POLICY ISSUE
INFORMATION

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FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

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

PURPOSE:

To report to the Commission on the findings from the Medical Pilot Program and how insights gained from the inspections will be used.

BACKGROUND:

SECY 00-0001, "Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement," dated January 3, 2000, presented the Commission with an initiative for streamlining regulation of materials licensees. The purpose of the Medical Pilot Program was to make inspection and enforcement efforts more risk-informed and more focused on licensee program performance. The Medical Pilot Program used focus elements (FEs) as indicators to assess licensee performance relative to desired safety-related outcomes. Specific nuclear medicine programs (programs licensed in accordance with 10 CFR 35.100, 35.200, and 35.300) were selected as the target group of licensees for the Medical Pilot Program. The Commission approved the proposal of the Medical Pilot Program in the Staff Requirements Memorandum to SECY 00-0001, dated February 14, 2000. Temporary Instruction (TI) 2800/02, "Nuclear Medicine Programs," was issued in March 2000, to implement the Medical Pilot

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Program, and regional training was completed in June 2000, to start the inspection program. In a Staff Requirements Memorandum to SECY 00-0118, dated October 23, 2000, the Commission directed the staff to provide the findings from the Medical Pilot Program and indicate how the insights gained would be used. This paper responds to that direction.

DISCUSSION:

In accordance with the TI, the inspections were conducted, focusing on licensee performance, for radiation safety program elements having safety-significant outcomes. Safety-based and outcome-oriented FEs were verified during inspection. The extent and the depth of the verification process were commensurate with the potential radiological risk of each licensee's program. A nuclear medicine program for which all the FEs were verified was considered to be operating satisfactorily and protective of public health and safety from significant unintended radiation exposures.

For nuclear medicine program inspections, the specific desired outcomes for the FEs were to minimize:

- 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 was expected to demonstrate more effective, efficient, and realistic NRC activities in this sphere and to reduce unnecessary regulatory burden.

The pilot program shifted 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 included detailed examinations, interviews, and observations in those areas that were critical to ensuring that the desired outcomes were, and would continue to be, achieved. If the licensee achieved the desired outcomes in a given area, there would be no further inspection of that area. If the desired outcomes were not achieved, the inspector would 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 that might have contributed to the licensee's failure to achieve the desired performance outcomes.

By the end of the year-long pilot, over 200 inspections were completed. As directed by the TI, the Regions provided the inspection results to NMSS staff for evaluation. Direct inspection-effort (DIE) hours, and preparation and documentation times, were collected and analyzed. The results were compared with previous fiscal years (FYs), for the same licensees, using data available from the NRC Regulatory Information Tracking System. The attachment provides the results of that comparison. As shown in the attachment, the average and standard deviation for DIE hours have demonstrated a downward trend since FY 95. Although this trend started prior

to the inception of the pilot program, gains in inspection efficiency through the use of the pilot program helped continue the trend.

The preparation and documentation data did not reveal any similar decrease in expended hours. This may be due to a factor identified in the Phase II Byproduct Materials Program Review conducted in the Spring of 2001. The Phase II Report stated that some inspectors felt a need to maintain a greater level of detail, as anticipated in the Medical Pilot Program, in their inspection records, to demonstrate that all focus elements of the licensee's program were reviewed. In addition to analyzing the inspection data, the inspectors were interviewed to discern their views on the effectiveness of the Medical Pilot Program. More experienced inspectors indicated that the TIs better captured how they conducted their inspections than the existing Inspection Manual Chapter 2800 series of inspection procedures.

The staff reviewed enforcement data and inspection records from FY 96 to FY 01 to determine if there were any trends in the severity and number of cited violations. The data from the review are summarized in the attachment. No significant trends in escalated enforcement were indicated for the class of licensees subject to the Medical Pilot Program. Inspections under the Medical Pilot Program resulted in five escalated cases, between FY 00 and FY 01. The data from the non-escalated enforcement actions also did not reveal any significant trends. The absence of enforcement trends indicated that the efficiency improvements experienced through the pilot program had no apparent adverse impact on the effectiveness of inspections. The staff also reviewed the NRC Nuclear Materials Events Database. The event data are also summarized in the attachment and, like the enforcement data, no significant trends were discovered.

As noted above, the Phase II Byproduct Materials Program Review was conducted during the period of the Medical Pilot Program. Information from the Medical Pilot Program was exchanged with the staff conducting the Phase II Byproduct Materials Program Review, contributing to some of the recommendations from that review. The Phase II Byproduct Materials Program Review included recommendations to streamline inspection preparation and documentation partially in response to the lack of improvement in the preparation and documentation hours noted above. The Phase II Byproduct Materials Program Review recommendation to further revise Inspection Manual Chapter 2800 inspection procedures using performance elements was based, in part, on the focus element approach of the Medical Pilot Program. NRC staff has started task groups to implement the recommendations from Phase II Byproduct Materials Program Review and they are developing schedules for revising inspection procedures and training the inspection staff.

CONCLUSION:

The Medical Pilot Program was successful. The enforcement and event data indicate that the performance goal of maintaining safety, and protecting the environment was met. The inspection hours' data and interviews with inspectors indicate that there was some gain in efficiency, and the TI added realism to the inspection procedures. The reduction in DIE hours represented a reduction in regulatory burden. As a result, the staff is reviewing Inspection Manual Chapter 2800 to determine where similar risk-informed, performance-based changes can be adopted in other materials inspection procedures.

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Attachment: "Medical Pilot Program Inspection
and Enforcement Data"

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Attachment: "Medical Pilot Program Inspection and Enforcement Data"

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