

LICENSE REVIEWER GUIDANCE

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.

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.

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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 session 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.

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. 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