

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 4, 2020

ALL AGREEMENT STATES

NOTIFICATION THAT MAJOR REVISION TO INSPECTION MANUAL CHAPTER (IMC) 2800, "MATERIALS INSPECTION PROGRAM" IS A MATTER OF COMPATIBILITY AND TO PROVIDE ADDITIONAL INFORMATION AS RECOMMENDED BY THE STANDING COMMITTEE ON COMPATIBILITY (STC-20-082)

Purpose: To inform the Agreement States that a major revision to the Office of Nuclear Material Safety and Safeguards (NMSS) Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program" issued on March 2, 2020 is a program element that is a matter of compatibility and to provide additional information as recommended by the Standing Committee on Compatibility (SCC) at their April 20, 2020 meeting.

Background: On March 2, 2020, a major revision to IMC 2800, "Materials Inspection Program" was issued and became effective at the NRC. Also, on March 2, 2020, IMC 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters,' and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20" was cancelled. The reciprocity requirements contained in IMC 1220 were incorporated into the revised IMC 2800.

On March 13, 2020, STC Letter 20-023 dated March 13, 2020 was issued that informed the Agreement States of the revision of IMC 2800 and the cancellation of IMC 1220. STC-20-023 further stated that IMC 2800 has been a matter of compatibility in the past and the SCC will discuss the revised IMC 2800 at their April 20, 2020 meeting to determine the compatibility and implementation implications for the Agreement States.

As a result of the April 20, 2020, meeting, the SCC recommended that an STC letter be issued to include the following items regarding the revised IMC 2800:

- Integrated Materials Performance Evaluation Program (IMPEP) project management should provide guidance regarding how the revised IMC provisions regarding reciprocity will be reviewed under the IMPEP;
- b. Describe NRC's plans to implement the reciprocity provision of the revised IMC 2800;
- c. A statement that the Committee determined that the revised IMC 2800 is a program element designated as Compatibility Category C and implementation by the Agreement States is required within 6 months of the STC letter's issuance; and
- d. Note the website address where the Inspection frequency list is now located, (previously an Appendix to IMC 2800).

Discussion: In response to the recommendations of the SCC, the following is being provided to the Agreement States for their action or information:

a. Guidance on the revised reciprocity inspection requirements during IMPEP reviews.

The Agreement State should document any changes to their reciprocity inspection program and when the revised program was implemented based on the criteria outline in the revised IMC 2800. The IMPEP review team should evaluate the Agreement State's

reciprocity inspection program for the entire review period based on the procedure (IMC 1220 or revised IMC 2800) implemented with the least restricted criteria. The IMPEP review team should also note any changes to the reciprocity inspection program in the report and any impacts on the Agreement State's implementation in accordance with NMSS Temporary Instruction TI-003, Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as Part of the Integrated Materials Performance Evaluation Program.

b. <u>U.S. Nuclear Regulatory Commission's (NRC's) plans to implement the reciprocity provision of the revised IMC 2800</u>

On November 13, 2020, the Division of Materials Safety, Security, State, and Tribal Programs issued *Guidance For Conducting NRC Reciprocity Inspections* to the NRC Regional Offices for implementation on December 1, 2020. The guidance document is enclosed with this letter.

c. Compatibility of the revised IMC 2800 dated March 2, 2020

During the April 20, 2020, SCC meeting, the committee determined that the revised IMC 2800 "Materials Inspection Program" dated March 2, 2020, continues to be a matter of compatibility under the Inspection program element. This procedure continues to be designated as Compatibility Category C. In accordance with NRC Management Directive 5.9 Adequacy and Compatibility of Program Elements for Agreement State Programs, implementation of this procedure by the Agreement States is required within 6 months of the date of this STC letter.

d. Web address for Inspection Frequency List

The inspection frequency list is contained in the "Program Codes" link in the Materials Licensees Toolkit Index. Please see "Program Codes" in the following link: https://www.nrc.gov/materials/miau/mat-toolkits.html#10.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Enclosure: Guidance For Conducting NRC Reciprocity Inspections

GUIDANCE FOR CONDUCTING NRC RECIPROCITY INSPECTIONS

Reciprocity inspections are conducted in response to a request from a licensee of an Agreement State to perform work in an NRC jurisdiction (i.e., a non-Agreement State or an area of exclusive federal jurisdiction). When assessing the need for a reciprocity inspection, the following concepts should be considered in reaching a determination on whether a reciprocity inspection is warranted:

- Persons applying for reciprocity are licensed by another regulator. That regulator has reviewed the licensee's program for handling nuclear material and has found it to be acceptable.
- 2) Decisions concerning reciprocity inspections should be risk informed. Risk-informed decision making includes a risk component and a deterministic component. The risk component is provided by the application of the risk triplet (i.e., What can go wrong? How likely is it? What are the consequences?). The deterministic component is provided by the Agreement State licensing and inspection process. The Agreement State licensing process provides for a baseline review of a licensee's radiation program and the inspection process provides a review of its ability to execute that program. Because the NRC's determination as to whether to conduct a reciprocity inspection takes into account both the risk component and the deterministic component, this determination is risk-informed and not just risk-based (i.e., solely based on risk information). (See https://usnrc.sharepoint.com/teams/FutureNRC for discussion of Risk Smart).
- 3) Some activities are of sufficient risk or consequence to merit safety oversight, independent of the jurisdiction in which the activity occurs. These activities may merit reciprocity inspection as a means to provide appropriate safety oversight.
- 4) Past performance of a licensee, either enforcement or inspection, that is obtained from NRC or Agreement State sources may be useful in reaching a decision to conduct an inspection.
- 5) Announcing inspections is consistent with accomplishing the goals for conducting reciprocity inspections for high-risk activities.

Reciprocity notifications are made using NRC Form 241. As part of licensing activities, the NRC regional office will evaluate each initial Form 241. To the maximum extent possible, given the information provided on the form, this evaluation will include a review of the activities to be performed. This evaluation may also include a review of inspection and enforcement history and a determination of whether other indicators for the consideration of reciprocity inspections, as listed in IMC 2800, exist. Initial results of the evaluation of the forms should be passed to the Region's inspection personnel for further consideration.

When evaluating an activity for risk, high-risk activities are those that have a higher probability of a failure in either equipment or procedure and a high consequence to public health and safety due to either exposure of personnel or contamination. Operations with a higher probability of failure can generally be considered to include nonroutine operations (e.g. repairs or modifications). Operations with a high consequence to public health and safety can generally

be construed to include activities performed by Priority 1 and Priority 2 licensees that directly involve high activity sources. The most common activities meeting both these criteria include source exchange, repair or modification of medical equipment containing large sources such as self-shielded irradiators or gamma stereotactic radiosurgery units. Since these are infrequently performed, high consequence evolutions, possibly conducted outside the licensee's originally licensed locations of use, high consideration should be given for conducting an inspection. To facilitate open and transparent communication and coordination with licensees, these inspections should typically be announced to provide certainty that NRC inspectors will be present to observe the high-risk activity. If, after reviewing the Form 241, the regional office decides not to conduct a reciprocity inspection for a high-risk activity, the rationale for this decision should be documented. Documentation should include an assessment of the risk of the activity (qualitative or quantitative), inspection resource challenges, licensee past performance, or other information supporting the decision to not conduct the inspection.

Decisions concerning whether to conduct a reciprocity inspection will also be required for lower risk activities. These activities may include (but are not limited to) those of Priority 3 and lower priority licensees or those activities that do not directly affect sources of any size or directly affect sources of lower activity (e.g., in-field use of portable moisture density gauges, support for Nuclear Materials Users (NMU) decommissioning activities). More broadly, a lower risk activity may be construed to mean any activity that is not a high-risk activity as defined above. When making such decisions, the facts that the activity in question is of lower risk and that the licensee has been licensed and inspected by an Agreement State and found to have an effective program for using nuclear materials provides a basis for not expending NRC resources to conduct a reciprocity inspection. However, in a minority of cases, there may be sufficient justification for the expenditure of NRC resources to conduct a reciprocity inspection of a low risk activity. The basis for conducting such an inspection may include any of the criteria contained in IMC 2800 and, particularly, past performance information available from either the NRC or Agreement States concerning enforcement and/or inspection results. Given the presumption (based on Agreement State actions), that reciprocity inspections are not a necessary expenditure of NRC resources for most low risk activities, decisions to conduct a reciprocity inspection for a low risk activity should be documented. Announcing a low risk inspection may or may not be necessary. That decision is left to the discretion of the organization performing the inspection.