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. If the licensee does not use the NUREG-1556 series, the review of the applicant's submittal may take longer to complete.

Reviewers should use, as a minimum, 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 Inspection Manual Chapter 2800 to identify the program code with the highest inspection priority. The program code with the highest inspection priority should be identified as the primary program code in the LTS, and this program code will dictate the inspection frequency for this license.

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

Note: For the C.6 Checklist in Appendix C, refer to ML063480256 for supplementary guidance that is nonpublicly available. The checklist will be completed for all applications to ensure that radioactive materials will be used as intended, i.e., as per a specific license.

4.2 PROCESSING NEW APPLICATIONS

Applicants for new licenses are expected to provide all the information specified on NRC Form 313, "Application for Material License." 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 public 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 provided in the appropriate NUREG-1556 volume, and guidance supplemented in

relevant TAR responses. The reviewer will also complete the C.6 Checklist in Appendix C to ensure that radioactive materials will be used as intended.

Note: Confirm that none of the staff members is banned from NRC licensed activities by checking the escalated enforcement actions issued to individuals. Go to the Office of Enforcement page on the external web site (www.nrc.gov/OE/). Select "Enforcement Actions" from the buttons on the left side of the screen. Select "Escalated Enforcement Actions Issued to Individuals" from the links at the bottom of the page. Go to the Edit drop-down menu, and select "Find in Frame." Search for the individual's last name. If an order was issued to the individual, read the order and confirm whether the restrictions still apply. Consult with OE *before* taking any action for an individual who appears to be banned from NRC activities.

Sections of the application that do not conform to, or fail to address areas in the appropriate guidance, become 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 deficiencies should be clearly documented and communicated to the applicant. Reviewers should apply the guidance in the NUREG-1556 series to the extent suitable to the applicant's proposed activities and should not apply any standards or criteria for which there is no specific regulatory basis. Reviewers should accept only procedures or proposals that result in a level of safety at least 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 provided in the original application changes in a way that requires an amendment to the license as specified in the NUREG-1556 series, or in any way affects specific items 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 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 the entire application, the reviewer should request that the licensee specifically identify the requested changes. The licensee may opt to resubmit the request and only discuss the specific changes, or may identify the changes by marking or highlighting the modified text. The reviewer will complete the C.6 Checklist in Appendix C to ensure that radioactive materials will be used as intended.

4.4 PROCESSING RENEWALS

NMSS has developed a license renewal system that primarily focuses resources on applications from licensees whose performance indicates potential programmatic weaknesses, and on licenses with program areas that have undergone major changes that could affect radiation safety. Each renewal application will be screened against a specific set of performance indicators, discussed in this section, to determine whether the application will receive a comprehensive or limited review.

The reviewer will complete the C.6 Checklist in Appendix C to ensure that radioactive materials will be used as intended.

4.4.1 DETERMINING REVIEW STATUS

The first task for the reviewer is to review the Docket file(s) and inspection and licensing correspondence, and query NRC data bases (such as the Nuclear Materials Events Database (NMED) and the Licensee Event Reports (LERs)) to compare the licensee's effectiveness 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 technical review and 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. NRC licensing management reserves the option to request that the licensing staff 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. These particular management 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 using the following guidance. This checklist serves as an OAR because it contains the technical basis of a decision 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 5 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 or pending enforcement action without the written concurrence of the appropriate office.

2. Loss of Material

   If the licensee has been cited with a violation for the loss of control of a reportable quantity of licensed material presumed to be in the public domain in the last 5 years, the license application will be considered for a comprehensive review.

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 5 years, the license application will be considered for a comprehensive review.

4. Overexposure

   If the licensee has been cited for a radiation exposure in excess of regulatory requirements in the last 5 years, a comprehensive review of the license application will be considered. Exposures 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. 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, it must include a means for adjusting the cost estimates and associated funding levels periodically over the life of the facility (see 10 CFR 30.35(e), 40.36(d), and 70.25(e)). Periodic adjustments are expected to range from 1 to 5 years. Any proposal to wait more than 5 years before adjusting cost estimates and funding levels should be coordinated with NMSS management (branch level or above) before it is approved.

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.

Note: Confirm that none of the staff members is banned from NRC licensed activities by checking the escalated enforcement actions issued to individuals. Go to the Office of Enforcement page on the external web site (www.nrc.gov/OE/). Select "Enforcement Actions" from the buttons on the left side of the screen. Select "Escalated Enforcement Actions Issued to Individuals" from the links at the bottom of the page. Go to the Edit drop-down menu and select "Find in

Frame." Search for the individual's last name. If an order was issued to the individual, read the order to confirm whether the restrictions still apply. Consult with OE *before* taking any action for an individual who appears to be banned from NRC activities.

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.

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, the license reviewer should use the most efficient process available to fully communicate issues to licensees, document the request, and elicit the appropriate applicant response. The reviewer should use the telephone, facsimile, and e-mail to communicate with licensees, thereby reducing reliance on formal letters. All substantive communications must be clearly documented. Draft documents from the applicant should not be accepted or scanned into ADAMS and cannot 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.

Application for a New License or for an Amendment

A. Complex Deficiencies

1. Any significant or complex deficiencies in an application for either 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. Deficiency letters can be sent by regular mail, e-mail, or facsimile. The letter to the applicant should contain a statement that specifies that NRC will assume the applicant does not wish to pursue its application if NRC does not receive a reply within 30 calendar days from the date of the letter. The reviewer should complete an LTS form that instructs the LA to enter a milestone 14 into the LTS database for tracking the specific licensing action.
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, the licensing staff should consider the application as abandoned for failure to provide the requested information. This abandonment is without prejudice to the resubmission of the application. Prompt action (5 working days) should be taken to void the application.
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 unless the application was subject to full cost recovery. The "voiding" of this type of application should be closely coordinated with OCFO.

B. Simple Deficiencies

1. To expedite the issuance of a license or license amendment, reviewers are encouraged to use the telephone or e-mail to obtain clarifying information from an applicant and to notify an applicant of the existence of simple deficiencies in their application. Inform the applicant that the request will be considered void or abandoned without prejudice if they fail to respond. Simple deficiencies can include such items as 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. For most applicants, simple deficiencies do not include training and experience of individuals, descriptions of radiation safety programs, etc.
2. The reviewer should document the telephone call or e-mail, including the warning about failure to respond. A copy of the conversation record should be provided to the applicant. Complete the appropriate LTS form, and instruct the LA to enter a milestone 15 for the specific licensing action. Documentation of the telephone call or e-mail should be entered and profiled in ADAMS as outgoing licensing correspondence.

3. Monitor the licensee's response with the LTS tickler system. If a response is not received within 35 calendar days from the original contact, void the action. Any response received after the action is voided should be handled as stated above.

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 most expedient 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 the letter should not include a formal warning. A milestone 14 should be entered into the LTS database for the specific licensing action.

   NRC's licensing 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, facsimile, or e-mail, 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 LTS milestone date changes should be made by the LA to track each application

properly and record extensions of time for responses. The reviewer should keep NRC management informed of licensees' continued requests for extensions.

4.6 CREATING THE LICENSE

4.6.1 STANDARD LICENSES AND STANDARD LICENSE CONDITIONS

For consistency within NRC Regions and Headquarters, the license reviewer should use the sample licenses from the appropriate NUREG series volume as a standard when creating a license for an applicant. Some instances may exist where the reviewer may need to customize a license. Since an applicant may request authorization to use licensed materials in more than one program type, the reviewer may need to review the sample licenses in more than one NUREG series volume and then combine the pertinent license conditions into a single license, where appropriate. In some complex licensing 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. The program code that identifies the highest inspection priority (shortest inspection cycle) should be the primary program code in the LTS, as this program code will dictate the inspection frequency for the license.

In some specific instances, 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 first 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 the NUREG-1556 series or existing technical guidance outlined in TARs. The reviewer should use standard license conditions whenever possible; however, custom conditions may be used when necessary. The license reviewer should write the custom license condition to state the requirement clearly and simply. Custom conditions should be approved by the appropriate branch chief, and the approval should be documented (e.g., e-mail, note to file, etc.). This strategy is intended to streamline the licensing process to be more responsive to stakeholders, to empower staff, and to reduce management reviews.

Issues not currently addressed in the NUREG series and thought to be critical to a specific type of licensing action should continue to be coordinated with Headquarters. If the Region believes that a special condition is appropriate, it should also be coordinated through Headquarters. In addition, license reviewers should explain these conditions to inspection staff and licensees to ensure that all parties have the same understanding, especially those unique to a specific type of licensee. It is anticipated that license reviewers will provide an explanation in the cover letter issuing the license or 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 10-year license term limit. The Commission's actions also 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 exist for 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.
>
> **Enforcement History:** The licensee, in the last inspection or 5 years (whichever is longer), had a Severity Level I, II, or III violation.
>
> **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 for a 2-year term, and decommissioning issues will be addressed at that time.
>
> **Other:** Other situations that would warrant increased attention. These conditions will be addressed by the licensing staff 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 required. This checklist is designated an OAR because the basis of a decision is not documented elsewhere. If the license reviewer recommends that the license term should be shorter than 10 years, a term of 5 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 and the original signed license.
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 license reviewers may elect to use attachments.
4. For licenses that 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 OARs and will be maintained in ADAMS.
6. Appendix D also provides a sample cover letter for terminating a license.

4.7 GUIDANCE FOR MULTI-SITE LICENSES

NRC on occasion receives applications for new licenses, amendments, and renewals ("applications") that request authorization for use of NRC licensed material at multiple sites under one license. Many of these applications represent categories of licensees for which 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 specific license condition, 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 in no way attempts 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 license 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 these 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 authorizes two or more locations of use that are specifically identified on the license. Such authorized locations will typically include either: (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 activities are ongoing, with the exception of temporary job sites, broad scope licensees, or mobile nuclear medicine services. A multi-site facility may also include those groups of licensees for which the addresses of use are geographically separated. These facilities may each be under the direction of a single corporate RSO, or they may have site RSOs who report to a corporate RSO. The corporate RSO is usually the RSO of record on the license.

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

Multi-Site Examples:

1. Radiopharmacy licensees with multiple radiopharmacy 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 NRC-licensed materials should be identified on the license when issued.

Communication

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

1. Delegation of clear and appropriate levels of authority within the licensed entity, indicating that sufficient organizational freedom exists and management has established prerogative to communicate with, train, and direct personnel according to NRC regulations and/or license provisions;
2. Descriptions of program reviews or audits and the reporting of such activities on a regular basis;
3. Mechanisms for addressing urgent situations;
4. Mechanisms in place to inform all personnel of radiation safety program changes;
5. Provisions and techniques in the application to make personnel aware of the appropriate representatives to contact at each level of authority;
6. Assurance provided in the application 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 radiation safety records available for NRC review, after receiving reasonable notice from NRC. The license application should specify 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 authorized sites;
2. Applicability of decommissioning requirements;
3. Sharing of safety equipment between sites; and
4. Coordination among sites for inventory control of licensed material, with the intended focus of continually monitoring types and quantities of material to ensure that the total possession limits specified in the license are not exceeded.

4.8 OPPORTUNITY FOR AN INFORMAL HEARING – MATERIALS LICENSING

The purpose of this section is to provide license reviewers with 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, entitled, "Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings." Reviewers should become familiar with the provisions of this Subpart. Specifically, reviewers should be aware that in many materials licensing actions, notices are not published in the *Federal Register*. In such instances, 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 specific regulatory 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 4.10 of this NUREG). After NRC's technical review, 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 specific reference to Subpart L and the opportunity for a hearing.

Although unusual, reviewers should be aware that there have been occasions where 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, requiring 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 with the Secretary. If the license reviewer determines that the request from a

member of the public was not filed with the Secretary of the Commission, the license reviewer should discuss the matter with the Office of the Secretary and the Office of the General Counsel before proceeding with any additional activities or notifications.

4.9 LICENSING SITE VISITS

Licensing visits should be conducted for all new byproduct material applications involving large programs or license programs that present significant or unique technical issues. Additional guidance is provided below.

Purpose of Licensing Visits

Licensing site visits are conducted by the responsible license reviewer or a designated inspection staff member in order to accomplish one or more of the following objectives:

1. Evaluate the applicant's ability to conduct safe operations and comply with requirements;
2. Ensure that requested materials will be used as intended by completing the C.6 Checklist in Appendix C and refer to supplemental guidance in ML063480256 (nonpublicly available).
3. Evaluate safety and technical issues that are not easily understood through correspondence or telephone conversations;
4. Expedite resolution of issues and concerns through discussions with the applicant;
5. Verify statements and commitments in the license application; and
6. Provide a first-hand review of the 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 or distributors using unsealed radioactive material or significant quantities of sealed material;
4. Requests for certain radionuclides in the C.6 Checklist, Table of Risk Significant Quantitites (see Appendix C);
5. Radioactive waste brokers;
6. Radioactive waste incinerators;
7. Commercial nuclear laundries; and

8. Any other application that, in the judgment 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 by NMSS for amendments involving significant modification to the types of operations listed above.

Licensing Visits for Renewals

Licensing visits are encouraged by NMSS for renewals involving the types of activities listed above; however, in many cases, resource limitations can make this difficult for the Regions to support. For each significant renewal, an evaluation of proposed 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 implementing 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" outlined in 10 CFR 51.22(c)(10) and (14) and therefore do not require environmental analyses. A categorical exclusion is defined as 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 10 CFR 51.22, and for which neither an environmental assessment nor an environmental impact statement is required."

The next two subsections provide guidance on determining when materials license actions qualify for categorical exclusion in accordance with 10 CFR Part 51 and 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 10 CFR 51.22(c)(14)(i) Through (xv)

License actions that clearly qualify for categorical exclusion – License actions that clearly qualify for categorical exclusion under the provision of 10 CFR 51.22, with the exception of license termination actions, are not required to have an Environmental Assessment (EA) or documentation in the license file specific to the issue of an EA. Such categorically excluded 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 after NRC's staff has completed additional technical and/or license-based justifications – Such categorically excluded license actions do not need an EA, nor do they need to be coordinated with NMSS with regard to the necessity of an EA. Unless otherwise stated below, the licensing staff is required 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 ON-SITE IS RELEASED INTO THE ENVIRONMENT

If a research and development or academic institution application proposes to release to the environment radioactive materials that originated on-site (i.e., within the controlled property of the licensee), an EA is normally not needed and is covered under categorical exclusion 10 CFR 51.22(c)(14)(v), provided:

- All releases originating on-site 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 10 CFR 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 10 CFR 20.1101(d)).
- All releases on-site comply with all applicable decommissioning requirements (e.g., decommissioning recordkeeping 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 on-site, 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 10 CFR 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 10 CFR 51.22(c)(14)(xvi). The Commission indicated to the staff in SECY-83-286 that there should be careful documentation in cases where these categorical exclusions are applied. Appendix I provides examples of the specific type of information that should be submitted to Headquarters to assist Headquarters staff in preparing this documentation.

When a TAR is received from the Region, IMNS will review the documentation and determine if the action qualifies for a categorical exclusion. IMNS then will provide a memorandum to the Regions, documenting the results that need 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 by IMNS or DWM that bounded the environmental radiological hazards or impacts to the public for the specific generic issue under consideration, and the Region believes its specific license action is within the safety envelope of the previous generic analysis, the Region need only 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 10 CFR 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 10 CFR 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 10 CFR 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 10 CFR 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 only be denied pursuant to 10 CFR 2.103(b) if the staff cannot make the findings required by the regulations (e.g., 10 CFR 30.33, 40.32, or 70.23, as appropriate) because either:

1. The applicant does not satisfy the substantive requirements for receiving a license, even after providing information on which the staff can make a decision; OR

2. The applicant has not submitted adequate information (see 10 CFR 2.108). Denial pursuant to 10 CFR 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 and provide information or the response is not considered adequate.

To ensure that denials, where appropriate, are issued in a timely manner, it is important for the licensing staff to perform follow-up on oral and written communications with applicants. In special situations, they should grant extensions for replies and prepare denial correspondence in accordance with this NUREG. License reviewers should note that applicants have the right to request a hearing concerning the denial pursuant to 10 CFR Part 2 (see Section 4.8 of this NUREG). Sample denial letters informing applicants of this right and providing other information supporting the denial 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 on these issues is 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 necessitates case-by-case consideration. The C.6 Checklist provides the mechanism to notify Headquarters if the reviewer and the cognizant supervisor are not reasonably assured that the requested radioactive materials will be used as intended.

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 on-site inspection. The selection criteria should not be considered all-inclusive, as there may be unique indicators that suggest that a licensed program has changed significantly. Significant licensing actions identified by the license reviewer should be brought to the attention of licensing and inspection managers so that appropriate action is taken to make an assessment if there is a need for the Region to conduct an on-site inspection. A sample memorandum is provided in Appendix C.

All license reviewers should understand the elements of the checklist and complete it for significant amendment or renewal licensing actions. The checklist need not be retained as an OAR if no inspection is recommended; however, if an inspection is recommended, the checklist should become an OAR.

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 requesting exemptions must provide sufficient information for the license reviewer to determine that the proposed exemption is authorized by law; 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 keyed to specific 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," when processing proposed exemption requests. 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 to specific regulations contained in Appendix K may be granted by the Regions without coordination with Headquarters. All requests for exemptions 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 exemption request must be accompanied by:

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

Each Appendix K section describes the specific part(s) of a regulation that may be considered for exemption, outlines any other commitments or additional information that the licensee must submit prior to issuance of the exemption, and provides the license condition to be issued upon review and determination that the exemption can 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; however, the exemption request should be discussed with IMNS whenever possible. Temporary exemptions may be appropriate in circumstances where:

- 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 and temporary and that an exemption will not endanger life, property, or the common defense and security, and that it 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 regulatory requirements for which an exemption is requested and the identification of the specific regulation(s) or license condition(s) involved in the exemption;
- A discussion of circumstances surrounding the situation requiring a temporary exemption to NRC regulations, including the need for prompt action by NRC licensing staff, and the probable consequences to the licensee if the request is not granted;
- A preliminary evaluation of the safety significance and potential consequence(s) of granting the proposed request;
- A description of any compensatory measures, if appropriate; 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 up within 24 hours with written documentation. The follow-up written request must confirm the information submitted orally and upon which NRC specifically relied when granting the exemption.

This specific type of exemption may be granted orally by the Director, DNMS. After granting the request, the Director, DNMS shall promptly send a letter to the licensee. This letter should follow the standard format provided in Appendix D, which documents the circumstances surrounding the temporary exemption request, a statement as to whether the exemption was granted, and the duration of the exemption. The letter signed by the Director, DNMS should include the appropriate licensing action and should normally be issued within 3 working days of granting the request. Concurrent with issuing the license, an entry must be made into the LTS. The ADAMS assession number identifies the OAR of the letter sent to the licensee and should be sent 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, in a TAR, to the appropriate NMSS Division Director. The Regions should closely follow the guidance contained in Section 4.16 for TARs and submission of exemption requests for consideration of approval. All exemption requests should be entered into the LTS and ADAMS upon receipt. Examples of exemptions that require coordination with NMSS before processing by the Region, which also should be recorded in the LTS and ADAMS, are provided below. Additionally, when an exemption is being considered by NMSS, 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, authorized nuclear pharmacists, and RSOs. These requests are coordinated with 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 an exemption or temporary exemption to a licensee, the reviewer should describe the specific exemption in the cover letter accompanying the amendment authorizing the exemption. This cover letter should include any special provisions or conditions associated with this exemption. Additionally, the reviewer should record the exemption on the LTS worksheet and identify the specific section of the regulation to which the exemption was granted. Refer to Appendix F for specific guidance about entering and controlling data integrity in the LTS.

4.14 TECHNICAL ASSISTANCE REQUEST – MATERIAL LICENSEES

The purpose of this section is to provide procedures for the preparation and processing of TARs related to material, including sealed source and device evaluations; and issues involving the storage, use, and disposal of radioactive material. These instructions pertain to all TARs submitted by the Regions to the NMSS, including those for sealed source and device design evaluations. As per the C.6 Checklist in Appendix C the Regions may submit a TAR to request an additional evaluation of an application to ensure that radioactive materials will be used as intended.

Regional Preparation of TARs

Regional Division Directors will submit all TARs, except those requiring sealed source and device design evaluations going to IMNS, using the TAR form and instructions provided in Appendix B and requests for an additional evaluation to ensure that radioactive materials will be used as intended (see the C.6 Checklist in Appendix C) The supplemental guidance in ML063480256 includes an example of a completed TAR. This request should be submitted electronically with any needed attachments. TARs should be placed in ADAMS and designated non-publicly available. Electronically submitted versions of the TAR should be sent by the Region to the lead Division Director in NMSS, with a copy to the IMNS secretary. For information that may not be electronically available (e.g., medical consultant's reports), indicate in the electronically submitted version those attachments that could not be sent electronically and

indicate on the TAR form that they will be sent with the hard copy of the TAR. The TAR provided by the Regions 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 an estimated 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 Regional LA shall change the milestone in the LTS to 19 and change the license reviewer code to A2 to identify IMNS. When the Region receives a final response to the TAR from Headquarters, the Region shall change the milestone in the LTS to 20, and the reviewer code should be changed back to the Regional reviewer's code.

Sealed Source and Device (SSD) Evaluations

Sealed source and device (SSD) evaluations will be performed by the Sealed Source Safety Staff (SSSS) in IMNS, not by the Regions. IMNS will deal directly with the applicant to resolve any deficiencies in the SSD application. Although an applicant may apply directly to IMNS for an SSD evaluation under 10 CFR 32.210, license applications submitted to the Regions may require an SSD evaluation also. The portion of the application requiring an SSD evaluation should be sent to IMNS using NRC Form 567, not a TAR Form (see Appendix B). NRC Form 567 is available in the InForms application on the NRC computer system. When submitting an NRC Form 567, the Regional LA shall change the milestone in the LTS to 19 and change the license reviewer code to I5 for "Custom Review." The Region should inform the applicant that an SSD evaluation is needed and advise them that someone from IMNS may be contacting them if additional information is needed.

Coordination of the final licensing action will be negotiated by Regional and IMNS reviewers on a case-by-case basis. The use of sealed sources and devices often has a significant impact on the applicant's facility and operations. Regional reviewers may be an integral part of the SSD evaluation process. Upon completion of the review, IMNS will send a letter, with a copy of the registration certificate, to the applicant and the regional license reviewer (as appropriate). The Regions will receive a monthly report on the status of all sealed source and device pending cases, independent of the weekly Division Response Action Tracking program (DRAT) report on open TARs. The LTS milestones and license reviewer codes should be changed as appropriate for the final licensing action.

Headquarters Processing of TARs

When the TAR and associated documents are received, the lead Division will assign the TAR and notify the IMNS secretary of the due date and person assigned to complete the task. The TAR will be entered into the IMNS DRAT, be designated as having been received, and be assigned a DRAT number with a specific due date of 10 working days from the date of receipt. The responding branch will perform a completeness review of the TAR with a goal of within 5 working days, but not to exceed 10 working days from its assignment to a Headquarters reviewer. The purpose of the completeness 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 supervisor. 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 10 working days (goal of within 5 working days, not to exceed 10 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 for the Headquarters staff member 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. If a TAR is referred to NSIR as per the C.6 Checklist in Appendix C, the turn around goal is 60 days. For TARs that involve enforcement-related issues, the Director, OE should be in concurrence. Responses to certain TARs 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. 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. DRAT includes the title of the TAR, the Control Number, the due date, and the current Headquarters contact.

Before management signs and concurs on the TAR response, 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 and concurrence, or if there is no legal objection. If OGC fundamentally alters the TAR response, the revised draft response will be e-mailed again to the Region before IMNS management signature and concurrence. 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.

Distribution of TAR Responses

The TAR response, with all incoming documents, normally will be distributed electronically via ADAMS 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 TAR 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 electronic 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 10 CFR 2.790, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements in 10 CFR 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 information from the public 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 from 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 NRC plans to honor the request; however, the notification needs to inform the applicant that 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, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information. In all review situations, if 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 the 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

[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 criterion 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. This SRP has been issued as draft NUREG-1727 for public comment. The Handbook will be updated in the near future to incorporate the requirements of the LTR and the guidance in the SRP. 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.

"Materials License Termination/Retirement Form" contained in NUREG/BR-0241. Copies of the letter, terminated license, and retirement form should be maintained as OARs.

Appendix C

Checklists

C.6 Checklist to Ensure that Radioactive Materials Will Be Used As Intended

Applicability: The Checklist is applicable to materials license reviewers and is not intended for reviewers who authorize sources for reactor programs.

Instructions to Reviewers:
The Checklist modifies the process of issuing a specific license. Refer to the Implementation Guidance (ML063480256) which contains requirements and specific guidance to achieve the two essential objectives, below:

1. to ensure that a new applicant (e.g., an entity that has never had a license before or is unknown) requesting a specific license or a licensee requesting transfer of control to a new applicant and all applicants requesting risk significant quantities of certain radioactive materials (all forms, sealed and unsealed) indicated in the Checklist (Step 1, Table of Risk Significant Quantities) and that have not been subject to a Security Order or the additional requirements for increased controls will not be approved until the NRC or an Agreement State has determined with reasonable assurance that the requested materials will be used as intended (e.g., as authorized in a specific license), and

2. to notify the NRC Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Materials Safety and State Agreements (DMSSA), Source Safety and Security Branch (SSSB) of a request for a specific license for a type of use that is under a Security Order or subject to the additional requirements for increased controls.

Complete the Checklist, as follows. Complete Step 1 (Radioactive Materials and Quantities Requested) for **all** applications. If the responses in Items A and B are "NO", do not complete Step 2 or Step 3. If Item A or B is "YES" then complete Step 2 (Screening Criteria) as per the next paragraph. If the applicant requested a type of use that is under a Security Order then complete Step 3 (Notify NRC Headquarters), Item A, without delay. SSSB will contact the applicant directly to provide the instructions about the requirements for initial access authorization for Safeguards Information. SSSB will issue the Security Orders to the applicant when the NRC regional office or the Agreement State issues the specific license to the applicant. Security Orders for certain types of use are indicated on the NRC web site at the following link, http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html.

Complete Step 2 (Screening Criteria) to identify inconsistencies between the safety-related information in the application and additional sources of information about the applicant that are already publicly available. For each criterion, indicate the publicly available information that was considered and whether there is a concern for a potential security risk and the basis for the concern. The screening criteria may be used during a licensing site visit to document the additional review of an applicant. If a particular screening criterion is "not applicable" for the review of a particular application, just indicate "NA" in the last column instead of leaving it blank.

Complete Step 3, Item B, to notify SSSB without delay after making the decision to apply or void the additional requirements for increased controls. Refer to the "Guide for Applying the Additional Requirements for Increased Controls," (ML063470434) which is available in the Increased Controls Toolbox.

Complete Step 3, Item C, without delay if the reviewer is not reasonably assured that the requested materials will be used as intended. SSSB will coordinate an additional evaluation of the applicant with the Office of Nuclear Security and Incident Response (NSIR).

NOTE–If the case is turned over to NSIR, do not contact the applicant until further notice. In particular, do not attempt a licensing site visit while NSIR is completing an additional

evaluation of an applicant. Following a determination that there is no security risk, SSSB will notify the reviewer to proceed with the licensing process. The additional evaluation, site visit (if needed), and reply to the reviewer will be completed within 60 days so that the licensing process is not significantly delayed.

Sign, date, and place each completed form in ADAMS as the Official Agency Record (OAR), profiled as Sensitive and Non-Publicly Available, except when all responses are "NO" for Step 1, the profile should be marked as Non-Sensitive and Non-Publicly Available. Alternatively, when all responses for Step 1 are "NO," it is acceptable to annotate the licensing action summary sheet to certify that Step 1 was completed.

DOCKET FILE INFORMATION
C.6 Checklist to Ensure That Radioactive Materials Will Be Used as Intended
(ML063480221)

Applicant Information: **Control No. XXXXXXXX**

Name:	Type of Request: New, Renewal, or Amendment Program Code(s):
Location:	License No.: Docket No.:

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If Step 1, Items A and B, are "NO" then do not complete Step 2. Sign and date the completed form and add it to ADAMS as Non-Sensitive and Non-Publicly Available. If a "YES" response is indicated for Item A or Item B, add the completed form to ADAMS as Sensitive and Non-Publicly Available, and complete Step 2 (Screening Criteria). If the type of use is subject to a Security Order complete Step 3, Item A, without delay. If the additional requirements for increased controls will be applied or voided, complete Step 3, Item B, without delay.	YES or NO
A. The applicant is an entity or a licensee transferring control to an entity that has never had a license or is unknown.	
B. The applicant is requesting certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, as "highlighted" by the reviewer **and** has not been subject to a security order or additional requirements for increased controls.	

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])	Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226[2]	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

[1] The primary values are TBq. The curie (Ci) values are for informational purposes only.
[2] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule were completed. NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	YES , NO, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the Risk Significant Quantity (TBq) for the radionuclide.	
Unity Rule–multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B) + etc. ÷ etc.] $\geq$ 1.0.	

Signature and Date for Step 1: _____
License Reviewer and Date

STEP 2–Screening Criteria: **Control No. XXXXXXXX**

Instructions for Step 2: Complete Step 2 for any application that yielded a "YES" response in Step 1, Item A or Item B. Use safety information in the application as well as sources of information that are outside of the application. Document the review of each applicable screening criteria below. If a criterion is not applicable in a particular case, mark "NA" in the last column for that criterion. Otherwise, provide a preliminary indication in the last column as to whether an additional evaluation may be needed to reasonably assure that the requested materials will be used as intended. Summarize the review at the bottom of the table and sign, date, and place the completed form as the OAR in ADAMS, as Sensitive and Non-Publicly Available.

Refer to the Guidance (ML063480256) for each criterion, below.	Review Notes	Indicate YES, NO, or NA
A. Request for Materials		
B. Former Licensee or Authorized User		
C. Ownership/Senior Management		
D. Radiation Safety Officer		
E. Authorized User		
F. Fee Payment		
G. Financial Assurance		
H. Deficiency Correspondence		
I. Contacts to the Applicant		
J. Public Web Sites		
K. Pre-Licensing Visit		
L. Security		
Summary	Within the context of the entire set of screening criteria, the reviewer was **not** reasonably assured that the requested radioactive materials will be used as intended and an additional evaluation of a potential security risk is needed. **[NOTE–If "YES" is indicated in the last column then complete Step 3, Item C, without delay.]**	
Supporting rationale for an additional evaluation.		

Signatures and Dates for Step 2: _____ _____

License Reviewer and Date Supervisor and Date

STEP 3–Notify NRC Headquarters at FSME/DMSSA (SSSB): Control No. XXXXXXXX

Instructions for Step 3: Mark the type of notification below and attach a copy of the additional information, as appropriate. Place the competed form with attachments as the OAR in ADAMS, as Sensitive and Non-Publicly Available. Designated staff will reply to the incoming email or TAR package and indicate the proposed action(s) and schedule to closure.

☐ A. Security Orders — The cognizant supervisor sent an email to **SECURITY_ORDERS@NRC.GOV** requesting SSSB to prepare Orders to accompany the specific license and providing the applicant's contact information. A copy of the email is attached.

☐ B. Increased Controls — The cognizant supervisor sent an email to **SECURITY_ORDERS@NRC.GOV** requesting SSSB to update the National Source Interim Inventory to apply or void the increased controls. The following update information was provided: license number, docket number, license name, address (city, state, and zip code), main contact name, title of contact, phone number, email (if available), date the license condition is effective, ADAMS accession number. A copy of the email is attached.

☐ C. Request for additional evaluation of the applicant — As per NUREG-1556, Volume 20, Section 4.14, Technical Assistance Request–Materials Licensees, the cognizant supervisor sent a TAR package to SSSB after Step 2 was completed. Based on a preponderance of inconsistent information, the reviewer was not reasonably assured that radioactive material will be used as intended. The package included the TAR form, the completed Step 2 form, and the relevant information from the application. The TAR package from an Agreement State supervisor was routed through the NRC Regional State Agreements Officer as per Management Directive 5.7, "Technical Assistance for Agreement States," (revised November 19, 2004).

Signatures and Dates for Step 3: _____ _____

License Reviewer and Date Supervisor and Date