass through either 2 or 3 of these tunnels.

The average dimensions of the tunnels are 2 meters (6.5 feet) high and 3 meters (10 feet) wide. The calculated volume of the tunnel between the release point and the first detector location ranges from approximately 784,000 to 1,577,000 liters (27,700 to 55,700 cubic feet) depending on whether the air flows into connecting or parallel tunnels. The calculated volume of the tunnel between the first detection point and the last detection point is 1,104,000 liters (39,000 cubic feet). The total volume of all the tunnels the xenon is expected to flow through is about 12,000,000 liters (412,000 cubic feet).

The air flow at the release point is expected to be 1,400,000 liters per minute (50,000 cubic feet per minute). One air exchange in the part of the mine exposed to xenon should occur every 8.3 minutes. The length of a xenon-133 slug is about 390 meters (1,200 feet).

Study Description

The study is expected to extend over one weekend in the next 12 months. It is not expected to be repeated. Pressurized xenon-133 gas will be released into the fresh air stream at the xenon release point which is within the mine at the beginning of an area referred to as the "coal reserve for standard samples" ("coal reserve"). The detector will be positioned close to the floor downstream from the xenon release point and be constantly sampling the air during the measurement part of the study. Since the University of Kentucky has only one analytical xenon-133 gas detector, multiple xenon-133 gas releases are necessary to collect data at each of the five detection points and to collect data for multiple measurements at each detection point. The detector was built specifically for the xenon mine study and its performance will be an integral part of the study.

The xenon-133 analytical detector has a 8.1-liter counting chamber with a 15 milliliter per minute pump. The instrument can detect concentrations of xenon-133 as low as 3.7 becquerels per liter (0.1 nanocurie per liter).

Three 3,700 megabecquerel (100 millicurie) xenon-133 vials will be used during the study. At the Mine, the 3,700 megabecquerels (100 millicuries) of xenon-133 will be injected into an evacuated 28.3 liter (1 cubic foot) pressure cylinder. Nitrogen gas will be added to the gas cylinder until the xenon concentration is 22.6 megabecquerels per liter (0.61 millicurie per liter) (i.e., the cylinder is pressurized to approximately 585 kilopascals (85 pounds per square inch) and contains164 liters of gas). If all

11,100 megabecquerels (300 millicuries) are used in the study, the pressurized tank filling procedure will be repeated two more times.

In the first trial, 444 megabecquerels (12 millicuries) will be released to confirm that the xenon-133 goes into the air stream and the detector can measure it. If the xenon-133 is detected, three other 444 megabecquerel (12 millicurie) releases will be made. A total of 4 xenon-133 releases and detector measurements will be made for each detector location. There will be a total of 5 detection points.

If the xenon-133 is not detected, the first measurement will be repeated with a 1,776 megabecquerel (48 millicurie) release. If the xenon-133 is then detected, the experiment will continue with 4 more 1,776 megabecquerel (48 millicurie) releases (one for each new detector location). If the xenon-133 is still not detected, the experiment will be terminated.

The xenon release point, approximately 165 meters from the coal mine entrance, will remain stationary. The xenon-133 gas will be released through a tube terminating 183 centimeters (6 feet) downstream from the cylinder and the researchers. For the first measurement, the detector will be approximately 107 meters away and a total of 444 megabecquerels (12 millicuries) of xenon-133 will be released over a 2-minute period. The mine air flow will be adjusted so that at the xenon release point it is 1,400,000 liters per minute (50,000 cubic feet per minute). If the xenon is evenly distributed throughout the 2-minute slug of air, the xenon-133 concentration in the slug would be 159 becquerels per liter (4.3 nanocuries per liter) and the slug will be about 390 meters long.

The calculated volume of the tunnel between the xenon release point and the first detector location ranges from approximately 784,000 liters (27,700 cubic feet) to 1,577,000 liters (55,700 cubic feet) depending on whether the air flows into the connecting or parallel tunnels in the "coal reserve." The calculated volume of the tunnel between the first detection point and the last detection point is 1,104,000 liters (39,000 cubic feet). The total volume of all the tunnels from the xenon release point to the mine exhaust point (the mine's main entrance) is about 12,000,000 liters (412,000 cubic feet). With an air flow of 1,400,000 liters per minute, one air exchange should occur every 8.3 minutes during the study in the part of the mine exposed to xenon.

If the air flow is 1,400,000 liters per minute, the front of the slug should move from the xenon release point to the first detector point in either 30 or 60 seconds and to the fifth detector location in either 75 or 135 seconds. The straightest air path to this point includes four 4-meter (12-foot) dead-end side corridors, 2 right-angle turns preceding short dead-end tunnels, and a 250 foot dead-end tunnel. These side corridors and tunnels are expected to create eddy currents and dead spaces that will affect the shape of the xenon slug and the concentration of xenon-133 in the slug. Some xenon-133 may settle out in dead air spaces. once the xenon slug passes the fifth data collection point, there are approximately 1.5 kilometers (4,800 feet) of tunnels before the xenon exhaust point is reached.

The Environment

The regional geology of the Bruceton Research Center consists of sedimentary rocks of the Pennsylvania and Permian periods. The Monogahela Group, a cyclic sequence of shale, limestone, sandstone, and coal, tops the hills at the site. The Pittsburgh Coal within this group has been extensively mined out in the area. The Conemaugh Group, a cyclic sequence of sandstone, shale and limestone, underlies the Monongahela Group. The stream beds and river valleys are lined with quaternary alluvium. Two clay veins run over the xenon study area. (A clay vein is a geological crack in the coal formation that filled with clay and earth during the geological development of the area.)

Two surface streams, McElheny Run and Lick Run, are located at the boundaries of the Bruceton Research Center. McElheny Run flows into Lick Run which in turn converges with Peters Creek which empties into the Monogahela River about 5.5 miles down stream. The Experimental mine is described as a dry mine with little or no water seepage.

Most drinking water comes from surface water drawn from the Monogahela River either at Elrama (about 9.7 kilometers (6 miles) upstream from Peters Creek) or Becks Run (about 23.3 kilometers (14.5 miles) downstream of Peters Creek). Thirteen houses within a 6.4 kilometer (4 mile) radius and two others within a 1.6 kilometer (1 mile) radius of the Bruceton Research Center receive their drinking water from ground wells.

The closest wetland is located along Lick Run near the Wallace Road-Cochran Mill intersection. This wetland has a 0.16 kilometer (0.1 mile) frontage on Lick Run and is classified as R30WZ (i.e., riverine upper perennial open water intermittently exposed/permanent). According to the Pennsylvania Game Commission, there are no endangered or threatened animals in the vicinity of the Bruceton Research Center. The mine is actively used for experiments and there are no known animals living in the Experimental Mine.

The nearest communities consist of two separate housing developments about 1.6 kilometers (1 mile) northeast and southeast of the Center, respectively. Each development has approximately 1,000 residents. The closest residences are approximately 0.2 kilometers (0.13 miles) from the property line. Only two houses within the 1.6 kilometer (1 mile) radius have drinking water wells.

Pathways to the Environment

The natural dynamics of sun, wind, and rain are factors in determining the xenon-133 movement in the environment. Xenon, a noble gas, is chemically inert, heavier than air, essentially insoluble in water, and temporarily adheres to some plastics and rubber.

In general, xenon-133 gas presents a submersion hazard, rather than an inhalation or absorption hazard. Xenon-133 gas is generally washed out of the lungs in one or two breaths regardless of whether the xenon-133 is administered as a gas or in saline suspension. (As demonstrated in diagnostic studies on humans using 10 to 30 millicuries of xenon-133, xenon-133 is physiologically inactive and gas entering the circulatory system is returned to the lungs and exhaled after a single pass through the peripheral circulation.)

Xenon-133 has a radioactive half life of 5.24 days and decays by beta emission to stable cesium-133. The primary radiation products are a beta particle with a maximum energy of 346 kiloelectron volts and cesium X-rays with an energy of 81 kiloelectron volts).

Within the Mine. The xenon-133 gas is expected to be pushed as a rather large slug through the mine. The Experimental Mine has a number of auxiliary tunnels and rooms with dead ends between the xenon-133 release point and the mine entrance (i.e., the xenon exhaust point). Each one of these areas is expected to set up eddy currents that can either spread out the slug or pull xenon133 out of the main air stream into the dead air spaces. Xenon133 is not expected to permeate the rock or coal formations, but may move through actively venting cracks or boreholes. The existing bore holes from the surface to the mine tunnels are capped and not expected to affect the air flow. Although the air stream is expected to take the path of least resistance through the mine, it should also move air into all available spaces. Xenon-133 remaining in the main air stream is expected to exit the mine in the first air exchange

(approximately 8.3 minutes). Xenon-133 moved into the side tunnels and dead air spaces will take longer to flush out and may decay first.

The worst case mine situation would be if the ventilation system failed after the second of two 1,776 megabecquerel (48 millicurie) releases. Since the complete air exchange in the Experimental Mine (i.e., approximately every 9 minutes) is approximately equal to the time needed to set up and measure each release, it would be difficult to have more than two xenon-133 air slugs in the mine once the ventilation system failed. In this case, the researchers exiting the mine through the mine entrance (the mine exhaust tunnel) would have to walk through one or two of the xenon slugs.

The maximum instantaneous air concentration of xenon-133 in an existing slug (0.159 or 0.636 becquerels per milliliter (4.3 or 17.6 picocuries per milliliter)) is generally less than the Title 10 Code of Federal Regulations Part 20 limits for occupational exposure to xenon-133 air concentrations when averaged over a year. The Part 20 limits are 0.37 and 3.7 becquerels per milliliter (10 and 100 picocuries per milliliter), before and after January 1, 1994 respectively. If the ventilation system failed during the production of a slug, the xenon-133 concentration in the partially formed slug could be much higher than the concentration in the existing slug.

The researchers will not be exposed to any slug for a prolonged period of time. Assuming each person in the mine moves through the existing slug for a total of 15 minutes while exiting the mine (a conservative estimate of the time spent in the slugs), the total dose per person would be 10 microsieverts (1 millirem) whole body or 1 microsievert (0.1 millirem) deep dose equivalent. For the partially formed slug, the xenon-133 concentration would have increase by a factor of 5,000 or 50,000 to either 3 or 30 kilobecquerels (80 or 800 nanocuries per mililiter) for the same individual to receive 50 millisieverts (5 rem) whole body dose or deep dose equivalent, respectively, in fifteen minutes. Further, the mine could be closed until the xenon decayed or the ventilation system was able to clear the mine to preclude other xenon exposures. The doses could be reduced further if the researchers exited the mine upstream from the xenon release point before entering the last 46 to 90 meters (150 to 300 feet) of the exhaust tunnel. This dose could be reduced to zero by exiting the Experimental Mine through the Research Safety Mine but this should not be necessary.

Outside the Mine. Xenon-133 is not expected to either enter underground potable water supplies or remain in plants or animals because of its short radioactive half-life and its chemically inert properties. The short half-life precludes it from reaching underground potable water supplies before it decays away. This also precludes it from migrating through the rock and coal to the work places located above the mine before it decays. It could be forced through open active ventilating cracks to these structures, but the path of least resistance is to remain in the much larger tunnels. Further, since the experiment will be performed in the winter, the xenon-133 will have decayed away before the normal plant growing season.

Although xenon may become mechanically suspended in water, it does not chemically react with the water molecules and is expected to outgas quickly. Xenon temporarily suspended in rain, snow, or fog may initially become part of the surface water, but would outgas in a short period of time. Xenon in contact with plant or animal life is metabolically inert and not expected to be taken up and retained in either plants or animals. Animals ingesting xenon suspended in water are expected to exhale the xenon.

If the experiments work, all of the xenon-133 released (i.e., from 240 millicuries to the entire 300 millicuries on site) is expected to be lost to the environment. It should be lost in increments of 444 or 1776 megabecquerels (12 or 48 millicuries). In extremely stagnant outdoor air conditions, the xenon being heavier than air would be expected to flow down hill. Instead of dispersing, under these conditions

it may collect in low lying areas or depressions. This situation can be avoided by ensuring the studies are not performed on foggy or still days. Under normal weather conditions of natural air turbulence, the xenon should rapidly dispersed once it leaves the mine.

Environmental Effects and Conclusions

Pathway to Humans. Several factors, such as scheduling the xenon-133 releases on a weekend, restricting access to the mine during the releases, and the distance from the mine entrance to the boundary of the Pittsburgh Research Center, make it unlikely that the xenon-133 will come in direct contact with the general public.

The most significant hazard to humans is the external radiation hazard from the beta particles and x-rays associated with being submersed in the xenon-133 gas cloud, i.e., the most probable route of exposure is direct contact with the radioactive xenon-133 gas.

Internal hazards are not as significant because, if inhaled the metabolically inactive xenon-133 is rapidly removed by exhaling. In medical studies xenon-133 is generally washed out of the lungs in one or two breaths regardless of whether the xenon-133 is administered as a inhaled gas or injected in saline suspension. (As demonstrated in diagnostic studies on humans using 10 to 30 millicuries of xenon-133, xenon-133 is physiologically inactive and gas entering the circulatory system is returned to the lungs and exhaled after a single pass through the peripheral circulation.) This gives a very low probability of internal exposure. The possible ingestion route involves swallowing xenon-133 gas either temporarily trapped in particles or mechanically suspended in water. In this situation, like the injected xenon, the xenon is also expected to be exhaled rapidly. As discussed before, xenon-133 will not get into potable ground water, or the plant or animal food chain.

Effects On Plant and Animal Species. Because no known plants or animals live in the Experimental Mine, plants and animals exposed to the xenon-133 have to live at the Bruceton Research Center or in the surrounding area. Since the xenon-133 air stream is expected to be dispersed and diffused once it leaves the mine, few plants or animals are expected to come into prolonged contact with the xenon-133 beta particles or x-rays. Further, the probability and consequences of effects will diminish with time, as the xenon-133 decays.

Effects on Endangered or Threatened Species. There are no known endangered or threatened species either living or having home ranges in the vicinity of the Experimental Mine or Bruceton Research Center.

Agencies and Persons Contacted

In performing this review, the staff contacted the Bureau of Mines ' Pittsburgh Research Center and the University of Kentucky, Department of Mining Engineering.

References

Kim, Ann G., and Chaiken, Robert F., "Abandoned Mined Land Fire Survey and Evaluation," Proceedings of the 12th annual NAAMLP Conference: Returning Mined Land to Beneficial use, Breckenridge, Colorado, September 16-20, 1990.

APPENDIX I

Diamond, W. P., Irani, M. C., Aul, G.N., and Thimons E.D., Chapter 6 "Instruments, Techniques, and Equipment", Methane Control Research: Summary of Results, 1964-80, Bureau of Mines Bulletin 689, 1988.

Donna-Beth Howe, Ph.D.
November 23, 1993

NOV 16, 1993

MEMORANDUM FOR: William L. Axelson, Director
Division of Radiation Safety and Safeguards, RIII

FROM: Carl J. Paperiello, Director
Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT: DEPARTMENT OF ARMY PROPOSAL TO STORE FOR DECAY DISCARDED PROMETHIUM-147 WEAPON SIGHTS (LICENSE NO. 12-00722-07) RESPONSE TO REGION III QUESTION ON NEED FOR AN ENVIRONMENTAL ASSESSMENT

This refers to a telephone conversation with John Madera, of your staff, concerning whether the Department of Army's request, to amend the license for the Fort Bragg, North Carolina, site to store for decay, weapon sights containing promethium-147 (Enclosure 1), will require the NRC to perform an environmental assessment (EA) pursuant to 10 CFR Part 51. The Army's request has been reviewed by the Division of Low-Level Waste Management and Decommissioning (LLWM). LLWM's analysis (Enclosure 2) was forwarded to you in an earlier memorandum (Enclosure 3). Based on the technical analysis provided by LLWM and pursuant to 10 CFR 51.22(c)(14)(xvi), an EA will not be required. Unless there are other issues involved, Region III can amend the Army's license to authorize its request to store the sights for decay or it can decommission the Fort Bragg site (the Ammunition Supply Point (ASP) Yard) for unrestricted use. Should the Army choose to decommission the ASP Yard, where the sights are buried, the Army will still be responsible for all nonradioactive hazards at the Yard, such as unexploded munitions.

10 CFR 51.22(c)(14)(xvi) excludes an applicant/licensee from an environmental review on licensing and regulatory actions for "any use of source, byproduct, or special nuclear material not listed above, which involves quantities and forms of source, byproduct, or special nuclear material similar to those listed in paragraphs (c)(14)(i) through (xv) of this section (Category 14)." The staff has found the Army's proposed amendment request to be similar to the following categorical exclusion paragraphs discussed below:

1. 10 CFR 51.22(c)(14)(i), "Distribution of radioactive material and devices or products containing radioactive material to general licensees and to persons exempt from licensing."

   Already discussed in the LLWM's technical analysis (Enclosure 2), 10 CFR §§ 30.14, 30.15, and 30.19 authorize a member of the general public to receive and possess devices containing Pm-147 (up to 2 μCi) in sealed sources, and products containing Pm-147 (up to concentrations of 200 pCi per gram) without further regulatory control. Once these devices and products (e.g., timepieces, lock illuminators, self luminous products, etc.) have served their useful life, the devices and products are normally disposed of as trash, by either incineration or burial in a landfill. The disposal of hundreds of timepieces annually to a large municipal landfill, in addition to disposal of other used devices and products under 10 CFR §§ 30.14, 30.15, and 30.19, is similar to the Army's proposed activity to decay in storage the gunsights, containing Pm-147 microspheres, at the Ft. Bragg ASP yard, resulting in a very unlikely hypothetical annual maximum dose of .0036 millirem to an intruder into the fenced off area.

2. 10 CFR 51.22(c)(14)(xiii), "Manufacturing or processing of source, byproduct or special nuclear materials for distribution to other licensees, except processing of source material for extraction of rare earth and other metals."

All NRC licensees that manufacture or process sealed sources or devices containing Pm-147 are required under 10 CFR 30.35(g) to maintain records that the Commission considers important to decommissioning such as: (1) §30.35(g)(3)(ii) which states, "All areas outside of restricted areas that require documentation under § 30.35(g)(1)."; or (2) § 30.35(g)(3)(iv) which states, "All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 10 CFR 20.302 or 20.2002." These and other decommissioning requirements (e.g., submittal of a decommissioning plan) are intended to provide the staff sufficient information to identify all potential health and safety problems before the Commission authorizes the termination of a materials license. Therefore, routine licensing actions, such as the decommissioning of the site used by a manufacturer of sealed sources or devices, are normally categorically excluded from an EA pursuant to 10 CFR 51.22(c)(14)(xiii).

The Army's activity is similar to that of a manufacturer or processor of sealed sources or devices containing Pm-147 in that both are required to maintain records for decommissioning, all areas, outside of restricted areas that have been contaminated with soil containing Pm-147 exceeding NRC limits for release of area for unrestricted use. These contaminated areas could have occurred from incidents such as inadvertent leaks from restricted areas (addressed under §30.35(g)(3)(ii)) or spills during transport of Pm-147 over unrestricted areas (addressed under §30.35(g)(3)(iv)).

Although the Army's proposed activity is not covered under a specific categorical exclusion paragraph in 10 CFR 51.22(c)(14)(i)-(xv), pursuant to 10 CFR 51.22(c)(14)(xvi), the Army's proposed activity is similar to the activities of either 10 CFR 51.22(c)(14)(i) or 10 CFR 51.22(c)(14)(xiii), and therefore qualifies for categorical exclusion.

If you have any questions, please feel free to contact Susan Greene of my staff at (301) 504-2686 or Joseph Wang at (301) 504-2611.

Carl J, Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:
1. Ltr fm D. Skogman to NRC dtd 10/28/92 **(NOT ENCLOSED)**
2. Memo fm J. Austin to J. Glenn dtd 9/8/93
3. Memo fm J. Glenn to J. Madera dtd 9/17/93

September 8, 1993

MEMORANDUM FOR: John E. Glenn, Chief
Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety, NMSS

FROM: John H. Austin, Chief
Decommissioning and Regulatory Issues Branch
Division of Low-Level Waste Management and
Decommissioning, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST - DEPARTMENT OF ARMY PROPOSAL TO STORE FOR DECAY DISCARDED PROMETHIUM-147 WEAPON SIGHTS (LICENSE NO. 12-00722-07)

In February 1993, you forwarded a Technical Assistance Request (TAR) to the Division of Low-Level Waste Management and Decommissioning (LLWM) regarding the U.S. Army's request to store for decay discarded Promethium-147 (Pm-147) weapon sights at its Fort Bragg, North Carolina site. You asked us to review documents submitted by the licensee, and provide an environmental assessment based on our findings, including any concerns about Nuclear Regulatory Commission policy that may have been raised by the situation.

LLWM originally stated in 1991 that this would be treated as a 10 CFR §20.302 disposal request. However, review of information from the licensee has led us to propose that the site could be released for unrestricted use (from a radiological standpoint) in accordance with appropriate decommissioning criteria.

Appendix A to this memo presents some background history of the site, and a description of the source term. Appendix B presents a radiological impacts analysis prepared by LLWM.

Since Region III will continue to hold an active license for the U. S. Army, possibly still including the Fort Bragg site, we suggest that the Region determine the proper licensing action for this decommissioning. If an Environmental Assessment is needed, the Region should use the site history and radiological impacts analysis provided herein to prepare the Environmental Assessment.

We request that Region III keep us on concurrence and distribution for correspondence pertaining to the release of this site to ensure that our data base on these types of releases, which we maintain for the agency, remains current.

If you have any questions, please contact me at 504-2560 or Bill Lahs at 504-2569.

John H. Austin, Chief
Decommissioning and Regulatory Issues Branch
Division of Low-Level Waste Management and
Decommissioning, NMSS

Enclosures: As stated

APPENDIX A: HISTORY OF SITE AND SOUR TERM DESCRIPTION

I. Site Background and History

From 1987 to 1989, between 3,000 and 4,000 expended rocket tubes with radioactive sights were discarded in two locations at Fort Bragg. The tubes were equipped with weapon sights that originally contained 3 μCi of Pm-147 encapsulated in ceramic microspheres. The Pm-147 is licensed by the Nuclear Regulatory Commission under license BML 12-00722-7.

In one location -- the Ammunition Supply Point (ASP) Yard -- the sights were randomly dumped over an area measuring roughly 100 yards by 300 yards. The Army graded the area to consolidate the material. Attempts by the Army to recover the weapon sights in the ASP were discontinued following the discovery of live ammunition mixed with the sights in the debris. The graded earth was subsequently pushed into a single large pile within the ASP. The Army reports that the pile currently measures 35 ft. by 50 ft. by 10 ft (17,500 cubic feet). The ASP is now bounded by a security fence to prevent unauthorized entry due to its use as an ammunition facility.

In the second location -- the Directorate of Personnel and Community Environmental Hygiene Agency (DPCA) Recycling Yard -- the weapon sights were discarded in two trenches. In 1990, the rocket tubes were crushed, pushed into a trench and buried in the DCPA yard. The Army stated that tubes placed in the DCPA yard were completely recovered.

II. Source Term Description

According to the licensee, all the weapon sights were manufactured in 1977 or earlier. The licensee also indicated that 1,000 intact sights and 500 damaged sights were recovered; we therefore used a conservative number of 3,000 sights remaining in the pile in the ASP. Using the Pm-147 half-life of 2.6 years, it can be calculated that the current total activity in the disposal area is no more than 150 mCi. The calculated average concentration of Pm-147 in the affected soil is about 200 pCi/g. Pm-147 is effectively a pure beta emitter (0.23 MeV max.) which decays to Sm-147, an alpha emitter with a half-life of 1 E+11 years. As a result, the total activity of Sm-147 will not exceed about 230 pCi [9 Ci x ($2.6/1 \times 10^{11}$) = 230 pCi]. If this material were dispersed over 17,500 ft^2, the resulting concentration would be insignificant.

APPENDIX B: RADIOLOGICAL IMPACTS-ANALYSIS

Because of both (1) the physical and chemical characteristics of the sights containing the Pm-147 (ceramic microspheres), and (2) the magnitude and half life of the total radioactivity at the site, the potential pathways for radiological exposure to members of the general public are limited. The leach rate of Pm-147 from the ceramic microspheres has been shown to be very small. Thus, when coupled with the small inventory of Pm-147 and its 2.6 year half-life, exposures through water dependent pathways are not considered credible.

For the same reasons, together with the unavailability of the land for near term agricultural use (due to the unexploded ordnance in the Ammunition Supply Point yard), exposures through the plant/meat/milk pathways are also not considered credible. The limited inventory and areal extent of the Pm-147 contamination preclude any significant direct exposure from the beta activity, and these factors and the microspheric physical form preclude resuspension-inhalation from being considered a credible pathway. As a result, the only pathway considered credible for this radiological impact analysis is secondary ingestion; that is, direct ingestion of soil containing the sights.

Quantitative data for secondary ingestion rates range from 10 mg to 500 mg per day. Using 200 pCi/g as the average concentration of Pm-147 over the contaminated area, an individual could theoretically ingest 3.65 E-2 uCi annually. 10 CFR Part 20 Appendix B to §§20.1001-20.2402 provides annual limits on intake (ALIs) by a reference man for given radionuclides. The value for Pm-147 is 5E+3 uCi (stochastic). Since this value would result in a committed effective dose equivalent of 5 rems, the hypothetical dose from ingestion of 3.65 E-2 uCi annually can be calculated to be 3.6 E-2 mrem.

In the Order Establishing Criteria and Schedule for Decommissioning the Bloomsburg Site (57 FR 6136, February 20, 1992), the Nuclear Regulatory Commission staff provided maximum soil concentration values for release of property whose soil shows evidence of radioactive contamination. Although Pm-147 was not among the radionuclides for which soil concentrations were provided, the Order did include a value for strontium-90 of 5 pCi/g. The decay of Sr-90 and its daughter Yttrium-90 involve beta emissions with maximum energies of 0.55 and 2.27 MeV, respectively. The energy of these betas can be compared with the 0.23 MeV maximum energy of the beta emission from Pm-147. This energy difference, along with other considerations, results in the ALI for Sr-90 being 40 uCi (stochastic). Without considering the limited extent of the theoretical exposure pathways for Pm-147 discussed above, a comparable soil release criterion for Pm-147, based on the ratio of ALIs, would be about 625 pCi/g.

Enclosure 2

OCT 20, 1993

MEMORANDUM FOR: Charles W. Hehl, Director
Division of Radiation Safety and Safeguards, RI

FROM: Carl J. Paperiello, Director
Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT: SENECA ARMY DEPOT - TECHNICAL ASSISTANCE REQUEST ON REQUEST FOR AUTHORIZATION TO DECONTAMINATE EQUIPMENT (CONTROL NUMBER 116420)

This is in response to a memorandum from Dr. Ronald Bellamy, of your staff, to Dr. John Glenn, dated June 11, 1993 (Enclosure 1), on whether the NRC should require the Department of the Army, Seneca Army Depot, to submit additional information, as part of its license renewal application, for the NRC to perform an environmental assessment (EA) pursuant to 10 CFR Part 51. In its license renewal application dated November 2, 1992, Seneca Army Depot requested authorization to receive, store, and decontaminate machinery and equipment contaminated with depleted uranium. Based on the information provided by Seneca in the license renewal application and its response, dated September 2, 1993, to Region I's request for additional information (Enclosure 2), an EA will not be required if Seneca limits the interim storage period of other Agencies' (i.e., the Department of Energy's (DOE's) and the U.S. Air Force's) contaminated machinery and equipment at Seneca to less than 180 days.

10 CFR 51.22(c)(14)(xvi) excludes an applicant/licensee from an environmental review on licensing and regulatory actions if "any use of source, byproduct, or special nuclear material not listed above which involves quantities and forms of source, byproduct, or special nuclear material similar to those listed in paragraphs (c)(14)(i) through (xv) of this section (Category 14)." Seneca's new proposed activity (i.e., decontamination of contaminated machinery and equipment), as described in its license renewal application, consists of three different uses of licensed material. These are: (1) receipt and possession of licensed material; (2) use, processing, and packaging of licensed material; and (3) shipping and disposal of licensed material. Each "use" has been evaluated by the staff against the appropriate categorical exclusion paragraph and found to be similar to the following categorical exclusion paragraphs discussed below:

1. <u>"Receipt and possession of licensed material" is similar to 10 CFR 51.22(c)(14)(x), "Possession of radioactive material incident to performing services such as installation, maintenance, leak tests and calibration."</u>

   Since Seneca plans to decontaminate the DOE's and the Air Force's machinery and equipment contaminated with depleted uranium as well as that of the Army's, a licensing action which authorizes Seneca to conduct this specific activity is similar to that of a service licensee because Seneca will be receiving, possessing, and performing "maintenance" of the DOE's and the Air Force's contaminated machinery and equipment.

2. "Use, processing, and packaging of licensed material' is similar to 10 CFR 51.22(c)(xiii), "Manufacturing or processing of source, byproduct, or special nuclear materials for distribution to other licensees, except processing of source material for extraction of rare earth and other metals.'

   After receipt of the DOE's and the Air Force's contaminated machinery and equipment, unlike most service licensees, Seneca's maintenance activity could result in the generation of up to 10,000 kilograms of depleted uranium contamination. The contamination generated from Seneca's maintenance operation (i.e., decontamination) is depleted uranium. Seneca's proposed activity is similar to that of a manufacturer of depleted uranium penetrators or shielding because these manufacturers generate a large amount of depleted uranium-contaminated waste in the processing of source (i.e., depleted uranium) materials. Both Seneca and the source material manufacturer will also package the depleted uranium contaminated waste for disposal at a licensed land burial facility.

3. "Shipping and disposal of the licensed material" is similar to 10 CFR 51.22(c)(14)(xii), "acceptance of packaged radioactive wastes from others for transfer to licensed land burial facilities provided the interim storage period for any package does not exceed 180 days and the total possession limit for all packages held in interim storage at the same time does not exceed 50 curies."

   Unlike a source material manufacturer, Seneca will also ship not only its own waste, but also packaged radioactive wastes originating from another specific licensee (i.e., the DOE or the Air Force), to licensed land burial facilities. This proposed activity is similar to that of a waste broker because the waste broker is authorized to transfer other licensees' wastes to licensed land burial facilities.

   However, Seneca needs to be consistent with all restrictions (i.e., interim storage does not exceed 180 days and the total possession limit for all packages held in interim storage at the same time does not exceed 50 curies) placed on waste brokers under this categorical exclusion. Seneca has already committed to limit the contaminated machinery and equipment (including the Army's) to less than 10,000 kilograms of depleted uranium, or a total activity of 3.36 curies (Enclosure 2). Therefore, Seneca needs to commit to an interim storage period, for the DOE's and the Air Force's contaminated depleted uranium, of less than 180 days in order to qualify under this categorical exclusion. The need for this commitment is consistent with the staff's earlier response to ALARON's request to amend its waste broker license to store, repair, and maintain licensed material in contaminated equipment (Enclosure 3). Unlike waste brokers, Seneca is not commercially receiving, storing, and shipping radioactive wastes to licensed land burial facilities.

Although Seneca's proposed activity is not covered under a specific categorical exclusion paragraph in 10 CFR 51.22(c)(14)(i)-(xv), pursuant to 10 CFR 51.22(c)(14)(xvi), Seneca's proposed activity is similar to the activities of 10 CFR 51.22(c)(14), paragraphs (x), (xii), and (xiii) when taken together, and therefore qualifies for a categorical exclusion.

The contact person on my staff for this TAR is Joseph Wang who can be reached at (301) 504-2611.

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:
1. Memo fm R. Bellamy to J. Glenn dtd 6/11/93 **[NOT ENCLOSED]**
2. Ltr fm R. Johnson to J. Kinneman dtd 9/2/93 **[NOT ENCLOSED]**
3. Memo fm J. Glenn to R. Bellamy dtd 7/30/93 **[NOT ENCLOSED]**

Appendix J

Sample Denial Letters

SUMMARY OF SAMPLE DENIAL LETTERS

SAMPLE DENIAL	TYPE OF APPLICATION	REQUESTED AUTHORIZATION	DATE OF DENIAL	DENIAL PURSUANT TO	REASON FOR DENIAL (PERTINENT REGULATION)
A.	New	Radiography	9/88	10 CFR 2.103	Inadequate training and experience (10 CFR 30.33 (a)(3)); inaccurate information (10 CFR 30.9)
B.	Amendment	Relief from 10 CFR 35.60(b) re: labeling syringes and syringe shields	4/88	10 CFR 2.103	Does not protect public health and safety; may lead to misadministrations; does not fulfill intent of regulation
C.	Amendment	Relief from 10 CFR 20.205(b) re: monitoring external surfaces of incoming packages	11/84	10 CFR 20.501	Does not protect public health and safety; does not fulfill intent of regulation
D.	New	License pursuant to 10 CFR 32.51 to distribute device to persons generally licensed pursuant to 10 CFR 31.5	7/85	10 CFR 2.103	a. Device not covered by 10 CFR 31.5 b. Training in radiation safety required (10 CFR 32.51(a)(2)(i)) c. Loss of source and doses exceeding limits possible (10 CFR 32.51(a)(2)(ii))
E.	New	License pursuant to 10 CFR 32.11 to distribute irradiated gemstones to persons exempt from licensing	6/89	10 CFR 2.108	Failure to provide adequate information

APPENDIX J

SAMPLE DENIAL	TYPE OF APPLICATION	REQUESTED AUTHORIZATION	DATE OF DENIAL	DENIAL PURSUANT TO	REASON FOR DENIAL (PERTINENT REGULATION)
F.	New	Well logging	5/86	10 CFR 2.103	Possession of licensed material without valid license (10 CFR 30.3); lack of candor with staff in violation, and careless disregard, of regulations
G.	Amendment	Extension of interval for service and inspection of teletherapy unit from 5 years to 7 years	10/78	10 CFR 2.103	Equipment inadequate (10 CFR 30.33(a)(2)) if not inspected and serviced at intervals not to exceed 5 years
H.	Amendment	Use of Sr-90 plaque to treat skin cancer	7/86	10 CFR 2.103	a. Medical treatment not authorized by 10 CFR 35 b. Equipment inadequate (10 CFR 30.33(a)(2)) in that treatment not shown to be safe and effective; reviewed by ACMUI in accordance with Medical Policy Statement (44 FR 8242)
I.	New	Radiography	5/88	10 CFR 2.103	Inadequate training and experience (10 CFR 30.33(a)(3)) as demonstrated by poor past performance as Agreement State licensee
J.	Amendment	Addition of therapist	9/80	10 CFR 2.103	Therapist not a physician as defined in 10 CFR 35.3(b)

SAMPLE DENIAL	TYPE OF APPLICATION	REQUESTED AUTHORIZATION	DATE OF DENIAL	DENIAL PURSUANT TO	REASON FOR DENIAL (PERTINENT REGULATION)
K.	New	Well logging	1/89	10 CFR 2.103	Inadequate training and experience (10 CFR 30.33(a)(3)) as demonstrated by possession of licensed material without valid license (10 CFR 30.3); lack of candor (which occurred before effective date of 10 CFR 30.9)

SEP 06 1988

Licensee A
ATTN: Mr. John Doe
Any Address
Anytown, Anystate 12345

Gentlemen:

This is in reference to your application dated March 3, 1988, requesting a byproduct material license for the utilization of sealed sources and devices for use in industrial radiography.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, your request is hereby denied for reasons set forth below.

1. You are not considered qualified by training and experience to use the material for the purpose requested. To receive such a license, you must be qualified pursuant to Section 30.33(a)(3), Part 30, Title 10, Code of Federal Regulations.

   This conclusion was reached after review of the documentation submitted with your application and subsequent March 23, 1988 letter. We determined that you were not approved as a radiographer as inferred in the information supplied. This determination was made as a result of correspondence dated June 16, 1988 received from Company X which indicated that you had not worked in its employment as a radiographer. Furthermore, June 16, 1988 correspondence received from Company Y indicates that you did not attend the "The Radiography Course" as represented in your certificate dated November 15, 1980.

2. You have not provided the NRC with complete and accurate information as required by Section 30.9, Part 30, Title 10, Code of Federal Regulations.

   The NRC relies upon the applicant to submit accurate and true information to demonstrate the applicant's qualifications to ensure that possession and use of radioactive material will be conducted in a manner that protects health and minimizes danger to life or property. Since the sponsor of the training course and your previous employer have been unable to confirm your training qualification statements, we conclude that you have misrepresented information, possibly falsified documentation and cannot be relied upon to safely conduct a radiography program under an NRC license.

SAMPLE DENIAL A

As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning this denial. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Assistant General Counsel for Hearings, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555. The request should reference this letter and Docket Number 030-00000.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosure: 10 CFR Part 2

22 APR 1988

License No. 12-34567-89
Docket No. 030-00000
Control No. 123456

Licensee B
ATTN: John Doe
Any Address
Anytown, Anystate 12345

Gentlemen:

This letter is in response to the request made in your letter dated June 12, 1987, to amend your license to be exempted from requirements of 10 CFR 35.60(b) for conspicuously labeling each syringe or syringe radiation shield. Specifically, you assert that preparation of a unique label for each syringe would be unproductive, time-consuming and result in small additional radiation exposure to the individual doing the labeling.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, this letter constitutes denial of your request to be exempted from the requirements of 10 CFR 35.60(b) for the reasons stated below.

10 CFR 35.19 states in part that the Commission may grant exemptions from the regulations in this part as it determines to be in the public interest.

The NRC has found that the labeling of a syringe that contains a radiopharmaceutical, or syringe radiation shield that contains such a syringe, as to radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name are effective ways to assure that the prescribed radiopharmaceutical is delivered to the correct patient. Comments similar to yours were addressed in the Statements of Consideration prior to adoption of this requirement. At that time, the staff noted: "... some misadministrations have been caused by accidentally transposing syringes after drawing two dosages. Therefore, the benefits from avoiding misadministrations outweigh the costs to the licensee." (51 FR 36932, p. 36944, October 16, 1986). Further, other licensees have developed procedures for efficiently labeling syringes, or syringe shields, without increasing personnel exposure. Therefore, your assertion that such labeling is unproductive does not justify an exemption from the regulation as being in the public interest.

SAMPLE DENIAL B

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, you may request a hearing with respect to this denial within 20 days of the date of this letter. If you wish to request a hearing, submit a request to the Director, Division of Radiation Safety and Safeguards, USNRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The request should reference this letter and Docket No. 030-00000.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosure: 10 CFR Part 2

NOVEMBER 28, 1984

Licensee C
ATTN: John Doe, Ph.D.
Radiation Safety Officer
Any Address
Anytown, Anystate 12345

Dear Dr. Doe:

This is in reference to your letter dated August 22 1984 requesting an exemption from the requirements in paragraph 20.205(b), Part 20, Title 10, Code of Federal Regulations (10 CFR), to monitor the external surfaces of certain packages containing radioactive material for contamination upon receipt of the packages.

In accordance with Section 20.501, Part 20, 10 CFR, your request to amend License No. 12-34567-89 is hereby denied for the reasons set forth below.

The provisions of paragraph 20.205(b), Part 20, 10 CFR, are needed to aid in protecting health and minimizing danger to life and property by promptly identifying packages with excessive contamination of external surfaces either because of an accident or, in the absence of an accident, because of improper assembly or closure of the package. The monitoring and reporting requirements of this paragraph are important in: preventing excessive spread of contamination as has occurred in past incidents; alerting you, the recipient of the package, to potential contamination problems when opening the package in your facility; advising the carrier of possible contamination of its vehicle and facilities and allowing the Commission to alert the Department of Transportation to a possible contamination incident; and permitting the Commission to determine the cause of the leakage and to take necessary corrective action.

SAMPLE DENIAL C

In your request, you stated that out of 1,965 orders of radioactive material received by Licensee C during a one-month period, approximately 1.5 percent, or 30 of them, required external monitoring for contamination. This information, with your other submitted data, does not provide substantive justification from a health and safety standpoint for an exemption from the requirements and therefore your request is denied.

Sincerely,

/RA/

[NAME], Director
Division of Fuel Cycle and Material Safety

Enclosure: 10 CFR Part 20

JUL 29 1985

Licensee D
ATTN: Mr. John Doe
Executive Vice President
Any Address
Anytown, Anystate 12345

Gentlemen:

This letter refers to your application dated March 14, 1985, requesting a license to distribute devices and source heads to persons generally licensed pursuant to Section 31.5 of 10 CFR Part 31 of Nuclear Regulatory Commission (NRC) or equivalent Agreement State regulations. Pursuant to Section 2.103 of 10 CFR Part 2, your application is hereby denied for the following reasons:

A. Section 31.5(a) of 10 CFR Part 31 covers only generally licensed devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The purpose of the your device is to produce images of objects placed in a radiation field, for observation by the user; that is, the device is a radiographic device. Although in some cases the device may be used for some of the purposes listed in Section 31.5(a), its potential uses are not limited exclusively to those purposes, and Section 31.5 was not intended to cover radiographic devices. Therefore, the device does not meet the requirements of Section 31.5(a).

B. Section 32.51(a)(2) of 10 CFR Part 32 requires that an applicant provide reasonable assurance that a proposed device can be safely operated by persons not having training in radiological protection. The application states that users will take the manufacturer's training course, which includes training in radiological protection and training on NRC regulations related to radiological protection. The device is normally a portable, hand-held device, although in some cases it can be installed in a fixed location. In either case, the user must work in close proximity to the device in order to observe images and hold objects in the radiation beam. The device contains iodine-125 in radioactive sources up to 500 millicuries in size. The radiation levels from the source vary with distance, but can be as high as 4.5 rems per minute near the source. Therefore, it is important that the user not place any part of his body in the radiation beam either inadvertently or deliberately (to observe an image of his hand). The requirement that the user work in close proximity to the device at all times, while avoiding exposure to the radiation source, dictates that the user have training in radiological protection to appreciate potential hazards and safety requirements. Therefore, the device does not meet the requirements specified in Section 32.51(a)(2)(i) of 10 CFR Part 32.

SAMPLE DENIAL D

C. Section 32.51(a)(2)(ii) of 10 CFR Part 32 also requires that the applicant provide reasonable assurance that, under ordinary conditions of handling, storage and use of the device, the radioactive material will not be released or inadvertently removed from the device, and that it is unlikely that any person will receive radiation doses above specified levels. The device is portable and designed for exchange of source heads containing radioactive material by the user. Therefore, it is reasonable to assume that a person untrained in radiological protection could remove and lose or misplace a source head. Furthermore, it is reasonable to postulate that a person untrained in radiological protection could inadvertently or deliberately place his hand in the radiation beam and receive a radiation dose in excess of the specified levels. Therefore, the device does not meet the requirements of Section 32.51(a)(2)(ii) of 10 CFR Part 32.

As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning this denial. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The request should reference this letter and Docket Number 030-00000.

We note that your letters to Congressman John B. Smith dated February 27, 1985 and June 10, 1985, discuss medical use of the device by general licensees. Section 35.2 of 10 CFR Part 35 prohibits human use of radioactive material except pursuant to a specific or general license issued pursuant to 10 CFR Parts 35, 30, 32 or 33. There is no general license in our regulations which covers medical use of devices such as your device. Therefore, use of the device for medical use by general licensees is prohibited, and we cannot issue a license to you under current regulations which would authorize such use by general licensees.

Your correspondence with Congressman Smith also discusses the possibility of amending our regulations or granting exemptions from our regulations. It is correct that we have amended our regulations to allow use of your device by group medical licensees, and in some cases we have granted individual exemptions to podiatrists and dentists because they did not meet the definition of a physician as specified in Section 35.3(b) of 10 CFR Part 35. In these cases, the users are specifically licensed and receive training in radiological protection.

We believe that our regulations are sound and that it is in the interest of public health and safety to require that users of your device be specifically licensed and trained in radiological protection. There are currently about 20,000 NRC and Agreement State licenses issued for industrial and medical use, and NRC alone processes about 6,000 licensing actions per year. There is an established procedure for issuing specific licenses. We believe that regulating your device under specific licenses assures protection of public health and safety and does not place an undue burden on users. However, if you wish to formally request any amendments to NRC regulations, Section 2.802 of 10 CFR Part 2 provides the requirements for submission of a petition for rulemaking to the Commission. Please note that we are in the process of publishing a proposed rulemaking for a major revision to 10 CFR Part 35 in the *Federal Register* within the next few weeks, and you may wish to make any submissions in light of that rulemaking.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosure:
10 CFR Parts 2, 31, 32, and 35

JUN 07 1989

Licensee E
ATTN: Mr. John Doe
President
Any Address
Anytown, Anystate 12345

Gentlemen:

This is in reference to your May 31, 1986 application for a license to be issued pursuant to Section 32.11 of Title 10, Code of Federal Regulations, Part 32 to authorize distribution of irradiated "mineral crystals" to persons exempt from licensing. Your application was one of several similar applications that were precedent setting and necessitated consultation with the Nuclear Regulatory Commission (Commission or NRC).

Following the Commission's decision on the matter, the staff prepared guidance (Enclosures 1 and 2) on the preparation of applications such as yours. Enclosures 1 and 2 outline the information needed to satisfy the general and specific requirements of Sections 30.33(a) and 32.11 of Title 10, Code of Federal Regulations, Parts 30 and 32, respectively (Enclosure 3).

The staff forwarded Enclosures 1 and 2 to you by letter dated March 3, 1988, outlined some specific areas that you did not address in your original application, and asked that you submit the information requested in the enclosures. Your April 15, 1988 reply was reviewed in combination with your original application. By letter dated October 31, 1988 the staff notified you that the information you had submitted was inadequate and incomplete and did not permit the staff to make the findings required by Section 30.33(a) of Title 10, Code of Federal Regulations, Part 30. The letter also informed you that the staff anticipated denying your request for a license, but would postpone such a decision for 45 days (i.e., until December 15, 1988) to allow you another opportunity to submit full and complete responses to NRC's requests for information. Again the staff brought to your attention specific areas of your application that were lacking in detail.

By letter dated December 15, 1988, you requested a 30 day extension for reply to NRC's October 31, 1988 letter. On December 22, 1988, the staff notified you that it had granted your request and expected to receive your reply by January 18, 1989. The staff has reviewed your January 20, 1989 reply and found that you still have not provided all of the information requested in the guidance documents that accompanied NRC's March 3, 1988 letter.

SAMPLE DENIAL E

The staff finds that, despite its repeated requests, you have failed to provide a detailed description of how you will: receive gemstones; monitor them to identify and remove "rogue" or "hot" stones; identify and quantify all radionuclides (not only beta-gamma emitters, but also pure beta-emitters); weigh each stone; determine the concentration of each identified radionuclide in units of microcuries per gram; and, using the "sum of the ratios method," determine which stones may be released in accordance with the criteria in Section 30.70 of Title 10, Code of Federal Regulations, Part 30 and when they may be released. You have also failed to provide full and complete information on the quality assurance (QA) program you will implement to ensure that: your counting equipment is calibrated properly and continues to function within defined limits; your equipment and procedures are capable of detecting concentrations at or below those specified in Section 30.70 of Title 10, Code of Federal Regulations, Part 30; and your personnel follow step-by-step operating procedures (that have been approved by NRC) on a day-to-day basis.

In your initial application and subsequent correspondence, you have asserted repeatedly that your personnel have adequate training and experience; you have adequate facilities and equipment; and your procedures are adequate to provide reasonable assurance that the requirements of Section 32.11 of Title 10, Code of Federal Regulations, Part 32 will be met. However, you have not provided sufficient information to support your assertions. Also, in some responses, you have indicated that the information requested by the staff is "proprietary and irrelevant;" indicated that the "details such as counting sizes and efficiencies and maximum and minimum sample sizes" as well as lower limit of detection of your counting systems will be "worked out later;" and simply referred the staff to previously submitted information that the staff had identified to you as being inadequate and incomplete. Responses such as those outlined above do not provide the staff with the type of detailed information needed to make the findings required by Section 30.33(a) of Title 10, Code of Federal Regulations, Part 30.

Therefore, in accordance with Section 2.108 of Title 10, Code of Federal Regulations, Part 2, your application for a new license is hereby denied for failure to provide that information requested and required by the staff to make the findings required by Section 30.33(a) of Title 10, Code of Federal Regulations, Part 30. This denial will not adversely affect the Commission's consideration of any application you may file in the future.

In accordance with Section 2.103 of Title 10, Code of Federal Regulations, Part 2, you may request a hearing with respect to this denial within 20 days of the date of this letter. A request for a hearing shall be submitted to both the Executive Director for Operations and the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Also, please mail copies of any hearing request to the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, and the Assistant General Counsel for Hearings and Enforcement, Office of the General Counsel, at the address given above. If a hearing is requested, the Commission will issue an order designating the time and place. The

issue to be considered at such a hearing is: whether your application for a license pursuant to Title 10, Code of Federal Regulations, Part 32 was properly denied.

Sincerely,

/RA/

[NAME], Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards

Enclosures:
1. Information Needed from a Reactor...
2. Information Needed from an Importer...
3. 10 CFR Parts 30 and 32
4. 10 CFR Part 2, Subpart L

MAY 13 1986

Licensee F
ATTN: John Doe
Supervisor
Any Address
Anytown, Anystate 12345

Dear Mr. Doe:

This letter refers to your application dated January 21, 1986, requesting a license to utilize radioactive materials for well logging and tracer studies in oil and gas wells. On March 11, 1986, we sent you a letter requesting additional information concerning your application. Your response to this letter was received by us on March 25, 1986. Subsequent to these letters, however, we learned that you obtained and utilized an americium-241 well logging source prior to obtaining the required U.S. Nuclear Regulatory Commission (NRC) license.

In an interview with an NRC inspector on April 23, 1986, you denied possessing any radioactive material; however, you stated that you purchased a well logging truck and a gamma logging tool (non-radioactive) from Company X, a State of Kansas licensee. Region III contacted the Kansas Department of Health and Environment and was advised that the Company X license had expired and the Department was initiating an investigation to determine how Company X disposed of or transferred their 3 curie americium-241 well logging source. When you were confronted by the NRC inspector with this additional information on April 28, 1986, you admitted you were in possession of the 3 curie americium-241 well logging source, and then agreed, at Region III's request, to voluntarily surrender the source to the Illinois Department of Nuclear Safety (IDNS).

Your possession and use of the well logging source prior to receipt of an NRC license is in violation of and indicates careless disregard for NRC regulations. Accordingly, your application is hereby denied pursuant to Section 2.103 of 10 CFR Part 2 (enclosed). As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning this denial. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to

SAMPLE DENIAL F

the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The request should reference this letter and Docket Number 030-00000.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosure: 10 CFR Part 2

OCT 23 1978

Licensee G
ATTN: Dr. John Doe
Any Address
Anytown, Anystate 12345

Dear Dr. Doe:

This is in reference to your letters dated February 28, 1978 and August 4, 1978 and our letter dated May 25, 1978 regarding your request to extend the time interval for inspection and servicing of your teletherapy unit from the normal five (5) years to seven (7) years.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, your request to amend License No. 12-34567-89 is hereby denied for the reasons set forth below.

The staff of the Nuclear Regulatory Commission has determined that the criterion in the American National Standards Institute (ANSI) report N449-1974, "American National Standard Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment" needs to be followed to reduce the incidence of teletherapy machine malfunctions and personnel overexposure to radiation by requiring inspection, servicing, and repair or replacement of components of the source exposure mechanism that are worn or damaged. The experts who prepared the ANSI report recommended inspection and servicing of teletherapy unit after an interval not longer than five (5) years.

The staff has further determined (See Enclosure 4) that teletherapy units must be inspected and serviced at time of source change or every five (5) years, whichever comes first, in order to meet the requirement of Section 30.33(a)(2), Part 30, Title 10, Code of Federal Regulations, that a licensee's facilities and equipment be adequate to protect health and minimize danger to life and property. You have not provided substantive justification from a health and safety standpoint, for exceeding the five (5) year interval and therefore your request is denied.

SAMPLE DENIAL G

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, you may request a hearing with respect to this denial within twenty (20) days of the date of this letter.

Sincerely,

/RA/

[NAME], Director
Division of Fuel Cycle and Material Safety

Enclosures:
1. Ltrs dated 2/28/78 and 8/4/78 from Dr. Doe
2. NRC ltr dated 5/25/78
3. 10 CFR Parts 2, 30
4. AEC ltr dated 11/15/72 to all teletherapy licensees

JUL 25, 1986

License No. 12-34567-89
Docket No. 030-00000
Control No. 123456

Licensee H
ATTN: John Doe, M.D.
President
Any Address
Anytown, Anystate 12345

Gentlemen:

This letter is in response to your application dated March 6, 1984, and subsequent letters on the same subject, to amend License No. 12-34567-89 to authorize use of strontium-90 plaque applicators for the treatment of malignant skin lesions.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, this letter constitutes denial of your application to amend License No. 12-34567-89. The reasons for this denial are set forth below.

10 CFR 35.14(a) states that certain medical uses specified in Section 35.100 of Part 35 will be approved under certain conditions. Your proposed use of strontium-90 plaque applicators for the treatment of malignant skin lesions is not specified in Part 35.

10 CFR 30.33(a) states, in part: "An application for specific license will be approved if: ... (2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property ..." The Nuclear Regulatory Commission regards the applicator you propose to use as "equipment" within the meaning of this regulation.

In passing on whether or not a proposed use should be approved, the U.S. Nuclear Regulatory Commission's Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes (44 FR 8242) specifies, in part:

> The NRC will regulate the radiation safety of patients where justified by the risk of patients and where voluntary standards, or compliance with these standards, are inadequate.
>
> . . . .

SAMPLE DENIAL H

NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

In accordance with the policy statement, we twice referred your proposal to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for review. Based on the comments of the members of the ACMUI, and on the references to the literature you provided, the staff has determined that you have not established a basis for approval of your request. Specifically, the proposed treatment has not been demonstrated to be safe and effective.

Further, adequate voluntary standards for selection, treatment, and follow-up of patients do not exist. The staff believes that it is inappropriate for original research with isotopes on humans to be conducted in a private practice. This type of research should be conducted at an institution which has been issued a license of Broad Scope authorizing medical research and has established a committee to review, approve, and oversee protocols for proposed research on humans.

If you continue to strongly believe that this treatment modality deserves a clinical trial, you should consider becoming affiliated with an institution that is licensed by the NRC to conduct original research with strontium-90 on humans. Should you receive approval as an authorized user at such an institution, you could pursue the mode of radiotherapy you requested, in accordance with its approved protocol.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, you may request a hearing with respect to this denial within 20 days of the date of this letter. If you wish to request a hearing, submit a request to the Director, Division of Radiation Safety and Safeguards, USNRC Region 1, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The request should reference this letter and Docket No. 030-00000.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosure: 10 CFR Part 2

Docket: 030-00000 **MAY 24 1988**

Applicant I
ATTN: Mr. John Doe
Any Address
Anytown, Anystate 12345

Gentlemen:

This letter notifies you of denial of your application dated January 20, 1988, requesting a byproduct material license for use of sealed sources and devices for use in industrial radiography. As a result of a preliminary review of your application in February 1988 and various telephonic discussions with Mr. John Smith of my staff, you submitted a letter dated March 1, 1988, amending your application. Mr. Smith also performed a prelicensing visit at your facility in Anytown, Anystate, on March 3, 1988, and provided at that time a letter from NRC dated March 3, 1988, identifying items for which additional information was needed. You subsequently provided a response to this letter dated March 16, 1988.

During our review we also obtained enforcement history information from the Colorado Department of Health (CDH) which licensed radiographic operations for Company X for which you were an employee and the sole owner. This information indicates that CDH experienced difficulty in locating your operations during 1982, and when your operations were located and inspected, 20 violations of CDH requirements were identified. Repeated attempts failed to relocate Company X after the inspection and to serve a Notice of Violation and secure a response. A hearing was held by CDH on March 31, 1983, during which the license issued to Company X was revoked. The specific details of these events are detailed in Enclosure 1.

As a result of our review of the CDH findings we conclude that Applicant I has not met a general requirement for issuance of a specific license as described in Section 30.33(a)(3) of 10 CFR Part 30. This regulation states:

> "An application for a specific license will be approved if the applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property."

The enforcement history of Company X indicates an absence of the kind of training and experience that would lead this agency to conclude that the material would be used in such a manner as to protect health and minimize danger to life or property. Accordingly, your application is hereby denied pursuant to Section 2.103 of 10 CFR Part 2 (enclosed). As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning this denial.

SAMPLE DENIAL I

If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Assistant General Counsel for Hearings, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555. The request should reference this letter and Docket Number 030-00000.

In the event a hearing is held, the issue to be considered at such hearing shall be whether the facts about the prior enforcement history of Company X are a reasonable and adequate basis for denial of the license application filed by Applicant I.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosures:
1. Inspection and Enforcement History - Colorado Department of Health
2. 10 CFR Part 2

SEP 19, 1980

Licensee J
ATTN: Mr. John Doe
Administrator
Any Address
Anytown, Anystate 12345

Gentlemen:

This is in reference to your May 23, 1980 request to add Dr. John Smith as an authorized user on your teletherapy license (No. 12-34567-89).

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, your request to amend License No. 12-34567-89 is hereby denied for the reasons set forth below.

Dr. John Smith holds a document called a "limited license" issued by Indiana's Medical Licensing Board which authorizes him to practice only radiologic oncology and only at Terre Haute Regional Hospital. He does not hold a "controlled substance" license. Under this so-called "limited license," Dr. Smith is not allowed to dispense drugs, as a general matter, in the practice of medicine, but is limited to the practice of his specialty at a specific hospital.

License No. 12-34567-89, which authorizes possession and use of a cobalt-60 sealed source for treatment of humans, was issued pursuant to Section 35.13, Part 35, Title 10, Code of Federal Regulations. In part, this section requires that, "if the application is made by an institution, the individual user (1) has specialized training in therapeutic use of the radioactive device considered...and (2) is a physician." The term "physician" is defined in Section 35.3(b), Part 35, Title 10, Code of Federal Regulations, as "an individual licensed by a State... to dispense drugs in the practice of medicine."

Dr. Smith does not fully meet NRC's definition of a "physician" for two reasons. First, Dr. Smith is not a licensee of the State of Indiana. He holds a so-called "limited license". The Indiana Medical Practice Act (enclosed) does not define the meaning of the term "limited license" and, in fact, defines a "licensee" as a person who holds an "unlimited license." Section 1(g) of Chapter 1 of Article 22.5 of the Indiana Medical Practice Act defines "physicians" as "any person who holds the degree of doctor of medicine or doctor of osteopathy, or its equivalent and who holds a valid unlimited license (emphasis added) to practice medicine or osteopathic medicine in the State of Indiana." Section 1(e) of that chapter defines a "license" as any individual holding a valid unlimited license (emphasis added) issued by the Board (Medical Licensing Board of Indiana) under this article."

SAMPLE DENIAL J

Second, Dr. Smith is not licensed by Indiana to prescribe drugs for other medical care for radiation therapy patients. Dr. Smith would not be able to provide the full range of supportive medical care, including medications, necessary for the complete management of therapy patients. For example, he would not be able to prescribe medication for relief of radiation sequelae such as vomiting or skin reaction, and it may not be possible to delegate effectively these medical care aspects of radiotherapy.

Because most proposed individual users on teletherapy licenses are fully qualified physicians, we do not normally consider the medical care aspects of users' responsibilities. However, from a policy perspective and the standpoint of the health and safety of therapy patients, we do not believe that teletherapy users should have legal restrictions over their ability to provide all aspects of medical care for their patients. Therefore, for the reasons previously discussed, your request is denied.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, you may request a hearing with respect to this denial within twenty (20) days of the date of this letter.

Sincerely,

/RA/

[NAME], Director
Division of Fuel Cycle and Material Safety, NMSS

Enclosures:
1. 10 CFR Parts 2, 35
2. Indiana Medical Practice Act

JAN 10 1989

Docket No. 030-00000
EA No. 88-000

Applicant K
ATTN: Mr. John Doe
Any Address
Anytown, Anystate 12345

Gentlemen:

SUBJECT: DENIAL OF LICENSE APPLICATION

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted an July 20, 1987, and to the NRC investigation conducted during October and November 1987 by the NRC's Office of Investigations (OI), which was conducted to determine whether you had possessed radioactive material prior to your receiving an NRC license for which you applied on August 14, 1987. In addition, the investigation was initiated to determine whether you had been truthful when discussing these matters with a member of the NRC Region IV staff. The synopsis of this investigation is attached.

NRC's regulations in Section 30.33(a)(3) of 10 CFR Part 30 require that an applicant for a license be "qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property." Notwithstanding the fact that you, the applicant, proposed as authorized users individuals whose training and experience meet the requirements of 10 CFR Part 39, you have demonstrated inadequate training and experience with regard to NRC requirements in that you knowingly possessed licensed material without the license required by Section 30.3 of 10 CFR Part 30. Specifically, as a result of the NRC investigation referenced above, NRC has concluded that, in violation of NRC requirements known to you at the time, you possessed a radioactive source before obtaining an NRC license to possess such material. In addition, you provided inaccurate information to the NRC about your possession of this material. Possession of the radioactive source without a license is a violation of the requirements of Section 30.3 of 10 CFR Part 30, which prohibits any person from transferring, receiving, possessing, or using byproduct material without a specific license issued by NRC pursuant to Title 10 Chapter 1, Code of Federal Regulations. Had the lack of candor occurred on or after February 1, 1988 (the effective date of the regulation), it would have been in violation of Section 30.9 of 10 CFR Part 30, which requires applicants to provide complete and accurate information to NRC.

SAMPLE DENIAL K

Therefore, NRC does not have the requisite reasonable assurance that you would comply, in the future, with all Commission requirements, including 10 CFR 30.9. Thus, NRC cannot conclude that you would use licensed material in such a manner as to protect health and minimize danger to life and property. Accordingly, your license application is hereby denied pursuant to Section 2.103 of 10 CFR Part 2.

As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning this denial. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief. Docketing and Service Branch; U.S. Nuclear Regulatory Commission; Washington, D.C. 20555, with a copy to the Assistant General Counsel for Hearings; U.S. Nuclear Regulatory Commission; Washington, D.C. 20555. The request should reference this letter and Docket Number 030-00000.

In the event a hearing is held, the issue to be considered at such hearing shall be whether the facts regarding prior possession of material and the false statement proffered by a representative of Applicant K are a reasonable and adequate basis for denial of the license application filed by Applicant K.

Sincerely,

/RA/

[NAME]
Regional Administrator

Enclosures:
1. 10 CFR Parts 2 and 30
2. OI Report Synopsis

Appendix K

Routine Exemptions

The following format is used throughout this Appendix to allow the user to locate information quickly. The following box has a description in each segment that explains the information that will be located in that segment.

The first box segment describes the section of the regulation from which an exemption could be requested by a licensee.
The second box segment describes any additional information a licensee will need to submit or commit to other than information described in Section 4.13 of this NUREG.
The third box segment describes the license condition to be used once the Region determines the exemption should be granted.

K.1 10 CFR 35

K.1.1 Record keeping or posting

Requests for relief from record keeping or posting requirements, in Part 35.
The following information is sufficient: • A description of the exemption needed and the reason why it is needed; • A description of compensatory safety measures that will provide a level of protection equivalent to the regulation for which the exemption is being requested; and • A discussion of how reasonable alternatives have been considered.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 35._____, the licensee may use the alternative method for __(record keeping or posting)__ as described in the letter/application dated _____."

K.1.2 §35.315(a)(4) and §35.415(a)(4)

Regions may grant exemptions from §35.315(a)(4) and §35.415(a)(4) which require surveys in contiguous areas after the administration of a therapeutic radiopharmaceutical dosage or implantation of sealed sources for brachytherapy, respectively.

The following describes additional information needed:

a. The licensee must provide a detailed description of the rooms used for therapy, including the adjacent areas and the area above and below such rooms used for therapy. A sketch of the treatment rooms and adjacent areas should be submitted with the layout of the rooms and adjacent areas indicated.

b. The licensee must describe how it will evaluate the dose rates in areas adjacent to treatment rooms, and provide sample calculations. All assumptions used in the evaluation must be clearly identified. The licensee must describe what shielding is present in the walls/floor/ceiling. The licensee must state that if any of the parameters used in the initial evaluations change (i.e., room layout, increase in source activity, etc.), a new evaluation will be performed.

c. The licensee must provide enough information to determine that the requirements in §20.1301 (a) will be met. The licensee must also address how it will determine that dose limits to members of the public and other patients in unrestricted areas from multiple therapy patients or subsequent hospital stays in the same calendar year will not exceed 100 millirem per calendar year.

The following license condition should be used for exemptions from 10 CFR 35.315(a)(4):

"Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the letter/application dated _____."

The following license condition should be used for exemptions from 10 CFR 35.415(a)(4):

"Notwithstanding the requirements of 10 CFR 35.415(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the letter/application dated _____."

K.1.3 §35.400(d) and §35.400(q)

Regions may grant exemptions from the use requirement in §35.400(d) for iridium-192 and §35.400(g) for palladium-103 to allow other than interstitial treatment of cancer.
For the exemption to be granted, the licensee must specify iridium-192 (Ir-192) encased in nylon ribbon and palladium-103 (Pd-103) seeds. No additional radiation safety procedures need to be identified. Ir-192 and Pd-103 have been used for intracavitary use for many years and sources in the Sealed Source and Device Registry which have passed the testing criteria for interstitial use can be used in intracavitary or topical applications. Requests for authorization of gold-198 and iodine-125 seeds for intracavitary and topical applications should be coordinated with NMSS as identified in Section 4.13 of this NUREG.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions only to the extent that the instructions are not applicable to the type of use proposed by the licensee."

K.1.4 §35.404(a)

Regions may grant exemptions from the requirement in §35.404(a), that prohibits the release from confinement for medical care, a patient or human research subject with eye plaque implants until all sources have been removed.

Although the eye plaque implant is temporary, in that it will be removed after several days, the manner in which it is used is similar to a permanent implant. Because the implant is sutured into place, the device cannot be removed by the average patient, nor is it likely to become dislodged or lost.

For the exemption to be granted, the licensee must adequately commit to comply with the requirements described below to ensure adequate protection of public health and safety and to meet the survey requirements for permanent implant patients specified in §35.75(b). Specifically, the licensee must commit to comply with the following provisions:

a. The measured dose rate from the patient must be less than 5 millirems per hour at a distance of 1 meter;
b. The patient will be provided with radiation safety guidance on how to maintain doses to other individuals as low as reasonably achievable.
c. A radiation survey of the patient will be made with a radiation detection survey instrument after removing the eye plaque, but before release of the patient to ensure that all sources have been removed.
d. Upon removal of the eye plaque, the plaque will be disassembled and a physical inventory of the seeds will be conducted to confirm that all sources have been recovered.
e. The licensee must also address any specific radiation safety instructions to be provided to patients.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care a patient with a temporary eye plaque implant in place, in accordance with procedures described in letter/application dated _____."

K.1.5 §35.647

Regions may grant exemptions to §35.647 to extend the time for servicing and inspection of a teletherapy unit.
The following information is sufficient: • A description of the exemption needed and the reason why it is needed; • A description of compensatory safety measures that will provide a level of protection equivalent to the regulation for which the exemption is being requested; and • A discussion of how reasonable alternatives have been considered.
Standard License Condition 91 should be used. In general, the maximum interval from one inspection and servicing to the next is 6 years.

K.2 10 CFR 36

Although many provisions of 10 CFR Part 36 apply to converted teletherapy units, compliance with certain applicable provisions of the rule may be impractical, and exemptions will be granted from specific sections of 10 CFR Part 36, provided that the licensee requests and technically justifies the exemption. The following are technical justifications and commitments acceptable for exemptions from specific sections of 10 CFR Part 36.

K.2.1 §36.23(a)

Regions may grant exemptions to §36.23(a) which states, in part, that ".. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources."...
Provided that the licensee commits to have the operator present for the entire period of time that the key is in the control panel. For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key-switch on many control panels is a 3-position switch which controls electrical power to the teletherapy unit. The key can only be inserted/removed in the "off" position, and in this position the main power and control circuits are without electrical power. Power is required to move collimators, activate field lights, align system, etc. Requiring a single key would not allow the licensee to operate these powered systems.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated _____."

K.2.2 §36.23(b)

Regions may grant exemptions to §36.23(b) which states, in part, that "... each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed."...
The Region may grant the licensee an exemption from this requirement provided that the licensee has an electrical interlock system meeting all of the conditions specified in §35.615(b) on each entrance to the radiation room. Alterations of the electrical interlocks of the teletherapy unit to meet the requirements of 36.23(b), may cause the interlock system to function incorrectly. A working electrical interlock system on each entrance suffices to prevent personnel entry while the source is exposed. In addition, the licensee must commit to having an operator present during the entire irradiation who can visually observe the entrance, and to having a radiation monitor that can be read prior to entering the radiation area.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 35.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the letter/application dated _____."

K.2.3 §36.23(c)

Regions may grant exemptions to §36.23(c) which states, in part, that ... "The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high."....
Alteration of the interlock system to meet this requirement would prevent entry to the treatment room to remove a patient in the event of a stuck source. The Region may grant the licensee an exemption from this requirement provided that the licensee has an electrical interlock system which will retract the source, upon opening access doors to the irradiation room and commits to its use. In addition, the licensee must commit to having an operator present and having a radiation monitor in the room, as discussed above.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 35.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the letter/application dated _____."

K.2.4 §36.23(d)

Regions may grant exemptions to §36.23(d) which states, in part, that ... "visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position."...
An acceptable justification is that an audible alarm within the treatment room may cause undue distress to the patients (human or animal). If the licensee commits to having a visual alarm provided on the outside of the treatment room, and to having the operator visually check the room prior to starting treatments, the Regions may grant the licensee an exemption from this provision of the regulations.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having a visible and audible alarm within the treatment area, based on the commitments described in the letter/application dated _____."

K.2.5 §36.23(f)

Regions may grant exemptions to §36.23(f) which states, in part, that "Each radiation room at a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door... has been closed within a preset time..."
Exemptions may be granted to licensees having teletherapy units that are being used for irradiation of materials only (no patients), provided the licensee commits to the operator visually verifying that the room is not occupied prior to closing the door, and that the converted teletherapy unit (irradiatior) activates a visual and audible alarm in the teletherapy room for at least 15 seconds prior to moving the source form the shielded position. This visual/audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual/audible alarm has been activated and is finished alarming. The use of a visual/audible alarm in a patient treatment room may cause anxiety for patient treatment (human or animal) and object or material irradiation may be authorized an exemption from §36.23(f) without the need to have a visual/audible alarm, if the licensee commits to having an operator visually verify that the room is not occupied prior to closing the door and if the licensee has a means of visual observation of the area as require in §35.615(e). If the unit is not used for patients, then the audible/visible alarm described above is required.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the letter/application dated _____."

K.2.6 §36.27(a) and 36.27(b)

Regions may grant exemptions to §36.27(a) which states, in part, that... "The sources must automatically become fully shielded if a fire is detected," and §36.27(b) which states, "The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas."
The Statements of Consideration state that the purpose of fire extinguishing system is to prevent a fire from damaging the access control system or preventing the sources from being shielded. Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. The licensee may be granted an exemption from these requirements by the Region provided that the licensee commits: to have smoke detectors, fire extinguishers and a fire alarm at the site to detect and fight small fires, and to alert authorities of the fire; to have a means of measuring the radiation levels in the radiation room during an electrical failure; and to instruct the operators to retract the source prior to exiting for a fire involving major portions of the facility, provided this action does not jeopardize the operator's safety.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from (as requested by licensee) based on the commitments described in the letter/application dated _____."

K.2.7 §36.31(a)

Regions may grant exemptions to §36.31(a) which states, in part, that... "The key must be attached to a portable radiation survey meter by a chain or cable. [...] The door to the radiation room must require the same key."
Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head; therefore, the Region may grant the licensee an exemption from this requirement provided that the licensee commits to having administrative controls in place to insure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted. The licensee must also commit to attach the survey meter to the exposure room door key.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated _____." The radiation room door key shall be attached to the portable survey meter.

K.2.8 §36.31(b)

Regions may grant exemptions to §36.31(b) which states, in part, that "The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in...transit."
In converted teletherapy units the source is moved nearly instantaneously from the shielded to the exposed position. Most teletherapy units are designed with two indicator lights. The green light indicates the source is in the fully shielded position; the red light indicates the source is exposed. During transit both lights are on indicating that the source is in transit. To require that the licensee install an electronic system to indicate "in transit" for the period of time the source is in transit, less than a second, does not provide any additional protection. Illumination of both lights simultaneously accomplishes the same safety goal as an "in transit" indicator; therefore, the Region may grant this exemption provided the licensee submits a description of its device indicators.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated _____."

K.2.9 §36.67(b)(2)

Regions may grant exemptions to §36.67(b)(2) which states, that a licensee must, "Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control."
Due to the risk of malfunction associated with alterations to the existing electrical interlocks of the teletherapy unit necessary to comply with this regulation, and the licensee's commitment to administratively control access to the room to meet the intent of this regulation, the Region may grant this exemption, if the licensee demonstrates that a retrofit to install such a control would not be possible with the teletherapy unit; and the licensee commits to the following: o The operator will close the doors immediately upon completion of the visual inspection required by §36.67(b)(1). o The operator will verify that each door has locked automatically before stepping to the control panel.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room which must be activated prior to irradiation which would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a present time, based on the commitments described in the letter/application dated _____."

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

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Kevin Ramsey, Vivian Campbell, Richard Gibson

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

As part of its redesign of the materials licensing process, The United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April1996. NUREG-1556, Vol. 20, "Consolidated Guidance about Materials Licenses: Guidance About Administrative Licensing Procedures," dated July 2000, is the twentieth guidance volume developed for the new process and is intended for use by NRC staff. It will also be available to Agreement States, applicants, and licensees. This document combines and updates the guidance for NRC license reviewers and licensing assistants previously found in the documents listed in Appendix A. When published in final form, NRC licensing staff will use these administrative procedures to process license applications and prepare licenses. Note that this document is strictly for public comment and is not for use in preparing or reviewing license applications until it is published in final form.

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