SECY-00-0001

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FOR: The Commissioners

FROM: William D. Travers /RA/
Executive Director for Operations

SUBJECT: PILOT PROGRAM FOR NMSS INITIATIVE ON STREAMLINING INSPECTION AND ENFORCEMENT

PURPOSE:

To inform the Commission of the staff's proposed medical pilot program (nuclear medicine program), as part of an initiative to begin to streamline inspection and enforcement of materials licensees.

BACKGROUND:

In November 1998, the Office of Nuclear Material Safety and Safeguards (NMSS) staff began developing initiatives for streamlining regulation of materials and fuel cycle licensees. These initiatives include streamlining materials and fuel cycle licensing. Another initiative, the subject of this paper, is to begin streamlining inspection and enforcement of materials licensees. (Streamlining inspection and enforcement of fuel cycle licensees will be addressed in a separate paper.) All of these NMSS initiatives reflect, and are designed to implement, the performance goals being developed for the nuclear materials safety strategic arena (foremost, maintaining safety and safeguards and protecting the environment; additionally, reducing unnecessary regulatory burden on stakeholders, increasing public confidence, and more effective, efficient, and realistic activities and decisions.) They parallel current efforts of the Office of Nuclear Reactor Regulation to achieve similar performance goals.

DISCUSSION:

NMSS is undertaking initiatives to improve the focus of inspection and enforcement, for materials licensees, on risk-informed outcomes and licensee performance. As an initial step, NMSS will conduct a pilot program in the medical area and evaluate the effectiveness of the initiative in accomplishing the objectives described above. If the pilot program is successful, the approach will be considered for implementation more broadly across NMSS.

The draft Temporary Instruction (TI) for the medical pilot program (Attachment 1) uses a focus element (FE) approach to assess licensee performance relative to desired safety-related outcomes. This approach was developed by a broadly based NRC working group (with representatives from NMSS, the Office of Enforcement, and the regions).

The TI, like the draft final rule 10 CFR Part 35, "Medical Use of Byproduct Material," is performance-based and also risk-informed. The TI focuses inspection effort on licensee performance for radiation safety program elements having safety-significant outcomes. However, the TI is part of a pilot program; it is not intended to necessarily represent a portion of the plan for enforcement and inspection that will be provided to the Commission when the final rulemaking for Part 35 is submitted for Commission approval.

The draft TI reflects comments received from the regions and each participating office. It also reflects comments received at, and subsequent to, a public meeting held on January 8, 1999. The draft TI requires that the inspector visit the site for observations, interviews, measurements, and selective review of records. For the medical pilot program, inspections cannot be done remotely.

This TI applies only to nuclear medicine programs licensed in accordance with 10 CFR 35.100, 35.200, and 35.300, involving use of unsealed material. Most nuclear medicine operations involving use of unsealed material, when conducted with basic safety precautions, are inherently of low radiological risk. (Programs that include additional areas, such as 10 CFR 35.400 or 35.500, involving use of sealed sources for diagnosis or therapy, are not to be inspected under this TI. This is to avoid intermixing the TI's FE inspection approach with conventional approaches presently utilized for inspections of other areas, e.g., nuclear medicine activities conducted by broad scope licensees.) The approximately 1200 licenses in this category represent nearly 21 percent of all materials licenses. The TI implements NMSS initiatives to streamline the inspection process by focusing the inspection efforts on radiological safety.

A limited number of safety-based and outcome-oriented FEs were chosen to be verified during inspection. To perform effective inspections and minimize potential impacts on licensees' resources, the extent and the depth of the verification process for each of six FEs will be commensurate with the potential radiological risk involved with the licensee's program. A nuclear medicine program for which all the FEs are verified will be considered to be operating satisfactorily, and protective of public health and safety from significant unintended radiation exposures.

In the nuclear medicine area, as for many materials licensees, satisfactory safety outcomes rely much more on human performance than on equipment or system performance. Accordingly, at this time, evaluation of FEs is considered a better approach for assessment of nuclear medicine licensee safety performance than use of the limited amount of objective data (performance indicators) available.

For nuclear medicine program inspections, the specific desired outcomes for the FEs, as stated in the TI, reflect the following overarching desired outcomes that are associated with maintaining safety, by minimizing the number of:

- overexposures of workers or members of the general public;
- misadministrations;
- unauthorized offsite releases or losses of licensed material; and
- unauthorized uses of licensed material.

Additionally, this streamlined approach to inspection and enforcement is expected to demonstrate more effective, efficient, and realistic NRC activities in this sphere and will also reduce unnecessary regulatory burden.

The staff anticipates that the present use of NRC Form 591, "Safety and Compliance Inspection," for no-violation inspections, for non-cited violations, and for many Severity Level (SL) IV violations, will be further utilized during the pilot program. SL IVs may result from examination of safety-related program elements associated with the six FEs (as listed in Part III of the TI Inspection Record). Representative elements to be considered in the FE verification process are listed in the same "Inspection Record" Appendix of the draft TI. Affected licensees would not be required to formally respond to Notices of Violation for SL IV violations documented on Forms 591. The Office of Enforcement notes that this pilot program does not involve policy changes to the enforcement process for nuclear medicine facilities because the NRC Enforcement Policy already provides the flexibility to document SL IV violations on Form 591.

To implement this TI, the inspector will shift the primary focus of inspection from a broad based and detailed examination of the licensee's processes, policies, and procedures, to a review of program outcomes, through verification of FEs. This verification process includes detailed examinations, interviews, and observations in those areas that are critical to ensuring that the desired outcomes are, and will continue to be, achieved. We believe that the FEs are sufficiently comprehensive to verify that public health and safety are being maintained. If the FEs' desired outcomes are not achieved, the inspector will then examine the licensee's processes, policies, and procedures. There would also be additional, more detailed, interviews of the licensee's staff; observation of the licensee's activities; and independent measurements and assessments, to identify the causes and root causes that may have contributed to the licensee's failure to achieve the desired performance outcomes. If the licensee were to achieve the desired outcomes in a given area, there would be no further inspection of that area. The medical pilot program will be for 1 year; completion is expected in fiscal year 2001.

RESOURCES:

Inspections using the draft TI are expected to require fewer staff hours. Currently, using the existing Inspection Procedure 87115, "Nuclear Medicine Programs," an average of 16.6 direct staff hours are required for inspections of nuclear medicine licensees. We will track hours and assess resource impact. Inspector training in the FE approach and in use of the TI will be required, before its implementation.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Information Officer has reviewed this paper for information technology and information management implications and concurs in it. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. The Office of Enforcement has reviewed this initiative, and the associated pilot program, and concurs in this paper.

RECOMMENDATIONS:

That the Commission note that the staff plans to proceed with the pilot program for nuclear medicine to streamline inspection and enforcement, and to implement the attached inspection guidance.

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Attachment:

1. Draft Temporary Instruction 2800/XXX, "Nuclear Medicine Programs"