POLICY ISSUE

(Information)

October 13, 1994 SECY-94-256

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: ANNUAL REPORT ON THE MEDICAL USE PROGRAM INCLUDING STATUS REPORTS ON IMPLEMENTATION OF THE MEDICAL MANAGEMENT PLAN AND QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE

PURPOSE:

To provide the Commission with an update on the medical use regulatory program, including status reports on implementation of the medical management plan (MMP) and Quality Management Program and Misadministrations Rule (QM rule). The MMP is described in SECY-93-244 and identifies 90 action items, including action items resulting from the findings of the Incident Investigation Team (IIT) for the November 1992 therapy misadministration that occurred in Indiana, Pennsylvania.

SUMMARY:

This annual report provides the status of implementation of the MMP and QM rule, as directed by the Commission. It also discusses the increasing role of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), major program areas being addressed by the staff, and associated resource issues. Status reports on implementation of the MMP and QM rule are provided in the "Discussion" section, and specific information and statistics are provided in

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NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON OCTOBER 20, 1994

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the eight attachments. At present, approximately 56 percent of the MMP action items are closed, and the QM rule has been in effect since January 1992. All licensee-submitted QM plans have been reviewed and deficiency letters have been forwarded to licensees. "Open" MMP action items are either partially closed, or not yet addressed because they depend on the closure of precursory action items. As a result, the staff continues to address short- and long-term action items to resolve policy issues and specific tasks, while adjusting program priorities in response to unforeseen events and changing needs.

BACKGROUND:

Each year, the staff provides the Commission with a status report on the medical use regulatory program. Historically, this annual report focused on the "Five-Point Plan," originally described in SECY-88-77, "Medical Use Program," to provide improved regulatory oversight of the medical use regulatory program. In recent years, the annual report gravitated toward a discussion of current issues and related actions by the staff to resolve them. Therefore, this year's report primarily focuses on the status of implementation of the QM rule, and MMP, as requested by the Commission in staff requirements memoranda (SRMs) dated June 19, 1991, and September 30, 1993, respectively. The SRM dated June 19, 1991, directed the staff, in part, to provide the Commission with an assessment of the effectiveness of the QM rule at the annual briefing on the medical use program, 3 years after the rule becomes effective. As a result, this annual report provides an assessment of the effectiveness of the QM rule, as will subsequent annual reports.

In an SRM dated May 24, 1993, the Commission requested the staff to provide semiannual reports on the status of IIT action items. The staff provided the first semiannual IIT report as Attachment 4 to SECY-93-244 (August 31, 1993), and the second report via a memorandum dated April 1, 1994. In a memorandum dated April 12, 1994, the Office of Nuclear Material Safety and Safeguards (NMSS) requested that the semiannual IIT report be discontinued in view of the annual MMP report, since the MMP includes the IIT action items. This request was granted; therefore, this annual report provides an IIT status report (Attachment 6), as will each subsequent annual report, until each action item has been resolved.

The direction of the MMP, and in particular, major revisions of 10 CFR Part 35, and those requirements in 10 CFR Part 30 that affect medical use licensees, may be altered significantly depending on the results of the National Academy of Sciences' (NAS') external review of the medical use program, and subsequent Commission direction based on the NAS findings. See Program Area 1, *"Policy Issues"* for further discussion on the NAS study.

DISCUSSION:

This section is divided into the following subsections: *I. "Status Report on the MMP;" II. "Status Report on Implementation of the QM Rule and Its*

Effectiveness;" III. "The ACMUI;" IV. "Major Program Areas Currently Addressed;" and V. "Resource Issues." The MMP status report provides general information on progress to date in the nine major program areas identified in the MMP. The status report on the QM rule discusses steps taken to implement the rule, contract support, inspection and enforcement issues and staff recommendations and a discussion on Agreement State compatibility with the rule. The other subsection titles are self-explanatory.

Six of the eight attachments provide specific information on MMP action items. Attachment 1: a Gantt Chart to demonstrate the status and current due date of MMP action items, by program area; Attachment 2: statistics on MMP action items; Attachment 3: information on progress to date on MMP action items by program area; Attachment 4: a list of documents issued since August 31, 1993, (SECY-93-244); Attachment 5: a list of documents or reports that are scheduled to be completed by December 31, 1994; and Attachment 6: a status report on IIT items. Attachment 7 is data on misadministrations that occurred from January 1993 through June 1994; and Attachment 8 is a list of staff presentations at public meetings, made since September 1993, discussing primarily QM and high-dose-rate remote afterloading brachytherapy issues. It should be noted that Attachment 3 provides an abbreviated version of the information contained in the following discussion of each MMP program area.

I. *STATUS REPORT ON THE MMP*

This section provides general information on progress to date in the nine major MMP program areas. The staff has completed several short-term action items and initiated steps to address many long-term action items. To date, approximately 56 percent (50 of 90) of the MMP action items are closed, including most IIT items.

Program Area 1. *Policy Issues*

The staff has taken the following actions to resolve the major policy issues identified in the MMP: 1) contracting with the NAS to conduct an external review of the medical use regulatory program; 2) evaluating each medical use rulemaking to ensure consistency with the 1979 Medical Use Policy Statement; 3) implementing a Memorandum of Understanding (MOU) with the Food and Drug Administration (FDA) to clarify our respective roles and address issues and events of mutual interest; 4) evaluating sealed source and device jurisdiction issues between the U.S. Nuclear Regulatory Commission, FDA, and the Agreement and non-Agreement States; and 5) working with the U.S. Environmental Protection Agency (EPA) and waste processor industry to address the IIT finding on the inadvertent transfer of licensed material to a non-radioactive waste processor.

The NAS study is underway, and the committee has held two meetings this calendar year and is scheduled to meet on October 11-13, 1994.

Cognizant NAS staff made a presentation to the ACMUI at the May 19, 1994 meeting to discuss the tasks and goals of this study. Additionally, at the request of NAS, NRC staff has briefed the Committee on medical use regulatory issues. This study is discussed in more detail in IV. *"Major Program Areas Currently Addressed,"* item C. *"National Academy of Science Study."*

Consistent with the SRM dated June 23, 1992, the staff is evaluating each medical use rulemaking to ensure its consistency with the 1979 Medical Use Policy Statement. The first proposed rule to be evaluated under this directive was the proposed patient release rule noticed in the Federal Register in June 1994. This rulemaking was determined to be consistent with the policy statement and had explicit evaluation and findings in the Federal Register notice.

The NRC/FDA MOU was signed on August 25, 1993, and has been fully implemented. Recently, NRC and FDA staff jointly investigated radiation therapy events occurring at two NRC-licensed facilities, both of which were caused by the same treatment planning error. The joint staff also investigated and took action to address a device failure involving a high-dose-rate remote afterloading brachytherapy device. In addition to collaborating on inspections, NRC and FDA staff conduct routine monthly meetings to exchange information of mutual interest. On August 25, 1994, the first annual meeting between the agencies was conducted to ensure full implementation of the MOU. The staff forwarded a memorandum to the Commission dated June 23, 1994, to provide a status report on implementation of the MOU. Additionally, NMSS recently issued Policy and Procedures Memorandum 1-45, to identify NRC and FDA staff and management contacts to facilitate the exchange of information.

As a result of the inadvertent transfer of the brachytherapy source in the IIT event, and Commission direction in response to SECY-94-073 regarding the recent contaminated ferrophosphorus incident, the staff will refer all incoming reports of emergencies involving unidentified radioactive material in the possession of an individual or group, not licensed by NRC or an Agreement State, to the EPA. This policy is in accordance with the Lead Federal Agency (LFA) provisions of the draft Federal Radiological Emergency Response Plan (FRERP). Because EPA is the LFA for such incidents, the staff will cease plans to issue guidance to the waste management community regarding events where licensed material is inadvertently received. In a memorandum dated June 21, 1994, the staff provided guidance to the regions regarding the referral of such incidents to the EPA.

Program Area 2. *Misadministrations and Patient Followup*

Evaluating medical misadministrations and determining licensee compliance with reporting and notification requirements have been

complex and resource intensive. The staff continues to provide additional guidance on the investigation of misadministrations, particularly patient notification and followup issues. As a result, two key documents were recently issued: 1) NRC Management Directive (MD) 8.10, "Medical Event Assessment Program"; and 2) Inspection Manual Chapter (IMC) 1360, "Use of Physician and Scientific Consultants." MD 8.10, which received Commission approval in May 1994, provides guidance to ensure that medical events (primarily misadministrations) are investigated in a prompt and consistent manner; that NRC provides the appropriate level of direction for followup of patients who have received an overdose of byproduct material; and to ensure licensee compliance with all notification requirements. It also provides criteria for when a medical event is escalated to involve an Augmented or Incident Investigation Team. IMC 1360 provides additional guidance on the use and role of physician and scientific consultants who augment an NRC inspection effort, and it established the role of the NMSS Misadministration/Medical Consultant Coordinator (MMC).

NMSS designated an individual with human factors expertise as the MMC to assist in the review of misadministration cases, ensure the availability of medical and scientific consultants, and to coordinate the collection and analysis of data. This individual coordinates with regional and Office for the Analysis and Evaluation of Operational Data (AEOD) staff to ensure the accuracy and completeness of event information that is entered into the AEOD Material Events Database (MED). (See Program Area 8, *"Information Management Systems,"* for additional information on MED.)

To ensure licensee compliance with misadministration notification requirements, the staff evaluated therapeutic misadministration data for calendar years 1990-1992, and is in the process of evaluating data for 1993 through June 1994. The results of the 1990-1992 evaluation were submitted to the Commission in a memorandum dated April 14, 1993. Subsequently, Headquarters staff issued guidance to the regions to identify licensees who, at that time, did not appear to be in compliance with 10 CFR Part 35 misadministration notification requirements. After identifying these licensees, a generic form letter was sent to each of them to clarify NRC notification requirements and stress the importance of making the required notifications, verbally and in writing, to the patient (or responsible relative or guardian), and the patient's referring physician. As a result, some licensees subsequently provided documentation to NRC that all required notifications had been made, whereas other licensees remained in non-compliance. In addition, several licensees raised concerns regarding NRC notification requirements, in particular the requirement to notify the responsible relative in certain cases. These concerns were addressed in a memorandum dated March 10, 1994, by the Office of the General Counsel (OGC) staff, at the request of NMSS. Appropriate enforcement action against licensees who remain in non-compliance was discussed at the May

1994, NMSS Counterpart meeting with regional branch chiefs and section leaders. In a memorandum dated July 21, 1994, NMSS, in coordination with the Office of Enforcement (OE), provided instruction to the regions to issue Notices of Violations for licensees who continue to be in non-compliance with these requirements. In cases where the licensee had not informed the patient, the regions forwarded a letter to inform the licensee that, based on OGC guidance, the patient's responsible relative or guardian must be informed regardless whether the patient was a competent, consenting adult. To date, all regions have resolved 100 percent of the cases.

Currently, the staff is reviewing misadministrations that occurred from January 1, 1993, through June 30, 1994. The purpose is to determine licensee compliance with all notification, reporting, and recordkeeping requirements and ensure that the appropriate enforcement action is taken. Current information indicates that licensee compliance with misadministration notification requirements has improved relative to previous years' data. Specifically, for 1993, verbal and written notifications to the patient or responsible relative were made in 90 percent (27 of 30) of the cases; and for 1994, verbal notification was made in 100 percent (14 of 14) of the cases, while written notification was made in 86 percent (12 of 14) of the cases. Neither the 1993 nor 1994 data is firm at this time. The number of misadministrations identified for each year may change as the result of licensee reports, inspection findings, and future interpretations by OGC. The staff will continue working to resolve all outstanding issues. Attachment 7 provides data on the 1993-1994 misadministrations.

Inspections have been conducted to determine the root cause of the misadministrations that occurred during the 1993-1994 period discussed above. Results indicate that violations of the QM rule (including the related training requirement described in 10 CFR 35.25) were identified in 58 percent of the cases (28 of 44), and of those 28 cases, more than 1 violation of the QM rule was cited in 36 percent of the cases (10 of 28).

Single errors that affect multiple patients or facilities warrant continued attention by the staff to ensure that generic issues are addressed and communicated to other NRC licensees. The staff is in the final stages of developing an information notice (IN) to alert NRC licensees to an event involving a computerized treatment planning error. Although not all cases were misadministrations as defined in 10 CFR 35.2, the error resulted in 11 patients receiving an administered dose that exceeded the prescribed dose by 5 to 30 percent. The eleven patients were treated at two NRC-licensed facilities that were serviced by a third facility where the treatment planning error occurred and went undetected by the personnel involved.

The staff continues to clarify and enforce NRC patient notification requirements by publishing guidance to regional staff and medical use licensees through INs and the NMSS Licensee Newsletter. The Enforcement Manual was recently revised to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements. The staff is also developing a generic letter to all medical licensees to clarify patient notification requirements. This generic letter will address several issues and will inform licensees that, in cases where the referring physician decides that, based on medical judgment, telling the patient would be harmful, the patient's relative or guardian must be informed of the misadministration whether the patient is incompetent or is a fully competent adult. The only case in which neither the patient, nor the patient's relative or guardian, is required to be informed is that in which the patient's referring physician decides that, based on medical judgment, informing either of them would be harmful to them.

Lawrence Livermore National Laboratory (LLNL) has reviewed all QM plans submitted by licensees to further reduce the likelihood of misadministrations or errors during the delivery process in those aspects of a licensed medical program that are subject to the QM rule. Also, the staff reviews licensee implementation of their QM plans, as part of reactive and routine inspections, to ensure compliance with the rule and further reduce the likelihood of a misadministration. Further discussion on this effort is provided in Section II, *"Status Report on Implementation of the QM Rule and Its Effectiveness."*

Adequacy of Misadministration Reporting Requirements

In an August 19, 1993 memorandum to the Commission, the Inspector General (IG) indicated a concern regarding the adequacy of current NRC misadministration reporting requirements. Specifically, the IG suggests that the intentional administration of non-prescribed dosages or increased dosages should be reportable to NRC, regardless of whether the event meets the 10 CFR Part 35 definition of misadministration. To address the IG's concern, the staff will consider modifying the 10 CFR Part 35 definitions of misadministration and related reporting requirements, during the major revision scheduled for completion in late 1997. As an alternative, the staff may propose to modify Part 30 to affect all materials licensees.

Program Area 3. *Rulemaking*

The MMP identifies five rulemaking actions that are in various stages of development, including three final rules, one proposed rule and one advance notice of proposed rulemaking (ANPR). Due to workload priorities and resource constraints, some of the rulemaking actions have been delayed.

In addition to the five rulemaking activities identified in the MMP, the staff is also developing one proposed rule, and recently submitted for Commission approval a second proposed revision of the Abnormal Occurrence (AO) Reporting Criteria for reporting materials events to Congress on a quarterly basis. Each effort is discussed below.

Near Completion - Final Radiopharmacy Rule
Currently, the staff is in the final stages of developing the language and associated regulatory guidance for the final rule entitled, "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use." The final rulemaking package, which will include draft regulatory guidance for public comment, is scheduled to be submitted during October 1994, for Commission approval. Since the interim final rule expires on December 31, 1994, the staff anticipates publication of the final rule by November 30, 1994, with an effective date of January 1, 1995. The corresponding draft SRPs and inspection guidance will be made available for use by regional staff by the effective date of the final rule.

Published for Public Comment - Patient Release, and Assessing Public Exposure
A proposed rule for revision of 10 CFR Part 35, and conforming revisions of 10 CFR Part 20 on patient release criteria, was noticed in the Federal Register on June 15, 1994. The rule would clarify that 10 CFR Part 35 governs the release of patients containing residual radioactivity, not 10 CFR Part 20. It also proposes a dose-based, rather than activity/radiation level-based, criterion. The comment period on the proposed rule expired on August 29, 1994, and the staff is reviewing the public comments received. The staff intends to submit a final rulemaking package during June 1995, for Commission approval. The final package will include the final Regulatory Guide.

Proposed revisions to 10 CFR Parts 19 and 20 were published for comment in the Federal Register on February 2, 1994, (59FR5132). Among the changes proposed was restoration of a provision to 10 CFR Part 20 to provide that whenever licensees are required to report exposures of individual members of the public to NRC, then those individuals are to receive copies of the report. While this portion of the proposed rule was not controversial, other portions were. The staff is working to resolve the public comments on these other issues. The final rule is currently scheduled to be submitted by December 31, 1994, for approval by the Executive Director for Operations. As an adjunct to this rulemaking, IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public," and MD 8.10, "Medical Event Assessment Program," were issued to instruct inspectors to notify the appropriate local officials and provide guidance on evaluation of events. Collectively, these efforts address the issues of notifying members of the public and local

officials, and assessing public exposures from medical events.

Proposed Rulemaking on Hold - Pregnancy and Nursing
The staff effort to submit a proposed rulemaking by December 31, 1994, to reduce the likelihood of an unintended radiation exposure to an embryo/fetus or nursing infant has been delayed. This is due to reallocation of resources to the development of the radiopharmacy rule and supporting guidance.

Advance Notices of Proposed Rulemaking
The staff is in the initial stages of developing an ANPR for major revisions of 10 CFR Part 35. This is a major task that will revise 10 CFR Part 35 in its entirety to address many of the MMP action items currently considered as "open." Such issues include defining adequate training and experience criteria for several categories of individuals using byproduct material and identifying radiation safety requirements for all types of medical use currently authorized. Additionally, the proposed rule will include minor revisions to Part 31, specific to in-vitro laboratories issued a general license. As is the custom for all medical rulemakings, the staff will also solicit input from Agreement State representatives and the ACMUI, at their periodic meetings. The ANPR is scheduled for publication in March 1995. In parallel with the medical use rulemaking, the staff is scheduled to make generic revisions to 10 CFR Parts 30 and 40. These revisions are necessary to emphasize the need for licensee management commitment to provide adequate resources for the radiation safety program and support for the radiation safety officer.

In addition to the rulemaking actions identified in the MMP, there are other rulemaking and policy activities. These are development of a proposed rule on the "wrong patient" issue and revision of the Agency's policy on reporting criteria for abnormal occurrences. These efforts are described below.

Proposed Rule under Development - Wrong Patient
The staff is currently developing a proposed rule that resulted from an enforcement case, and as directed by the Commission in an SRM dated May 10, 1994. Specifically, this rule will clarify that 10 CFR Part 35, not 10 CFR 20.1301, governs any administration involving byproduct material to an individual ("wrong patient rule"). The proposed rule will inform licensees that 10 CFR Part 35 misadministration definitions and associated reporting requirements apply in such cases. However, unresolved issues remain and the staff is working to submit the proposed rule during October 1994, for Commission approval.

Revision of the Abnormal Occurrence Reporting Criteria
During October 1994, the staff submitted, for Commission approval, a Commission policy statement to revise the Agency's criteria for

reporting "Abnormal Occurrences" (AO) to the U.S. Congress. This was submitted in response to an SRM dated May 19, 1994, which directed the staff to resubmit the reporting criteria and consolidate the various changes being considered into a single revision for Commission approval as a Commission policy.

Program Area 4. *Licensing Guidance*

Several licensing guidance documents have been issued and others are under development.

Issued
Policy and Guidance Directive (P&GD) 86-04, Revision 1, was issued to provide guidance for licensing remote afterloading brachytherapy, including high-, medium-, low-, and pulse-dose rate afterloading procedures. Regulatory Guide (RG) 10.5 was revised to provide additional guidance on licensing medical programs of broad scope. It is scheduled to be published for public comment soon, and the associated SRP for license reviewers was issued during June 1994, for use by regional staff. P&GD 94-04, "Identification of Licenses where Significant Licensing Action Warrants an Onsite Inspection," was issued to provide guidance for license reviewers on identifying material licensees whose programs have undergone significant growth and warrant an onsite inspection prior to the next routine inspection. This is a followup action to the inspections of changing/expanding licensed programs that were conducted by February 1994. IMC 1246 was issued to provide additional guidance on license reviewer training qualifications.

Under Development
Although RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs" will not be revised in its entirety until the major revision to 10 CFR Part 35 is completed, evolution in the medical application of byproduct material has created a need to partially revise RG 10.8 in the interim to address all types of medical use currently authorized. Therefore, eight working groups, composed of Headquarters and regional staff, were established to develop new, or revise existing, licensing guidance to reflect current licensing practices. Existing guidance currently under revision includes licensing for teletherapy; mobile nuclear medicine; and remote afterloading brachytherapy. New guidance is under development for gamma stereotactic radiosurgery; manual brachytherapy to include the use of strontium-90 eye applicators; and radiopharmaceutical therapy to include the therapeutic use of iodine-131, strontium-89, and other beta-emitting radiopharmaceuticals for therapy. New guidance will also be developed to clarify NRC's training and experience criteria for physician authorized users. All guidance described above will be issued as appendices to existing RG 10.8, for medical licensees. These draft appendices are scheduled to be published for public comment during September 1995. The Agreement

States and ACMUI will be provided an opportunity to comment on such guidance during the drafting stage. These appendices will be re-evaluated after the major revision to 10 CFR Part 35 is complete. In addition, the staff is revising three regulatory guides to provide guidance for licensees to implement the final radiopharmacy rule.

The staff will also develop licensing guidance for issuing master materials licenses for medical use, such as those licenses currently issued to the U.S. Departments of Navy and Air Force. As discussed below in Program Area 5, the corresponding inspection guidance was issued.

Program Area 5. *Inspection Guidance*

Several inspection guidance documents have been issued and others are under development.

Issued
The staff issued IMC 2810 to provide guidance on the inspection of master materials programs. Temporary Instructions (TI) were issued for inspection of licensees authorized for remote afterloading brachytherapy procedures (IMC 2800/024) and quality management programs (IMC 2800/025). As discussed under Program Area 2, MD 8.10 was recently issued to provide inspection guidance for medical events, in particular, misadministrations. In July 1993, the staff issued instructions to the regions to identify and inspect medical licensees whose programs had undergone significant growth. All such inspections were completed by February 1994, with no significant issues identified. As discussed previously, the staff also issued corresponding licensing guidance to ensure that this category of licensee is promptly identified and an onsite inspection performed, when indicated. Other inspection guidance issued includes Inspection Procedure (IP) 87103, and IMC 1302. IP 87103, "Inspection of Incidents at Nuclear Materials Facilities," was issued to provide additional guidance to management, when determining whether to dispatch one or more regional inspectors to conduct a special inspection in response to an incident, and to provide additional guidance to inspectors for determining the sequence of events leading to the event, the root cause, and the conditions that existed at the time the incident occurred. IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public," was issued to provide generic and specific guidance on the course of action to follow in situations involving radioactive material in the public domain. The staff also addressed the IIT finding on the PrimeAlert-10 area radiation alarm. See Attachment 6, *"IIT Action Item Update,"* action item 1c., for further information.

Under Development
A working group, composed of Headquarters and regional staff, has been

established to make major modifications to IMC 2800, "Materials Inspection Program." The revised guidance will focus on the core and non-core inspection program for materials licensees, greater flexibility in increasing or decreasing inspection frequencies and more emphasis on performing reactive inspections. The revision to IMC 2800 is scheduled for completion during January 1995.

The staff will continue to explore whether it is feasible for third parties to conduct routine inspections of NRC-licensed facilities, in lieu of a routine NRC inspection. Such third parties could include the American College of Nuclear Medicine, American Board of Radiology, or other medical professional organizations that have an interest in developing or revising an existing audit program, to meet NRC inspection goals. The staff requested and received guidance from OGC indicating there is no legal prohibition on the use of third parties to conduct inspections on behalf of NRC. At present, the issue of third-party inspections is not a high priority action item in the MMP. Additionally, after completion of the Functional Process Improvement (FPI) study (discussed under Program Area 8), the staff will determine whether analogous management principles can be applied effectively to the inspection program to increase efficiency.

Program Area 6. *Enforcement*

The staff has completed several actions to provide additional guidance on NRC's enforcement policy. This includes modifications to the enforcement manual, issuance of enforcement guidance memoranda (EGM), and initiation of an "Enforcement Policy Review Team," that will, as part of its tasks, reassess the materials civil penalty policy.

Enforcement Manual Revisions
Although issued prior to implementation of the MMP, it is important to discuss the following two staff actions to implement the QM rule. In a Federal Register notice dated April 2, 1993 (58FR17321), changes to NRC's enforcement policy were published. The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees. Enforcement decisions focus on violations that indicated a programmatic deficiency. The change also reflects the fact that violations that represent isolated mistakes, of limited consequence, that are not associated with a programmatic weakness of the licensee's QM program, will be considered less significant. In addition, on April 3, 1993, EGM 93-005 was issued to provide guidance on this modification to the enforcement manual.

In July 1994, the staff modified the enforcement manual to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements.

Enforcement Guidance Memoranda
On September 14, 1993, EGM 93-008 was issued to provide guidance on the System of Records maintained for enforcement actions against individuals. Further, OE distributes a list semiannually to identify individuals who have any restriction from NRC-licensed activities which license reviewers should review prior to issuance of any licensing action. Quarterly, NUREG-0940, Enforcement Actions, Significant Actions Resolved," is issued and orders to individuals are included in Section A unless a hearing has been requested. Also, copies of NUREG-0940 and orders to individuals are routinely forwarded to Agreement States.

From late 1992 through early 1994, the staff conducted a weekly enforcement panel, consisting of Headquarters and regional staff, to discuss current inspection and enforcement cases, to ensure consistent application of NRC's enforcement policy in cases involving violations of the QM rule described in 10 CFR Part 35. On March 23, 1994, EGM 94-003 was published to provide additional guidance for distinguishing between programmatic and isolated failures in the implementation of a licensee's QM program.

On February 10, 1994, EGM 94-001 was issued to provide guidance and instruct the regions to include the Board of Trustees for medical licensees on distribution for all NRC escalated enforcement actions against the licensed facility.

Additionally, on July 26, 1994, EGM 94-011 was issued to provide guidance on the "wrong patient" issue, as mentioned previously under Program Area 3. Specifically, the 10 CFR Part 35 definition of misadministration and associated reporting and notification requirements apply to any administration involving byproduct material to an individual ("wrong patient"). As a result, this type of event is not considered a violation of 10 CFR 20.1301.

Program Area 7. *Management and Radiation Safety Officer Responsibility*

Currently, there are primarily three efforts to provide additional guidance, to licensees, on the responsibilities of executive management and the radiation safety officer (RSO) for effective oversight of the licensed program and safe use of licensed material. First, the staff is near completion on development of a NUREG to provide guidance on effective management of radiation safety programs at medical facilities. The NUREG introduces the concept of the "management triangle" whose elements are executive management, the RSO, and radiation safety committee, when required. The draft underwent significant peer review by various aspects of the medical community, and was generally well received. The NUREG will be issued as draft for public comment, to seek additional comments from members of the public and the medical community.

Secondly, as mentioned under Program Area 3, *"Rulemaking,"* the staff will propose to revise Parts 30, 40, and 70 to emphasize a commitment by licensee executive management for support of the radiation safety program including support for the RSO.

Finally, the staff is also initiating steps to evaluate the adequacy of the radiation safety component of training programs completed by RSOs, and physicians who request authorization for the use of byproduct material. Training programs to be evaluated include residency training programs and programs offered outside of a residency program, such as those provided by private or professional organizations or programs in which the physician successfully obtains work and clinical experience in a private office or clinic, while under the supervision of a physician preceptor. This effort is part of the major revision of 10 CFR Part 35 discussed in program area 3.

Program Area 8. *Information Management Systems*

NMSS' Division of Industrial and Medical Nuclear Safety staff developed and uses a tracking system to monitor all division action items, including those identified in the MMP. This system allows the staff to monitor the progress of technical assistance requests from the regional offices, the development of guidance documents, responses to Congressional inquiries, and other routine tasks associated with the regulatory program.

A working group composed of NRC and Agreement State staff developed a prototype event database that was distributed to participants for use and comment during the month of May 1994. This is an enhanced version of the existing AEOD non-reactor event database and is referred to as the Materials Events Database. The purpose of the database is to provide a comprehensive sole source for information on medical events (particularly medical misadministrations), and other non-reactor events, that can be periodically evaluated and analyzed by the staff. The enhanced database includes NRC licensee data and Agreement State licensee data reported to NRC by Agreement States. An interim version of the database was recently distributed to NRC program offices and Agreement States. The staff will continue to modify the database based on current needs.

Although not identified in the MMP, NMSS is currently performing a 7-month study of the materials licensing process, with the objective of identifying recommendations for streamlining and automating the current process. Although not limited to medical licensees, it is anticipated that this project will be of great benefit to medical licensees in terms of providing cost savings in resources expended in the NMSS materials licensing process, improving communications with materials licensees, and decreasing the time needed to complete a licensing action. This

study was originally developed under the Business Process Re-engineering Initiative. Its objective is to use Functional Process Improvement (FPI) to conduct an analysis of the materials licensing process work flow to determine how the NRC processes an application from receipt to issuance, with the long-term goal of establishing a more efficient and potentially automated processing of material license applications and amendment requests. A major goal is to determine ways to streamline, automate, and avoid duplication of effort in processing a license request. NMSS is also analyzing the Licensing Tracking System, to improve its usability by licensees and NRC staff, and its compatibility with other Agency electronic information systems.

Program Area 9. *Research Studies*

Currently, there are three research contracts in progress, with final reports expected by March 1995. Final reports on Human Factors Evaluations for brachytherapy and teletherapy procedures are expected during January and March 1995, respectively. A final report on Quality Control/Quality Assurance (QC/QA) for Gamma Stereotactic Radiosurgery is expected during December 1994. The final report on QC/QA for Remote Afterloading Brachytherapy was received during mid-September 1994, and will soon be published as a NUREG/CR. The risk analysis methodology development, begun during the QC/QA projects, culminated in a workshop held during August 1994, and will be ongoing. The results of all contractor findings will be issued as NUREGs and considered by the staff during the major revision of Part 35 discussed in Program Area 3, *"Rulemaking."*

NUREG/CR-6088, "Summary of 1991-1992 Misadministration Event Investigations," was issued during February 1994, and subsequently distributed to NRC medical use licensees and the Agreement States. There were seven major findings on the root cause and contributing factors for each misadministration investigated. A more detailed discussion of these findings is provided in Item F. *"Independent Analysis,"* in *II. "Implementation of the QM Rule and Its Effectiveness."*

NCRP Commentary No. 9, "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child" was issued on May 1, 1994. This commentary was developed to assist the staff in identifying regulatory requirements regarding the unintended exposure of the embryo, fetus or nursing child as a result of medical procedures involving the administration of radioactive material. This commentary supplements NCRP Commentary 7, "Misadministration of Radioactive Material in Medicine - Scientific Background, published November 1, 1991.

II. *STATUS REPORT on IMPLEMENTATION of THE QM RULE and ITS EFFECTIVENESS*

Since the QM rule became effective on January 27, 1992, the staff has completed or initiated several actions to implement the rule. These include: (1) providing training to LLNL staff who review the QM plans submitted by licensees; (2) providing training for regional staff who inspect implementation of a licensee's QM plan; (3) conducting a weekly enforcement panel, consisting of Headquarters and regional staff, from November 1992 to March 1994, to ensure proper identification of violations and consistent application of NRC's enforcement policy; (4) providing additional enforcement guidance; (5) providing clarification of QM requirements and guidance described in associated Regulatory Guide 8.33; (6) assisting the Agreement States with implementation of the rule; conducting workshops; (7) making presentations at professional meetings; and (8) discussing implementation results with the ACMUI.

A. *Early Implementation*

The final QM rule became effective on January 27, 1992, for certain categories of medical licensees. However, in December 1991, the Office of Management and Budget (OMB) expressed concerns regarding the information collection requirements (ICRs) associated with the rule. On June 26, 1992, OMB disapproved the ICR for the final rule. On August 14, 1992, NRC sent a letter to OMB certifying a Commission override of the OMB disapproval. As a result of the OMB issue, medical licensees were confused about whether the QM rule was, or was not, in effect. Therefore, the staff forwarded letters dated April 8, 1992, to all medical licensees, either acknowledging receipt of their QM plan, or reminding them of the necessity of submitting a QM plan. Additionally, in a letter dated September 1992, NRC forwarded a letter to all medical licensees, describing the NRC override of OMB's disapproval of the ICR. This letter stated that NRC would exercise discretion not to take enforcement action for violations that occurred between June 26, 1992, and September 10, 1992, because of the confusion caused by OMB's disapproval. Therefore, full implementation of the QM rule was delayed because of unforeseen events.

B. *Contract Support*

During this time, the staff sought contractual support for the review of QM plans submitted by licensees, to ensure prompt and appropriate implementation of the rule. A contract was let with LLNL during July 1993. Soon after, a pilot program was conducted by LLNL and NRC staff, to compare submitted QM plans with implementation of the plan by the licensee. Ten QM programs were selected based on location and the date of the next scheduled routine inspection. During the pilot program, NRC staff observed that, in nine of the ten programs reviewed, the licensee had implemented a QM program that was much more comprehensive than the

written program submitted for NRC review. NRC subsequently provided training to LLNL staff, and its subcontractors, on various issues, including QM rule requirements, guidance described in RG 8.33, the objectives and conduct of the reviews, and deficiency letter format.

Oversight of the contractor required significant NRC resources partly because of the complexity of medical uses requiring a QM program, and LLNL reviewers' difficulty in determining whether the licensees' QM plans were adequate to ensure compliance with a performance-based rule. LLNL reviewed over 1700 QM plans submitted by licensees, and inherently, because of the number of plans reviewed, there were minor inconsistencies in the reviews, in a limited number of cases. Specifically, there were occasional inconsistencies among reviewers, and by individual reviewers, with respect to the findings identified for similar or identical QM programs reviewed. This was observed in a limited number of cases where the QM plans were prepared by the same consultant. Also, less than two percent of NRC licensees informed the staff that they disagreed with the LLNL findings, or complained about apparent inconsistencies in the reviews. In most cases, the staff did not find evidence to substantiate these comments, based on a re-review of the QM program in question by NRC staff. The contract dollars available for the LLNL reviews allowed for an initial review of each submitted QM plan, and a re-review of approximately 20 percent of submitted plans. The unexpected need to re-review a substantial number of QM programs found to be inadequate (approximately 80 percent of those submitted) resulted in the need to rely on NRC regional staff to conduct the re-reviews. The staff issued a TI to review the adequacy and implementation of licensees' QM programs at the time of a routine or reactive inspection. Additionally, beginning in June 1994, NMSS held several biweekly telephone conferences with regional staff to resolve administrative issues surrounding the review of the QM plans and processing of contractor-generated deficiency letters.

LLNL has completed all task work, including performing the QM plan reviews, and preparing letters for regional staff to forward that either describe weaknesses and or omissions in the submitted plans, or indicate that the QM plan appears to meet the requirements of the QM rule. LLNL also established a database to provide NRC staff with periodic status reports on progress to date on the conduct of the reviews, and its findings. A draft final project report from LLNL on its findings was recently received and is currently being reviewed by the staff.

C. *Staff Effort to Ensure Full Implementation*

Simultaneous with oversight of the contractor, the staff has taken several actions to ensure full implementation of the rule. This includes providing guidance and training to regional staff, licensees, and Agreement States on QM requirements and related inspection;

conducting a weekly enforcement panel consisting of Headquarters and regional personnel, to ensure proper identification of violations and consistent application of the NRC's enforcement policy; and identifying necessary revisions to the QM rule or associated RG 8.33. Each area is described in more detail below.

The staff has provided training to regional staff on the QM rule and its implementation, inspection of QM plans, the purpose of contract support, the regions' role in assisting the contractor, and the status of the reviews of QM programs to date. Additionally, three regional offices, supported by Headquarters staff held licensee workshops that focused on QM requirements, RG 8.33, and the results of prior reviews of submitted QM programs. These workshops benefited both parties highly, and allowed licensees an opportunity to ask questions and to provide input on the rule. The staff has also provided speakers, for many NRC and Agreement State medical licensee seminars and workshops, on the topic of compliance with the QM rule. Since June 1993, each *NMSS Licensee Newsletter* has had an article informing licensees of the progress and findings of the QM program reviews. These articles provide a vehicle for NRC to clarify issues identified by the staff, medical licensees, and interested parties.

D. *Inspection Effort*

A draft TI procedure was provided for use to regional staff during training sessions held in May and June 1992. In April 1994, the regions were provided a second draft TI for use and comment. On August 1, 1994, the final TI (IMC 2800/025) was issued that established areas of inspection and created a procedure for determining compliance with a performance-based rule. Training was provided to regional staff by Headquarters staff during February through March 1994. The staff will compile data collected through this TI to determine the effectiveness of the rule in reducing the number of mistakes or errors in the dose delivery process. This information will also assist the staff in identifying necessary modifications to the rule or guidance and might be useful as an indicator of the number of procedures, performed by NRC licensees, that require a written directive. The number is recorded by inspectors on the QM TI field notes and used to ensure that a statistically valid sampling method is used to evaluate the implementation of a licensee's program. This information, including the number of written directives prepared by the licensee, will be included in the TI data base and available for analysis by the staff.

As discussed in program area 2, *"Misadministrations and Patient Followup,"* a review of preliminary data indicates a total of 48 reported misadministrations for the period of January 1993 through June 1994. Inspections conducted in response to these events identified violations of the QM rule (including the related training requirement described in

10 CFR 35.25) in 58 percent of the cases (28 of 48), and of those 28 cases, more than 1 violation of the QM rule was cited in 36 percent of the cases (10 of 28).

E. *Enforcement Issues*

With respect to enforcement issues, NRC staff established a Quality Management Review Committee to review all violations associated with the QM rule, including those that resulted in a misadministration. The purpose of the weekly committee meeting was to address current inspection and enforcement issues and specific cases to ensure that violations were properly identified and NRC's enforcement policy was applied consistently where QM violations were identified. Committee members included representatives from NMSS including Myron Pollycove, M.D., (NRC's Medical Visiting Fellow), OE, the regions, and during the last calendar quarter, a representative from OGC. The committee met weekly for one year, and as needed thereafter.

F. *Independent Analysis*

NRC contracted with the Idaho National Engineering Laboratory (INEL) to conduct independent team investigations of misadministrations over a two-year period to perform a root cause analysis. The objectives of these reviews were to: 1) develop a more complete understanding of causes and contributing factors that result in misadministrations; 2) use the information to help determine whether the scope and depth of the QM rule are adequate; and 3) provide information to licensees. INEL conducted seven on-site team investigations with a team of three or more members with relevant expertise in the disciplines of radiation oncology, nuclear medicine, medical physics, risk analysis, and human factors. The INEL team investigated three manual brachytherapy, one teletherapy, two high-dose-rate remote afterloading, and one iodine-131 therapy misadministrations.

Seven major findings were identified by these investigations as common to several misadministrations. These findings were: 1) many misadministrations occurred due to a lack of procedures, or procedures that were incomplete or ambiguous; 2) although the QM rule has the potential to prevent many misadministrations, most licensees had not effectively implemented their QM program; 3) a lack of substantial, direct involvement on the part of the authorized users and RSOs is often a direct cause; 4) unique conditions or changes in routine are often factors; 5) hardware failures are rare, but many had severe consequences; 6) corrective actions were often narrow in focus; and 7) licensees often lacked systematic methods for detecting and mitigating misadministrations. In addition, INEL analyzed the AEOD database for Abnormal Occurrences, updated for 1987-1991, and all 1992 misadministrations, to evaluate common causes of misadministrations and

their possible preventability through proper QM program implementation. From the results of this analysis, INEL concluded that proper implementation of QM plans could have prevented a large majority (up to 94 percent) of past misadministrations. Also, based on their review of QM plans, LLNL observed that the '87-91 misadministrations would likely be eliminated or reduced as a result of implementation of the QM rule. INEL issued their final report in February 1994, NUREG/CR-6088, "Summary of 1991-1992 Misadministration Event Investigations." Copies were distributed to all NRC medical use licensees and the Agreement States. The contract with INEL has been continued to allow for team investigations for root cause analysis of up to four misadmininstrations per year.

G. *Staff Recommendations*

In response to the SRM dated June 19, 1991, on the QM rule, the staff submits the following regarding the need for rulemaking on comprehensive quality management, and on the status of the associated ANPR published in the Federal Register on October 2, 1987 (52FR36949). The staff believes that, at this time, no changes in the scope or focus of the rule is necessary. Rather, the staff will continue to gather information by evaluating the adequacy of licensee QM plans at the time of inspection, determining the root cause of misadministrations, identifying violations of the QM rule, and collecting and analyzing licensee data on the number of procedures performed that require a written directive. This will allow the staff to make an informed decision on the need for rulemaking on comprehensive quality management.

At present, the staff does anticipate a need, based on the experience gained during implementation of the rule and the contractor's findings as a result of reviewing the submitted QM programs, to modify 10 CFR Sections 35.2, 35.32, 35.33, and RG 8.33, "Quality Management Program." Modifications are needed to address the administration of fractionated doses in radiopharmaceutical therapy and brachytherapy; addition of strontium-90 eye applicator to the definitions and RG 8.33; and clarification of certain definitions contained in 10 CFR Section 35.2. Recently, the staff identified the need to revise the QM rule and associated guidance to address the use of strontium-90 eye applicators because they were not addressed specifically in the rule. As a result, NRC IN 94-17: "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use," published on March 11, 1994, clarified this issue and reminded licensees that strontium-90 eye applicators were brachytherapy devices, and a QM plan was required. These issues will be addressed as part of the major revision to 10 CFR Part 35.

H. *Agreement State Implementation of the QM Rule*

A number of Agreement States have expressed dissatisfaction with the division of compatibility assigned to various aspects of the QM rule. This issue was discussed with the Commission during a briefing that occurred on February 8, 1994. A presentation was made by Robert Kulikowski, Ph.D., Director, New York City, Director, Bureau of Radiological Health, serving as Chair of the Organization of Agreement States. Since that time, NMSS staff has been requested to review several suggested Agreement State regulations for implementing the rule and found inconsistencies in a number of the proposed requirements by the States. In addition, the staff has reviewed the model regulations for implementation of the QM rule, as prepared by the Conference of Radiation Control Program Directors, Inc. (CRCPD) SR-6 Committee. Essentially, the staff determined that the language proposed by this Committee would not satisfy the assigned Division Level II compatibility for the QM rule, if adopted by the Agreement States as written. NRC staff has provided these comments to the CRCPD SR-6 Committee and plans to meet with the committee at the Agreement State meeting scheduled for the week of October 24, 1994. Due to the perceived impending revision of 10 CFR Part 35, the Agreement States have expressed a strong reluctance to adopt the current QM rule, and some of the Agreement States will not meet the January 27, 1995, implementation date.

III. *THE ACMUI*

In recent years, the Commission has placed an increased emphasis on the use of the ACMUI, its composition, and administrative procedures. As a result, the committee meets more frequently (at least twice per year), is involved much earlier in the rulemaking and guidance development process, and serves as a major conduit for the exchange of information with various members of the medical community. Additionally the committee membership has increased and diversified to represent other areas of expertise, and to provide advice and recommendations on a wide variety of medical use issues.

A. *ACMUI Administrative Issues*

Currently, there are several efforts to address key administrative issues associated with management and use of the committee. Specifically, the staff is in the process of developing bylaws and changing committee membership to represent additional expertise. The staff is also implementing procedures for the selection of new committee members, as directed by the Commission in an SRM dated May 4, 1994.

The ACMUI currently has 12 members representing various medical specialties and other areas of expertise identified by the staff or Commission. The present members of the committee are: (a) physician specialists in nuclear cardiology, therapeutic radiology, nuclear

medicine research and nuclear medicine; (b) a nuclear pharmacist; (c) a medical physicist with emphasis in nuclear medicine; (d) one individual with experience in State regulation of radioisotopes; (e) a patient's rights and care advocate; (f) a health care administrator; and (g) a representative from the FDA. At present, the staff is evaluating nominations for the position of radiation therapy technologist/medical dosimetrist.

During the May 1994 meeting, the ACMUI strongly recommended that the Commission re-establish a second medical physicist position, with an emphasis in radiation therapy. This is necessary because of the diverse technical expertise required in the medical use areas of teletherapy and brachytherapy, versus nuclear medicine and radiopharmaceutical therapy. The staff agrees with the ACMUI, in that both specialties should be represented to facilitate a meaningful exchange of information, and serve as a resource to the staff and conduit to all portions of the medical community affected by NRC regulations. The staff recently forwarded its recommendation on this issue in a separate memorandum to the Commission, for approval.

To date, the ACMUI has not operated under a set of formal bylaws. In a memorandum dated September 16, 1994, the staff submitted a set of bylaws, developed with input from the committee and discussed at the May 1994 meeting of the ACMUI. The bylaws describe the procedures to be used by the ACMUI in performing its duties, and the responsibilities of the members. They were developed based on those used by the Advisory Committees on Nuclear Waste or Reactor Safety. The bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through NMSS, regarding the development of standards and criteria for regulating and licensing medical uses of byproduct radioactive material. The procedures are to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, and the resulting reports represent the best of which the committee is capable. The bylaws will be discussed at the ACMUI meeting scheduled for November 17 and 18, 1994, to be held in the Advisory Committee Conference room, Two White Flint North.

B. *Policy and Technical Issues Discussed with the ACMUI*

In recent years, the number and variety of medical use issues to be resolved by the staff and discussed with the ACMUI have increased significantly. The medical expertise represented by the committee members has proven invaluable when the staff is developing new or revised regulations, and considering the impact of the rule on the practice of medicine. Key issues discussed with the staff during the past year include: (a) implementing the QM rule; (b) developing the final radiopharmacy rule, and proposed rules for revision to Part 35

patient release criteria and prevention of inadvertent administrations of byproduct material to the embryo/fetus or nursing infant; (c) training and experience criteria for the use of byproduct material; (d) defining adequate supervision of individuals responsible for the safe use of byproduct material; (e) misadministration notification and reporting requirements; (f) defining who constitutes the wrong patient; and (g) brachytherapy issues including the safe use of remote afterloading devices and fractionated treatment regimes. In addition, the committee was provided two status reports on the revision of the Abnormal Occurrence reporting criteria. The staff will continue to consult with the ACMUI during the development of regulations, standards, and guidance to fully understand medical use issues and the impact of NRC regulation on the practice of medicine.

IV. *MAJOR PROGRAM AREAS CURRENTLY ADDRESSED*

Within the MMP program areas, some regulatory issues require more resources than others to fully resolve. Such issues include defining adequate training and experience criteria for physicians, physicists, RSOs and other licensee personnel; addressing the evolving medical technology of brachytherapy, particularly remote afterloading procedures; licensing medical research involving human subjects; and conducting the NAS study. Each issue will be discussed in more detail.

A. *Training and Experience Issues*

Soon, a major area of focus will be to identify adequate radiation safety training and experience criteria for individuals responsible for the safe use of byproduct material. Historically, this has been an area of great interest to NRC staff, the ACMUI and the Commission, particularly physician training and experience criteria. These criteria were not revised in the last major revision to Part 35, which became effective April 1, 1987; however, they are likely to be on the critical path in the next major revision of Part 35. During recent months, NRC has received several communications from medical organizations and their members regarding adequate radiation safety training and experience criteria for various types of authorized users of byproduct material. Clearly, there are diverse opinions within the medical community on adequate criteria, and a wide variety of criteria described in Part 35 for different types of authorized use that are not consistent. As a result, there are a number of actions the staff intends to take to address this issue; however, the staff will need to consider the impact of the findings of the NAS study.

As an initial step, the staff will solicit comment in the 10 CFR Part 35 ANPR, discussed previously under Program Area 3, *"Rulemaking."* Questions may include, but are not limited to, "Should different criteria be applied to physicians who request diagnostic

radiopharmaceuticals for single organ imaging?;" "How prescriptive should the regulatory criteria be and at what level in the medical services delivery system should NRC training and experience criteria be applied?;" "How can NRC establish criteria today that will be suitable for the twenty-first century?;" "Should status as an authorized user, in and of itself, be sufficient criteria for an individual to be identified as RSO?;" and "Should NRC narrowly focus on radiation safety, or should overall patient well being and risk be considered?"

Additionally, a related issue that warrants clarification is authorized users' responsibilities for the safe use of byproduct material by individuals who work under their supervision (10 CFR 35.25). Such individuals may include technologists, pharmacists, dosimetrists, physicists, and nurses. It is clear that, in some misadministration cases, supervised individuals have not been provided adequate instruction on licensee procedures, including QM or regulatory commitments, or followed the instructions provided by the authorized user to ensure the safe medical use of byproduct material.

The staff notes that there are a variety of views and interests inside and outside the medical community on the issue of adequate radiation training and experience criteria for individuals authorized by NRC. Therefore, NRC staff will provide several opportunities for input from these various interest groups by making presentations at professional meetings, conducting public workshops, meeting with the Agreement States, discussing these issues with the ACMUI, and issuing the Part 35 ANPR. In this regard, the staff is considering whether a full-fledged enhanced participatory approach should be followed for the major revision of 10 CFR Part 35, as discussed in program area 3, *"Rulemaking."*

B. *Brachytherapy*

The radiation therapy specialty of brachytherapy, particularly remote afterloading brachytherapy, continues to evolve and has become more complex, both to perform and regulate. For example, the staff recently evaluated several events involving errors in the delivery of brachytherapy doses that are fractionated (the prescribed dose is delivered in more than one administration). At the May 1994 ACMUI meeting, the staff sought input from the committee on current trends in brachytherapy. The ACMUI advised the staff that errors in the delivery of the prescribed dose for brachytherapy procedures, such as those recently evaluated by the staff, warranted further review to determine whether additional regulatory oversight is indicated to further reduce the likelihood of such errors. As a result of reviewing recent events, and identifying other emerging brachytherapy issues, the staff developed a matrix to identify regulatory issues associated with the use of all types of brachytherapy currently authorized. This matrix identifies

actions to resolve the regulatory issues, and appropriate time frames for completion of such actions. Most of these issues were identified after development of the MMP, and became apparent as licensees implemented their QM programs. The staff will solicit input from the medical community on brachytherapy issues by making presentations at various meetings of professional organizations during the next six months, and at ACMUI meetings. The information collected will affect the major revision of Part 35 and associated guidance.

C. *National Academy of Sciences Study*

The staff secured contract support from the Institute of Medicine (IOM), NAS to conduct an independent review of the NRC's medical use regulatory program, as directed by the Commission in an SRM dated December 21, 1992. The project has three major goals: 1) an examination of the overall risk associated with the use of ionizing radiation in medicine; 2) an examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical uses of byproduct material. The IOM has been asked to provide recommendations on two major issues: 1) a uniform national approach to the regulation of ionizing radiation in all medical applications; and 2) appropriate criteria for measuring the effectiveness of the regulatory program(s) to protect public health and safety. The IOM final report is expected in January 1996, after which the staff will review the findings and propose modifications to the medical use regulatory program, if indicated.

On request, the staff provides NAS with background information regarding various aspects of the medical use program, including: (a) the licensing, inspection and enforcement process; (b) jurisdiction issues; (c) management plans and processes used by NRC managers to provide oversight of the program; and (d) NRC's coordination with the Agreement States, States, and other Federal agencies. Additionally, the staff has prepared written statement or testified before various NAS subcommittees to provide comprehensive information on the regulatory program.

As mentioned previously, if the NAS recommends major modifications to the direction of the medical use regulatory program, the MMP, as described herein, will be revised as directed by the Commission, based on the results of these findings.

D. *Research Involving Human Subjects*

During the last year, steps have been taken to provide explicit, written guidance to regional license reviewers and inspectors regarding permissible activities with human subjects and byproduct material. Long-standing policy had been to authorize, by license condition, only

medical licensees who had licenses of broad scope and who had either a Radioactive Drug Research Committee (RDRC) or Institutional Review Board (IRB) approved by the FDA. This policy was partially expressed in guidance memoranda but had never been included in a Standard Review Plan or Inspection Manual procedure. A revised Standard Review Plan for applications for licenses of broad scope was issued in June 1994 and includes an appendix for regional reviewers to determine when medical research may be authorized by the region, and when NMSS must be involved. RES will soon publish for comment a revised RG 10.5 based upon the new SRP. Specific IP 87100 Appendices were modified March 7, 1994, to include a section on research involving humans. Inspectors are to verify that the licensee's committees (IRB or RDRC) are approved by the FDA, that institutional procedures require review by these committees, and that the licensee has implemented procedures to require that human subjects provide informed consent before initiation of the research.

The final rule would allow licensees, covered by the "Federal Policy for the Protection of Human Subjects," as adopted by another Federal agency to conduct human research without prior NRC approval. If a licensee's activities are not funded by another Federal agency which has adopted the Federal Policy, the licensee must apply for and receive a license amendment prior to conducting research involving human subjects using byproduct material. The proposed research must receive approval by an IRB and the human subjects must provide informed consent. In the proposed rule, the Commission solicited public comment on the number and type of research activities which would not be funded by another Federal agency which has adopted the Federal Policy, and thus would require a license amendment. There were no public comments received on this matter.

V. *RESOURCE ISSUES*

In SECY-93-244, the staff estimated a total of 50 direct staff full-time equivalent (FTE), over an approximate 5-year period, to fully resolve all MMP action items. For budget purposes, it was assumed that the required total FTE would be expended at a constant rate, for all affected offices (NMSS, RES, AEOD, OGC and OE). Inherently, implementation of the MMP during the first fiscal year confirms that the actual rate of FTE expenditure is not constant. In fact, the actual FTE expenditure for FY94 appears to be 50 percent greater than originally estimated (15.0 versus 10.0 FTE), and has been accommodated by reprogramming available resources. This appears to be partly caused by the staff effort to resolve many short-term action items, initiate action on certain long-term action items, promulgate several proposed and final rules, and develop the associated guidance that affects medical use licensees. Based upon FY94 FTE data, the staff projects that the total FTE expended to resolve all MMP action items will probably exceed the original estimate of 50 FTE. Specifically, resolving the action items identified in the misadministration,

rulemaking and guidance program areas will likely require the expenditure of resources in excess of that originally estimated. Additionally, this projection does not account for the impact of unforeseen events such as significant medical misadministrations, events/incidents, Congressional inquiries, the results of the NAS study, or the identification of additional related action items.

Obviously, certain aspects of the medical use program require more resources than others, and may require resources to be expended at unpredictable rates. For example, the medical use of remote afterloading brachytherapy, as discussed previously, has become more complex than predicted and will require more resources than initially estimated. The evaluation and analysis of misadministrations, and clarification of or revision to the related notification, reporting, or record keeping requirements will continue to require significant resources to fully resolve. The staff continues to develop guidance in this area and to evaluate the effectiveness of the QM rule, and the adequacy of RG 8.33, to determine whether modifications are needed to further reduce the likelihood of errors during the treatment delivery process. Additionally, the training and experience criteria issues described above will require significant resources to resolve. Although the staff had identified the need to determine the adequacy of NRC's criteria, the recent receipt of several letters from various medical professional organizations, and the apparent interest in this issue expressed by certain members of Congress, will likely increase the staff effort and may require more resources than originally estimated. To fully resolve these and other regulatory issues as they emerge, the staff will continue to adjust the priority associated with certain MMP action items, or routine work associated with the medical use program, to respond to unforeseen events and accommodate changing needs.

The staff intends to continue the Medical Visiting Fellows Program, thereby providing an additional resource for the staff. To date, two individuals have held the position of Fellow. Mark Rotman, Pharm.D., a board certified radiopharmacist, worked with the staff primarily on radiopharmacy issues for approximately 18 months, from December 1991 until June 1993. Myron Pollycove M.D., a nuclear medicine specialist, currently works with the staff and will complete his 4-year term in October 1995. The staff will soon issue a Federal Register notice to solicit a physician or physicist with expertise in radiation oncology or therapeutic radiological physics. It is expected that the Fellow will join NRC in late 1995 or early 1996.

CONCLUSION:

In summary, the MMP has been fully implemented and is on schedule. Since receiving Commission approval on September 30, 1993, the staff has addressed many short-term action items while initiating work on long-term action items, such as the development of guidance and rulemakings efforts. The staff does not recommend any modifications to the scope or focus of the MMP, but

recognizes that Commission direction in response to the NAS findings, Congressional inquiries or unforeseen medical events could redefine the MMP and other portions of the medical use regulatory program.

COORDINATION:

OGC has no legal objection to this paper.

James M. Taylor
Executive Director
for Operations

Attachments:
1. Gantt Chart
2. MMP Statistics
3. Information on Action Items by Program Area
4. Major Documents Issued Since 8/93
5. Major Documents Near Completion
6. IIT Action Item Update
7. 1993-1994 Misadministration Data
8. List of Public Presentations

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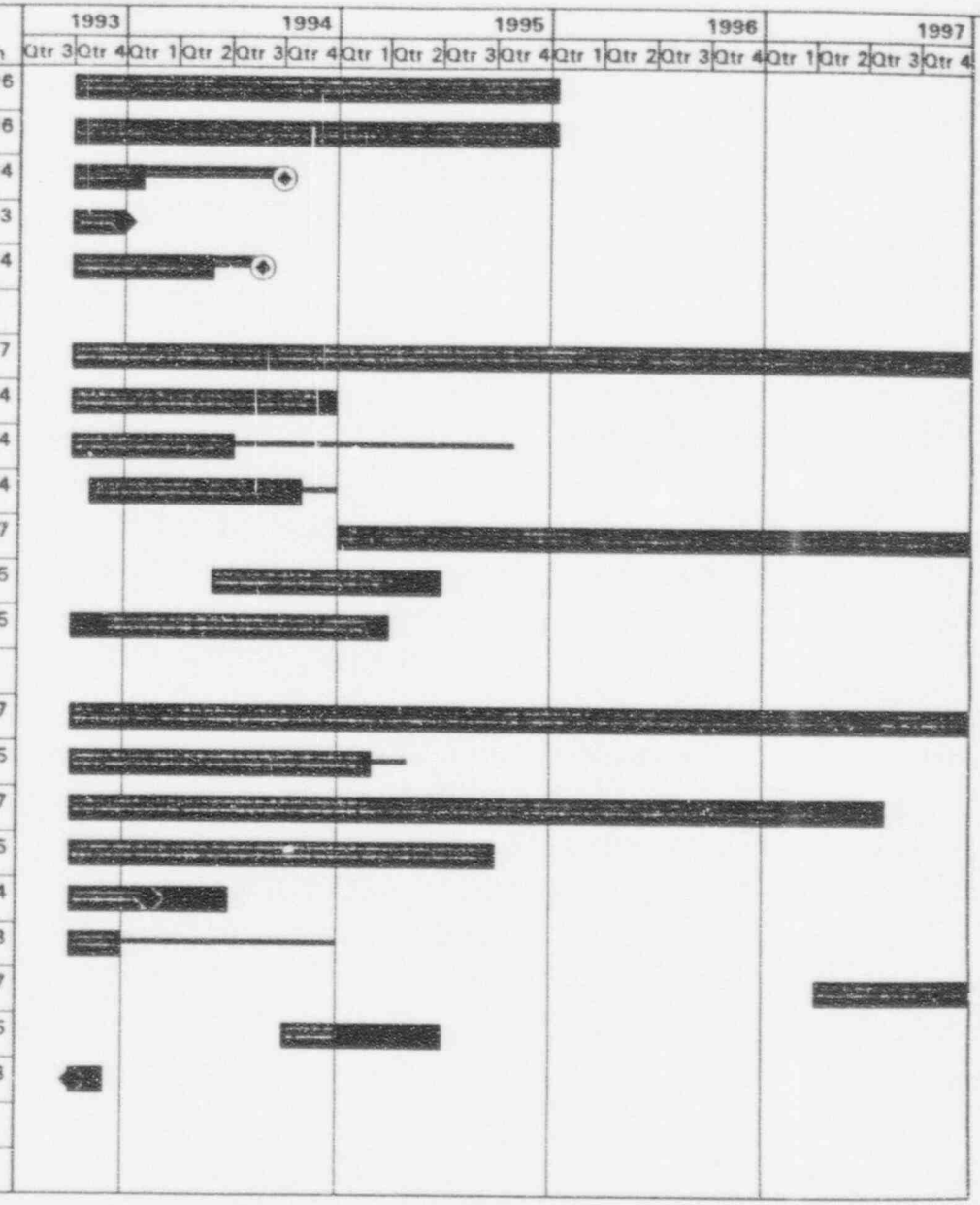
ATTACHMENT 1

GANTT CHART

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
POLICY ISSUES	1/12/96	1/12/96
National Academy of Science Study	1/12/96	1/12/96
Waste Processor Guidance	9/30/94	1/31/94
RES-1979 Med Policy	12/28/93	12/31/93
NRC/Agmt State Device Jurisdiction (MOU)	8/25/94	6/1/94
RULEMAKING	12/31/97	12/31/97
Embryo-Neonate Protection - Final	12/30/94	12/30/94
Part 20/35 Patient Release Criteria - Final	10/31/95	7/7/94
Pharmacy Rule - Final	1/1/95	11/1/94
Parts 31/35 Revision - Final	12/31/97	12/31/97
Adv. Notice of Proposed Rulemaking	3/31/95	6/28/95
Parts 19/20, Assess./Notif. - Final	2/28/95	3/31/95
LICENSING GUIDANCE	12/31/97	12/31/97
Reg. Guide 10.5 Broadscope - Final	5/1/95	3/1/95
Add Appendices to Reg Guide 10.8	8/1/97	8/1/97
Draft for Comment	9/29/95	9/29/95
Revise MC 1245 (1246) - est. lic. rev. qual.	2/17/94	6/30/94
Master Materials lic/insp manuals	12/30/94	12/31/93
Revise Reg. Guide 8.33	12/31/97	12/31/97
Issue Guidance on Temporary Exemptions	12/31/94	6/30/95
Issue P&GD 86-4 - (HDR)	10/8/93	11/30/93

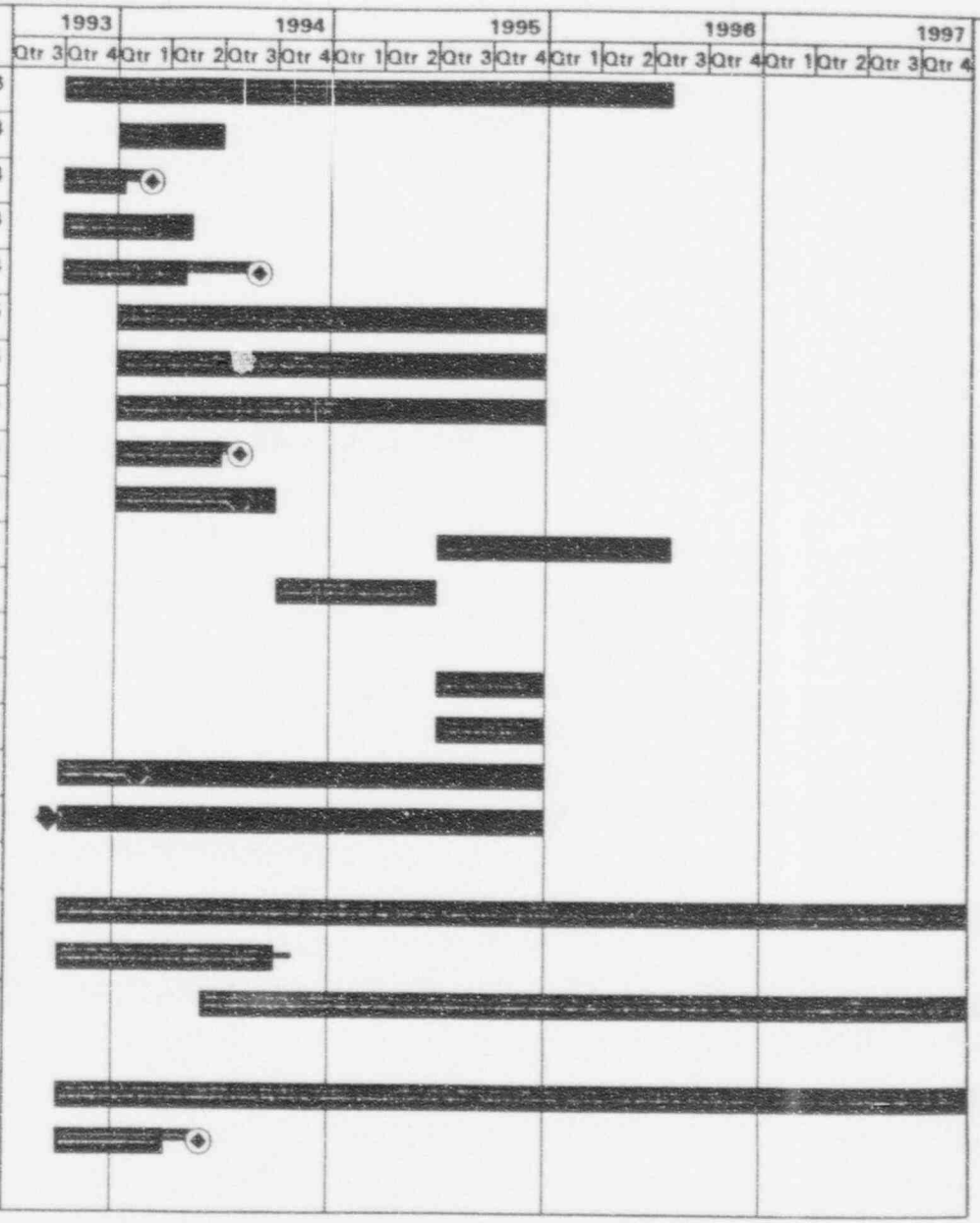


Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
INSPECTION GUIDANCE	7/31/96	7/31/96
Event Response Procedure	3/7/94	6/30/94
MC - Assessing Public Exp/Notification	2/28/94	1/13/94
Inspection of Expanding Programs	2/28/94	5/9/94
Prime Alert-10	9/1/94	4/29/94
Revise MC 2800	1/27/95	12/29/95
Program Expansion	1/27/95	12/29/95
Performance Adjustment	1/27/95	12/29/95
Medical Field Notes	8/1/94	6/30/94
QM Inspection Procedure	8/1/94	9/30/94
Third Party Inspection	7/31/96	7/31/96
Allegation Follow-up Procedure	6/30/95	6/30/95
ENFORCEMENT	12/29/95	12/29/95
Revision of the Enforcement Policy	12/29/95	12/29/95
Notifying licensee Boards or Trustees	2/10/94	12/29/95
Identify Indiv. w/lic. restrictions	9/14/93	12/29/95
MANAGEMENT & RSO RESPONSIBILITY	12/31/97	12/31/97
NUREG - Management/RSO	10/31/94	9/30/94
Rulemaking - Parts 30/40 - Final	12/31/97	12/31/97
INFORMATION MANAGEMENT SYSTEMS	12/31/97	12/31/97
Licensee Events - support to AEOD	5/31/94	3/31/94

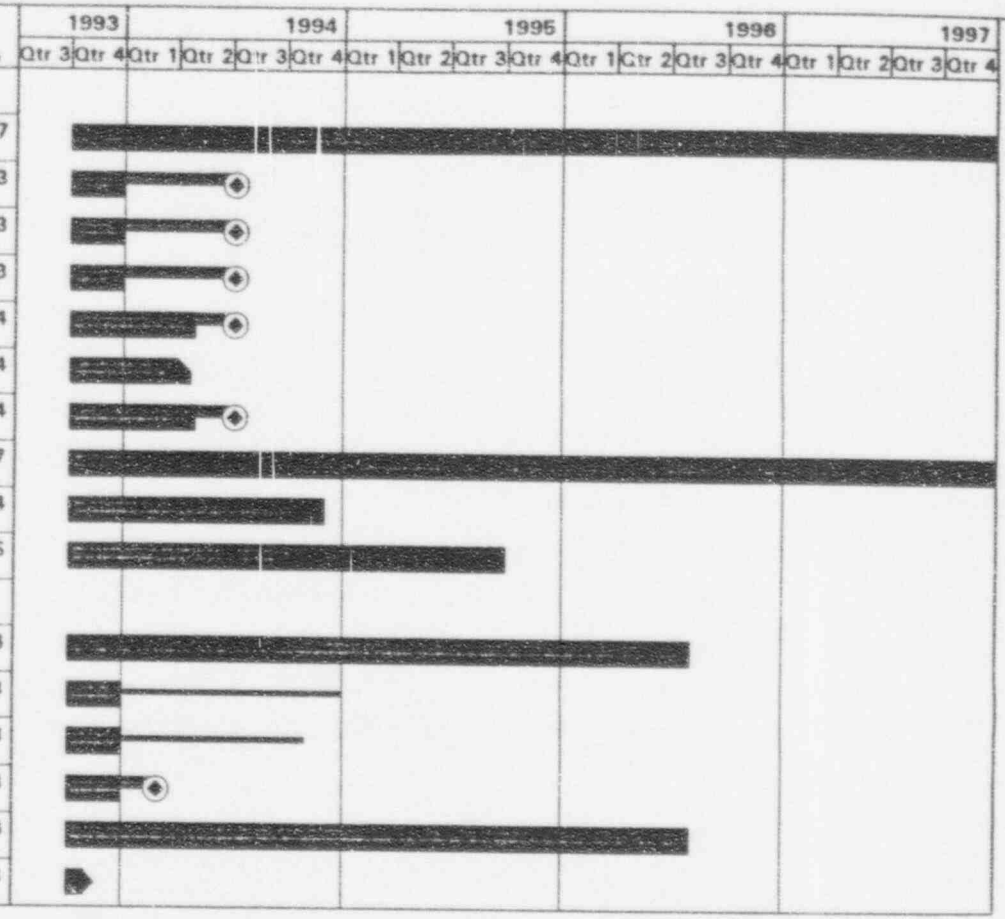


Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
MISADMINISTRATIONS	12/31/97	12/31/97
Management Directive	7/6/94	12/31/93
Patient Follow-up Policy	7/6/94	12/31/93
Notification of Local Authorities	7/6/94	12/31/93
AIT/IIT Guidance	7/6/94	4/29/94
Training on QM TI	3/31/94	3/31/94
Medical Consultant Policy	7/6/94	4/29/94
Misadministration Coordinator	12/31/97	12/31/97
Review all QM Plans	9/30/94	12/1/94
QM Rule Commission Briefing	9/30/94	9/29/95
RESEARCH	7/31/96	7/31/96
QA/QC & Risk for Gamma Knife	12/30/94	12/31/93
QA/QC Risk for HDR Afterloaders	10/31/94	12/31/93
Misadministration Events Analysis - INEL	2/28/94	12/31/93
Human Factors Studies	7/31/96	7/31/96
Southwest Research Source-Wire Eval.	10/26/93	10/29/93



Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

ATTACHMENT 2

MMP STATISTICS

MMP TRACK STATISTICS

Total # of Tracks:				90 Tracks
# of IIT action items (Tracks):		12%	11/90	
% of IIT Tracks Closed or Near Completion:	82%	9/11		
CLOSED Tracks:				
Percent Closed:			56%	50/90
Breakdown of Closed Tracks by Timeliness:				
% of Tracks Completed Early or on Time:		28%	14/50	
% of Tracks Completed Late:		30%	15/50	
% of Tracks closed prior to 8/31/93:		36%	18/50	
% of Tracks Requiring Ongoing Resources but Considered Closed (MED, Div. Trkng., and Misad. Coord):		6%	3/50	
OPEN Tracks:				
Percent Open:			44%	40/90
Breakdown by Open Status:				
% of "Open" Tracks Near Completion:		33%	13/40	
% of "Open" Tracks Partially Closed:		12%	5/40	
Others:		55%	22/40	

Attachment 2

ATTACHMENT 3

SPECIFIC INFORMATION ON MMP ACTION ITEMS BY PROGRAM AREA

SPECIFIC INFORMATION ON ACTION ITEMS
IDENTIFIED BY PROGRAM AREA

The information provided below is an abbreviated version of the information contained in subsection I. "Status Report on the MMP" of this report.

Program Area 1. Policy Issues

- **The NAS study began in January 1994 with a final report expected by January 1996.** See item I, Program Area 1, *"Policy Issues,"* in the Discussion section of this paper for details.

- **1979 Medical Use Policy Statement: ONGOING.** During each rulemaking the staff will ensure the final rule's consistency with the 1979 Medical Use Policy statement (in particular, the impact of the rule on the practice of medicine).

- **NRC/FDA MOU signed: 8/26/93.** The U.S.Nuclear Regulatory Commission and Food and Drug Administration (FDA) staff address issues of mutual interest, on an as needed basis consistent with the Memorandum of Understanding (MOU) signed on August 26, 1993. Routine monthly meetings between the staff are conducted and an annual meeting between agency management was held on August 25, 1994. A memorandum dated June 23, 1994, was forwarded to the Commission to provide a status on implementation of the MOU. Office of Nuclear Material Safety and Safeguards (NMSS) policies and procedures for implementing the MOU were issued August 25, 1994. Additionally, NRC and FDA staff have participated in joint inspections responding to medical events that have occurred at NRC-licensed facilities to determine root cause and ensure effective corrective action.

- **Waste Processor Guidance:** As a result of the inadvertent transfer of the brachytherapy source in the Indiana, Pennsylvania, Incident Investigation Team (IIT) event, and Commission direction in response to SECY-94-073, regarding the recent contaminated ferrophosphorus incident, the staff will refer all incoming reports of emergencies involving unidentified radioactive material in the possession of an individual or group without an NRC or Agreement State license to the EPA, in accordance with the Lead Federal Agency (LFA) provisions of the draft Federal Radiological Emergency Response Plan. Because EPA is the LFA for such incidents, the staff will cease plans to issue guidance to the waste management community regarding events where licensed material is inadvertently received. The staff issued guidance to the regions regarding EPA as LFA for such events by memorandum dated June 21, 1994.

Program Area 2: **Misadministrations and Patient Follow Up**

- During 7/94, NRC Management Directive (MD) 8.10, "Medical Event Assessment Program;" and Manual Chapter (IMC) 1360, revised, "Use of Physician and Scientific Consultants" were issued.

- **Resolving Related Regulatory Requirements: ONGOING.** On May 7, 1993, the staff issued Information Notice (IN) 93-36, "Notifications, Reports and Records of Misadministrations," to provide additional guidance to all NRC medical use licensees on its requirements. Since that time, various issues surrounding these requirements continue to be raised, particularly informing a patient's relative or guardian in the event that the patient is not informed based on medical judgment. As a result, the staff decided to issue a second Information Notice (IN) to clarify these requirements. The proposed IN was discussed with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) during the November 1993, meeting, and the IN was modified to include recommendations by the Committee. The IN has been escalated to a Generic Letter (GL) to emphasize the importance of the requirements to licensees and provide the Commission with an opportunity to provide comment on the staff's interpretation and related policy. The GL will be provided to the Commission in the near future.

  During November 1993 and May 1994, the staff discussed "patient notification," issues with the ACMUI to more fully understand the standards of medical practice and ethics when physicians manage patient information, including information on a misadministration, that could be considered part of the confidential physician-patient relationship.

- **Review of QM Programs: COMPLETE.** See discussion under *II, "Implementation of the QM rule and its Effectiveness."*

- **NMSS Misadministration/Medical Consultant Coordinator: ONGOING.** See item I, Program Areas 2, *"Misadministrations and Patient Followup,"* and 8, *"Information Management Systems."*

Program Area 3. Rulemaking

- **Radiopharmacy Final Rule Package: 10/94.** A final radiopharmacy rulemaking package is scheduled to be submitted to the Commission during October 1994, for approval. The staff intends to propose an effective date of January 1, 1995, since the interim final radiopharmacy rule expires on December 31, 1994.

- **Proposed Patient Release Rule: 6/95.** On June 15, 1994, the staff issued a proposed rule for revision to the patient release criteria described in 10 CFR Part 35, and conforming changes to 10 CFR Part 20 (59FR30732). The rule proposes a dose-based, rather than activity/radiation-level based, criterion. Comment period on the proposed rule expired on August 29, 1994. The staff also issued a Draft Regulatory Guide (DG-8015) and Regulatory Analysis, NUREG-1492). The staff is scheduled to submit a proposed final rule by 6/30/95, for Commission approval.

- **Revisions to 10 CFR Part 19 and 20 for Assessing Public Exposures: 12/94.** Proposed revisions to 10 CFR Parts 19 and 20 were published for comment in the Federal Register on February 2, 1994, (59FR5132). Licensees would be required to assess public exposure and notify individuals of their exposures as a result of inadvertent public exposures resulting from medical events. This rulemaking was combined with the 10 CFR Part 20 "controlled area" rulemaking, and is currently

scheduled to be submitted by December 31, 1994, for EDO approval. Adjunct efforts to provide additional guidance include issuance of IMC 1302 as discussed in program area 5, *"Inspection Guidance,"* and MD 8.10 as discussed in program area 2, *"Misadministrations and Patient Followup."*

- **Inadvertent Administrations to Pregnant Patients and Nursing Infants:** The development of a proposed rulemaking package to reduce the likelihood of an unintended radiation exposure to an embryo/fetus or nursing infant has been delayed due to the reallocation of resources to the development of the final radiopharmacy rule and associated guidance.

- **Revisions to 10 CFR Parts 20 and 35: 10/94.** The staff is developing a proposed rule to clarify that the 10 CFR Part 35 definitions of misadministration and associated reporting and notification requirements apply in cases involving the administration of byproduct material to an individual ("wrong patient"). 10 CFR 20.1301 public dose limits do not apply to these individuals. The staff is scheduled to submit the proposed rule during October 1994, for Commission approval.

- **PART 35 ANPR: 3/95.** The staff is in the initial stages of developing an Advanced Notice of Proposed Rulemaking (ANPR) for major revisions to 10 CFR Part 35, and plans to develop minor revisions to 10 CFR Part 30, 31, and 40. The revisions to 10 CFR Part 31 are specific to in-vitro laboratories issued general licenses. The more generic revisions to 10 CFR Parts 30 and 40 are to emphasize a management commitment to provide adequate resources for the radiation safety program and support for the radiation safety officer. For the major revision to 10 CFR Part 35, the staff expects to issue the ANPR in March 1995 and the final rule in late 1997, as scheduled. Final amendments to Parts 30, 31 and 40 are also scheduled to be completed by the end of 1997.

- **Revision of the Abnormal Occurrence Reporting Criteria: 10/94.** During October 1994, the staff submitted, for Commission approval, a Commission policy statement to revise the Agency's criteria for reporting "Abnormal Occurrences" to the U.S. Congress. This was submitted in response to an SRM dated May 19, 1994, which directed the staff to resubmit the reporting criteria and consolidate the various changes being considered into a single revision for Commission approval as a Commission policy.

Program Area 4. licensing Guidance

- **Revised Guidance: 9/95.** P&GD 86-04, Revision 2 Issued 9/94, licensing guidance for remote afterloading brachytherapy. Revised licensing guidance is under development to reflect the final radiopharmacy rule; address teletherapy, and mobile nuclear medicine.

  Regulatory Guide 10.5 has been revised to provide additional guidance on licensing medical use programs of broad scope. It is scheduled to be published for public comment in the near future and issued in final by May 1995.

- **New Guidance: 9/95.** Licensing guidance is under development for gamma stereotactic radiosurgery devices, manual brachytherapy, and radiopharmaceutical therapy.

  Policy and Guidance Directive 94-04 was issued 6/94 to provide guidance for license reviewers on identifying material licensees whose programs have undergone significant growth and warrant an onsite inspection prior to the next routine inspection.

  MC 1246 was issued 2/94 to provide guidance on NRC license reviewer qualifications.

Program Area 5: **Inspection Guidance**

- **Revised Guidance: 1/95.** A working group has been established to make major modifications to IMC 2800, "Materials Inspection Program." The revised guidance will focus on the core and non-core inspection programs for materials licensees, greater flexibility in increasing or decreasing inspection frequencies, and more emphasis on performing reactive inspections. The revision to IMC 2800 is scheduled for completion by January 31, 1995.

- **New Guidance: 9/93.** TI 2800/024 issued for inspection of licensees authorized for remote afterloading brachytherapy procedures. **7/94:** MD 8.10 issued to provide inspection guidance for medical events, in particular, misadministrations.

  By way of a 7/93 memorandum, instruction to the regions was issued to identify and inspect medical licensees whose programs had undergone significant growth. All such inspections were conducted by 2/94 with no significant findings. Corresponding licensing guidance was also issued.

  IP 87103, "Inspection of Incidents at Nuclear Materials Facilities," was issued 3/94 to provide additional guidance to management when determining whether to dispatch one or more regional inspectors to conduct a special inspection in reaction to an incident; and to inspectors for determining the sequence of events leading to the event and the conditions that existed at the time the incident occurred. IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public" was issued 2/94 to provide generic and specific guidance on the course of action to follow in situations involving radioactive material in the public domain. This includes notifying local authorities in response to a particular event.

  The staff addressed the PrimeAlert-10 area radiation monitor IIT finding by requesting specific information from the manufacturer on the use of, and problems observed with use of the device. In addition, the staff discussed this issue with participants at the American Association of Physicists in Medicine's Summer School during August 1994. There is no evidence to indicate that there are generic problems with these meters. Therefore, a TI is not needed.

- **Issue of Third Party Inspections: ON HOLD.** The staff has begun to explore the issue of inspection of medical licensees by third parties, such as the American College of Nuclear Medicine, American Board of Radiology, or other medical professional organizations who have an interest in developing, or revising an existing, audit program to meet NRC inspection goals. The staff requested and received guidance from the Office of the General Counsel indicating there is no legal prohibition on the use of third parties to conduct inspections on behalf of the NRC.

Program Area 6: Enforcement

FRN 4/93, changes to Enforcement Policy: The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees. Enforcement decisions focus on violations that indicated a programmatic deficiency. The change also reflects the fact that violations that represent isolated mistakes, of limited consequence, that are not associated with a programmatic weakness of the licensee's QM program, will be considered less significant.

EGM 93-005, 4/93: EGM 93-005 was issued April 2, 1993, to provide guidance on the modification to the enforcement manual described above.

EGM 93-008, 9/93: EGM 93-008 was issued on September 14, 1993, to provide guidance on the System of Records maintained for enforcement actions against individuals. Further OE distributes a list semiannually to identify individuals who have any restriction from NRC-licensed activities which license reviewers should review prior to issuance of any licensing action. Quarterly, NUREG-0940, Enforcement Actions, Significant Actions Resolved," is issued and orders to individuals are included in Section A unless a hearing has been requested. Also, copies of NUREG-0940 and orders to individuals are routinely forwarded to Agreement States.

Weekly Enforcement Panel, 11/92 - 3/94: The staff conducted a weekly enforcement panel consisting of headquarters and regional staff to review inspection and enforcement cases and ensure consistent application of the enforcement policy in cases involving violations of the QM rule.

EGM 94-001, 2/94: EGM 94-001 was issued on February 10, 1994, to provide guidance and instruct the regions to identify the Board of Trustees for medical licensees on distribution for all NRC escalated enforcement actions against the licensee.

EGM 94-003, 3/94: EGM 94-003 was issued on March 23, 1994, to provide additional guidance for distinguishing between programmatic and isolated failures in the implementation of a licensee's QM program.

EGM 94-011, 7/94: EGM 94-011 was issued on July 26, 1994, to provide guidance on the "wrong patient" issue. Specifically, the guidance is that the 10 CFR Part 35 misadministration definitions and related reporting requirements apply in cases involving the administration of

byproduct material to an individual ("wrong patient").

Modifications to Enforcement Manual, 7/94.: The staff modified the Enforcement Manual to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements.

Program Area 7: **Management and RSO Responsibility**

- **NUREG: 10/94.** The staff is near completion on development of a NUREG to provide guidance on effective management of radiation safety programs at medical facilities.

- **Rulemaking: 12/97.** The staff will revise Parts 30, 40 and 70 to emphasize a commitment by management for support of the radiation safety program.

Program Area 8: **Information Management Systems**

- **IMNS Tracking System: ONGOING.** The Division of Industrial and Medical Nuclear Safety developed and currently utilizes a tracking system to monitor all division action items, including those identified in the MMP.

- **AEOD database: ONGOING.** A working group composed of NRC and Agreement State staff developed a prototype database for non-reactor events which was distributed to participants for use and comment during the month of May 1994. This is an enhanced version of the existing AEOD non-reactor event database and is referred to as the Material Events Database. The enhanced database includes NRC licensee data and Agreement State data reported to NRC by Agreement States. An interim version of the database was distributed to NRC program offices and Agreement States during September 1994. The staff will continue to modify the database based on NRC needs.

- **Functional Process Improvement Study: ONGOING.** Although not identified in the MMP, NMSS is currently performing a seven-month study of the materials licensing process with the objective of identifying recommendations for streamlining and automating. Although not limited to medical licensees, this project is anticipated to be of great benefit to medical licensees in terms of providing cost savings in resources expended in the NMSS materials licensing process, improving communications with materials licensees, and decreasing the time needed to complete a licensing action. The objective of this study is to use Functional Process Improvement (FPI) to conduct an analysis of the materials licensing process work flow to determine how the NRC processes an application from receipt to issuance, with the long-term goal of establishing a more efficient and potentially automated processing of material license and amendment requests. A major goal is to determine ways to streamline, automate and avoid duplication of effort in processing the license request. NMSS is also analyzing the Licensing Tracking System to improve its usability by licensees and NRC staff, and compatibility with other agency electronic information systems.

Program Area 9: Research

- **Current Research Reports: 12/94, 1/95, 3/95.** Final reports on Human Factors Evaluations for brachytherapy and teletherapy are expected in January and March 1995, respectively. A final report on Quality Control/Quality Assurance (QC/QA) for Remote Afterloading Devices was recently received by the staff and will soon be published as a NUREG/CR. A final report on QC/QA for the Gamma Stereotactic Radiosurgery device is expected in December 1994. All final research reports will be issued as NUREG/CRs.

- **NUREG/CR-6088 Published: 2/94.** NUREG/CR- 6088, "Summary of 1991-1992 Misadministration Event Investigations" was issued 2/94 and distributed to NRC medical use licensees and Agreement States. There were seven major findings regarding the root cause and contributing factors for the events investigated.

- **NCRP Commentary No. 9: 5/94.** NCRP Commentary No. 9, "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child was issued May 1, 1994. This commentary was developed to assist the staff in developing requirements regarding the unintended exposure of the embryo, fetus or nursing child as a result of medical procedures involving the administration of radioactive material. This Commentary supplements NCRP Commentary 7, "Misadministration of Radioactive Material in Medicine - Scientific Background, 11/91.

ATTACHMENT 4

DOCUMENTS ISSUED SINCE OCTOBER 1, 1993

MAJOR DOCUMENTS ISSUED SINCE AUGUST 31, 1993 (SECY-93-244)

This list identifies only those documents issued to close, or partially close, MMP action items in the nine major MMP program areas. Additionally, the Gantt chart in Attachment 1 provides information regarding the date of actual versus scheduled completion, as originally identified in SECY-93-244, the MMP.

Inspection Manual Chapters (IMC):

IMC 1246 (2/94): "Materials License Reviewer Qualifications"

IMC 1302 (3/94): "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public"

IMC 2810 (6/94): "Master Materials Inspection Program"

IMC 1360 (7/94): "Use of Physician and Scientific Consultants"

Management Directive:

MD 8.10 (7/94): "NRC Medical Event Assessment Program"

NMSS Policies and Procedures Memorandum 1-45:

NMSS Memo 1-45: (8/94) "Implementation of the NRC/FDA MOU"
The policies and procedures memorandum provides instruction to NMSS staff on implementation of the NRC/FDA MOU. Specifically, it describes what types of information should be shared with FDA and how, and provides staff and management points of contact for both agencies. The memorandum was recently distributed to all NMSS staff, although the procedures had already been implemented.

Inspection Procedures:

MC 2800/024: (9/93) "Remote Afterloading Brachytherapy Inspections"

MC 2800/025: (8/94) "Quality Management Program Inspections"

Draft TIs were issued in April and June 1994 for use by the regional staff.

IP 87103: (3/94) "Inspection of Incidents at Nuclear Materials Facilities"

Enforcement Guidance Memoranda and Changes to the Enforcement Manual/Policy:

FRN (4/93): (58FR17321)	Changes to Enforcement Policy published. The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees.
EGM 93-005: (4/93)	Provided guidance on the Enforcement Policy modification described previously.
EGM 93-008: (9/93)	Provided guidance on Systems of Records maintained for enforcement actions against individuals.
EGM 94-001: (2/94)	Provided guidance that required that the Board of Trustees for medical licensees be placed on distribution for all escalated enforcement actions.
EGM 94-003: (3/94)	Provided additional guidance for distinguishing between programmatic and isolated failures in the licensee's implementation of the QM rule.
EGM 94-011: (7/94)	Provides interim guidance on the "wrong patient" issue. Specifically, 10 CFR Part 35 applies in cases involving the administration of byproduct materials to an individual.
Enf. Manual: (7/94)	Additional guidance was provided on how to process enforcement actions involving non-compliance with NRC misadministration requirements, including patient notification.

Policy and Guidance Directives:

94-04 (6/94):	"Identification of Licenses Where Significant Licensing Action Warrants an Onsite Inspection. Issued to provide guidance to license reviewers to identify medical use programs that undergo significant growth and may warrant an inspection prior to the next scheduled routine inspection.
86-04 (9/93): Rev.1	"Licensing of Remote Afterloader Brachytherapy." To provide guidance for licensing high-, medium-, low- and pulse-dose rate remote afterloading procedures.

Regulatory Guides:

10.5 (11/93):	"Application of Licenses for Broad Scope" Finalized by the staff and will soon be published for public comment.
DG 8015 (6/94):	"Release of Patients Administered Radioactive Materials" Issued in Draft for comment with the proposed patient release rule.

Information Notices:

IN 94-09 (2/94): IN 94-09: "Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas Due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20."

IN 94-17 (3/94): IN 94-17: "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use."

IN 94-37 (5/94): IN 94-37: "Misadministration Caused by a Bent Interstitial Needle During Brachytherapy Procedure."

IN 94-39 (5/94): IN 94-39: "Identified Problems in Gamma Stereotactic Radiosurgery."

IN 94-47 (6/94): IN 94-47: "Accuracy of Information Provided to NRC during the Licensing Process."

IN 94-64 (9/94): IN 94-65: "Potential Errors in Manual Brachytherapy Dose Calculations Generated Using A Computerized Treatment Planning System."

IN 94-70 (9/94): IN 94-70: "Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals."

Staff Papers:

SECY-93-259: "Federal Register Notice - Abnormal Occurrence Reports: Proposed Revision to Appendix A to Policy Statement to Include Examples for Reporting Medical Misadministrations as Abnormal Occurrences and Minor Conforming Changes to Existing Abnormal Occurrence Examples."

SECY-94-054: (3/94) "Proposed Amendments to 10 CFR Parts 20 and 35 on Criteria for the Release of Patients Administered Radioactive Material." SECY-94-054A responding to the Office of the Inspector General's concerns was submitted in April 1994.

Memo (6/94): "Food and Drug Administration, Memorandum of Understanding"

Memo (8/94): "Bylaws for the Advisory Committee on the Medical Uses of Isotopes"

NUREG/CR-6088: "Summary of 1991-1992 Misadministration Event Investigations."

This report was prepared by the Idaho National Engineering Laboratory and provides a summary of findings on the root cause of seven misadministrations reported to NRC, that occurred during 1991-1992. The study resulted in 7 major findings. This report was distributed to NRC medical licensees and the

Agreement States included in the briefing book to the National Academy of Sciences. The staff will consider these findings during the next major revision to Part 35.

Southwest Research's Final Report:

An evaluation of Southwest Research Institute's (SRI) Final report on the Omnitron Source Wire Failure was provided to the EDO's Office via a memorandum dated October 27, 1993. SRI concluded that root cause of the in-service failures of the source wires was environmentally-inducted embrittlement due the breakdown of the teflon lining of the storage cask sleeves in the presence of a high-radiation field and subsequent reaction or interaction with the Nitinol alloy. A copy of the staff's report was distributed to the Office of State Programs, and the findings were presented in an article in the *Sealed Source & Device Newsletter*. The newsletter article was distributed to all State programs which have product registration responsibility, the Atomic Energy Control Board of Canada, the International Atomic Energy Agency, and all vendors which are likely to be affected by the findings of the report.

NMSS Newsletter Articles:

Each quarter, NMSS publishes the *"NMSS Licensee Newsletter."* In each Newsletter, articles are published to provide up to date information to NRC medical use licensees on regulatory issues such as current rulemaking efforts, information notices, bulletins or generic letters published, upcoming events, future staff efforts, meeting notices, and additional guidance based on NRC's experience with implementation of the QM rule.

ATTACHMENT 5

DOCUMENTS NEAR COMPLETION (≤ 12/31/94)

MAJOR DOCUMENTS NEAR COMPLETION (≤ 12/31/94)

The following is a list of documents that are expected to be completed by December 31, 1994.

Rulemaking:

10/94: Final Radiopharmacy rulemaking package to EDO for Commission approval.

10/94: Proposed "Wrong Patient" rule to EDO for Commission approval.

12/94: Final rule on revisions to Parts 19 and 20, for notification of members of the public of their exposure as a result of events involving byproduct material, to the EDO for approval. This rulemaking effort was combined in the "Controlled Area" proposed rule published for public comment in the Federal Register on February 3, 1994.

Other Staff papers:

9/94: Revision of AO Criteria: Final paper to EDO for Commission approval.

9/94: Staff recommendation to add second medical physicist position to the ACMUI membership.

10/94: Staff options paper with a recommendation to issue a generic letter to clarify patient notification requirements, particularly, when the referring physician makes a decision not to inform the patient, and therefore, the patient's responsible relative or guardian must be informed, even if the patient is a consenting, competent adult.

Research Studies:

12/94: Final report on QA/QC for gamma stereotactic radiosurgery is expected in December 1994. (The related report on remote afterloading was received in September 1994).

NUREG:

10/94: NUREG: The staff expects to publish the NUREG on Effective Management of Radiation Safety Programs at Medical Facilities.

Attachment 5

Information Notices:

10/94: Facility Management's Responsibilities for Purchased or Contracted Services for Radiation Therapy Programs. This will stress the importance of management oversight of those portions of the radiation therapy program that are performed or supplemented by contractors.

Generic Letter:

12/94: A generic letter will be issued to address a recent observation by NRC staff regarding errors in the delivery of fractionated brachytherapy doses and gamma stereotactic radiosurgery doses. NRC will require licensees to report such events for review and evaluation for generic implications. This information will be used in part to determine whether modifications to 10 CFR Part 35 are needed to reduce the likelihood of such errors.

ATTACHMENT 6

IIT STATUS REPORT

IIT ACTION ITEM UPDATE (1/94)

Except for Action 1a., the "action plan" described for each item below, is the same information contained in the initial IIT status report provided as Enclosure 4, SECY-93-244, the MMP. The "update" section provides information on action to date since then.

Action 1a. Review Oncology Services Corporation's (OSC) corrective actions in response to the finding of ineffectiveness of the radiation safety program.

Action Plan:

The hearing before the Atomic Safety and Licensing Board (ASLB) regarding the suspension of licensed activities at six facilities owned and operated by Oncology Services, Inc. has been dismissed. On August 31, 1994, ASLB dismissed the hearing based on a joint motion by NRC and the licensee. A civil penalty (CP) in the amount of $280,000 has been imposed, and remittance has not been forwarded by the licensee. The CP is based on two Severity Level II violations ($100K each) and one aggregated Severity Level III ($80K). This action is considered closed.

STATUS: **CLOSED**
CONTACT: NMSS/IMAB: JGlenn

Action 1b. Evaluate the need to further define RSO and Authorized User responsibilities. Tracks 33, 51, 77.

Action Plan:

A task force of NMSS, Regional and Agreement State representatives met during the months of April, May, and July 1993, and is scheduled to meet during September and December 1993. Meetings during 1994 to be determined. The staff expects to publish the NUREG in mid calendar year 1994. Additionally, the staff will evaluate the need to further define and provide guidance on the responsibilities of the authorized user. This issue will be addressed during a major revision of Part 35 scheduled for completion in December 1997.

Update:

The Task Force met during September and December 1993, and January 31-February 2, 1994. The Draft NUREG was distributed for peer review and discussed with the ACMUI at the November 1993 and May 1994 meetings. The staff has addressed comments received and is in the final stages of drafting, and expects to publish the NUREG for comment by October 31, 1994.

STATUS: Open
COMPLETION DATES: Publish NUREG: 10/31/94
Evaluate authorized users; Possible rulemaking 12/30/97
CONTACT: NMSS/IMAB/JGlenn

Attachment 6

Action 1c. Evaluate performance and design of PrimAlert-10 Area Radiation Monitors and take appropriate follow up action. Track 52.

Action Plan:

The staff has written to the manufacturer (Victoreen) and requested an evaluation of the potential for non-ionizing radiation fields or electromagnetic fields (associated with linear accelerators) to cause spurious alarms by the PrimAlert-10 ARM as well as similar models used by medical licensees, such as the PrimAlert-50 ARM. In addition, NMSS will develop a Temporary Instruction (TI) for the Regions to review operation and reliability of PrimAlert ARM's as part of the routine inspection program. The staff will evaluate the information developed by the Regions as well as the manufacturer's response and, if appropriate, will issue an information notice to licensees.

Update:

Victoreen responded in October 1993, and NRC staff forwarded a second letter dated February 9, 1994, requesting additional specific information on instrument response at the high energy spectrum. NMSS evaluated the manufacturer's response and did not identify any generic issues. Additionally, at the American Association of Physicists in Medicine Summer School, NRC staff discussed this issue with the school participants. The commentors did not indicate problems with this device. The staff has not identified any generic issues, and therefore will not issue an Information Notice or Temporary Inspection Instruction. As a result, this item is considered closed as of September 1, 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Letter to Victoreen Issued:	09/09/93
	Response Received:	10/20/93
	2nd Letter to Victoreen:	02/09/94
	Decision on IN and TI:	04/29/94
CONTACT:	NMSS/IMOB/Combs	

Action 2a. Evaluate NRC's process for a) assessing exposures and consequences and b) notifying individuals and authorities following an elevated exposure. Track 53.

Action Plan:

The staff has developed guidance to address this recommendation for materials licensees based on the experience of the Amersham source incident. The guidance has previously been approved by the EDO. However, it is being revised to incorporate the lessons learned from the IIT, and will be issued as Inspection Manual Chapter 1302. The staff is in the process of addressing resolution of comments and expects to issue the IMC by 2/28/94.

STATUS:	**CLOSED**	
COMPLETION DATES:	MC 1302 Issued:	02/28/94
CONTACT:	NMSS/IMOB/Combs	

Action 2b. Evaluate the need to further define licensee responsibility for assessing radiation exposure and notifying members of the public and authorities. Track 54.

Action Plan:

The staff will forward a memorandum to OGC to request formal OGC interpretation regarding the applicability of Parts 19 and 20 to licensees for assessing radiation exposure and notifying members of the public and authorities. Staff will incorporate guidance into the appropriate Manual Chapter.

Update:

The staff received guidance from OGC regarding the applicability of Parts 19 and 20 to licensees for assessing radiation exposure and notifying members of the public and authorities. The Office of Research is scheduled to forward a rulemaking package to the EDO by 12/31/94 for approval. The rule makes minor modifications for clarification to Parts 19 and 20 to make reports to members of the public required by Part 20. Additionally, MC 1302 and MD 8.10 were recently issued and provide additional guidance on notifying local authorities in response to an event involving the release of licensed material into the public domain.

STATUS:	Open	
COMPLETION DATES:	Rulemaking package to EDO:	12/31/94
	Estimated Issuance of Final Rule:	03/31/95
CONTACT:	RES/DCool	

Action 3a. Evaluate the need to update licensing and inspection guidance and requirements for HDR afterloaders. Track 55 (See related Tracks 4, 5, 45).

Action Plan:

The staff has undertaken several efforts in this regard. A bulletin was sent to all remote afterloader users, imposing the requirements contained in Bulletin 92-03. Policy and Guidance Directive 86-4, is being revised to incorporate the requirements of the two bulletins. A Temporary Instruction has been drafted to provide guidance on routine inspection of HDR afterloaders. In addition, research efforts are continuing into QA plans for remote afterloaders and human factors related to brachytherapy. The results of these various efforts will be incorporated into a user need memorandum to RES to revise Part 35.

Update:

Policy and Guidance Directive 86-4; Revision 1 was issued September 30, 1993 and TI MC 2800/024 was issued September 23, 1993. The staff continues to monitor and evaluate contractors' findings regarding Quality Assurance/Quality Control and Human Factors Evaluations on Remote Afterloading procedures. These projects are monitored by NMSS and RES. Contractors' findings will be evaluated and incorporated into the proposed revisions to 10 CFR Part 35, when indicated.

STATUS:	Open	
COMPLETION DATES:	Bulletin Issued:	04/20/93
	Final P&GD 86-4 Issued:	09/30/93
	Final TI Issued:	09/23/93
	Evaluate QA/QC study:	11/31/94
	Final report received:	09/30/94
	Evaluate HFE studies:	02/28/95
	Final report expected:	01/31/95
	Issue Part 35 ANPR:	03/31/95
	Revise Part 35:	12/31/97
CONTACT:	NMSS/IMAB/Glenn NMSS/IMOB/Combs	

Action 3b. Evaluate the relative merits of performance-based approach vs. schooling or certifications to verify radiation safety knowledge of HDR afterloader users. Track 56.

Action Plan:

The staff will conduct an evaluation as requested and continue to discuss this issue with the Advisory Committee on Medical Use of Isotopes (ACMUI). The staff will incorporate this issue into the user need memo described in 3a. above, as appropriate.

Update:

This issue was discussed with the ACMUI in May 1993 and will be discussed at future meetings. In addition, the staff's plan to evaluate all current training and experience criteria will include a determination regarding the relative merits of different training approaches to ensure adequate radiation safety knowledge of all users. These findings will be incorporated into the ANPR for revisions to Part 35 scheduled to be published by March 31, 1995.

STATUS:	Open	
COMPLETION DATES:	Discussed with ACMUI:	5/93
	Incorporate into ANPR:	03/31/95
	Revise Part 35:	12/31/97
CONTACT:	NMSS/IMAB/Glenn	

Action 3c. Evaluate the licensing interface among NRC, FDA, and States/Agreement States for sealed sources and devices, including licensee requirements for design reviews and QA/QC. Develop a Memorandum of Understanding with the FDA to further clarify respective roles. Track 57.

Action Plan:

The staff has reviewed FDA's description of its regulatory review of devices such as the Omnitron 2000 and met with FDA staff to clarify the NRC/FDA interface. A MOU has been drafted by both parties and is expected to be signed in the near future. The staff will also review the interface between NRC and the Agreement States with respect to approval of sealed sources and devices and will make appropriate recommendations for improving the definition of that interface.

Update:

The NRC/FDA MOU was signed on August 26, 1993 and NMSS policy and procedures memorandum 1-45 was issued on August 25, 1994. In addition, the staff forwarded a paper to the Commission dated June 23, 1994, to describe implementation of the MOU. The first annual meeting between agency management was held on August 25, 1994 to ensure adequate implementation of the MOU. NRC and FDA staff will continue to conduct monthly meetings.

STATUS:	**CLOSED**	
COMPLETION DATES:	MOU between NRC and FDA Signed:	08/26/93
	Discussed at All Agreement State Meeting:	10/93
	Staff paper submitted:	06/23/94
	Issue NMSS Pol.& Proced. Memo:	08/25/94
CONTACT:	NMSS/IMAB/Glenn and SCDB/Haughney	

Action 3d. Revise the inspection guidelines to trigger consideration for licensees whose programs have significantly expanded or changed. Track 58.

Action Plan:

The staff is currently revising the guidance in Manual Chapter 2800, "Materials Inspection Program," to provide guidance on inspection of satellite facilities, field offices, and temporary job sites. This effort will be expanded to include development of a Policy and Guidance Directive that will provide criteria for license reviewers to use in determining if licensees' programs have significantly expanded or changed.

Update:

A Task Force composed of Headquarters and regional staff met during April and August 1994 to make significant changes to the inspection guidance in IMC 2800, "Materials Inspection Program." Areas to be addressed include guidance on inspection of satellite facilities, field offices and temporary job sites; and adjustment of inspection frequency based on performance. Policy and Guidance Directive 94-04 was issued June 21, 1994 to provide guidance for license reviewers to identify programs that have undergone significant growth and warrant onsite inspection.

STATUS:	Open	
COMPLETION DATES:	Task Force Met:	02/94,08/94
	P&GD 94-04 Issued:	06/21/94
	Draft for Comment Issued:	10/31/94
	Issue Revised MC 2800:	01/29/95
CONTACT:	NMSS/IMOB/Combs	

Action 3e. For near term and where indicated, conduct inspections of licensees whose programs have significantly expanded or changed since last routine inspection. Track 59.

Action Plan:

The staff issued a memorandum to the Regions requesting that they poll licensing staff to identify licensees whose programs (i.e., number of sites, scope of licensed activities, and/or possession limits) have significantly expanded or changed within the last two years, determine if inspections have been conducted since the changes, and where they have not, conduct inspections at those facilities.

Update:

The regions proposed a schedule and completed all inspections by February 28, 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Issued memorandum to Regions:	07/09/93
	Inspections Completed:	02/28/94
CONTACT:	NMSS/IMOB/Combs	

Action 4. Evaluate the need for assisting the nonradioactive waste processing industry in establishing guidance for detecting and obtaining expert assistance for handling of radioactive materials. Track 60.

Action Plan:

The staff has already initiated efforts to prepare such guidance. The staff met with representatives from the Agreement States and the waste processing industry on June 29, 1993, to develop the guidance. The guidance will incorporate lessons learned from the IIT.

Update:

The staff received diverse comments from the industry and Agreement States during 10/93. Two forms of guidance were drafted by NMSS. The staff was previously awaiting Commission direction on SECY-94-073, regarding the contaminated ferrophosphorus incident. As a result, AEOD, NMSS and the regions will refer reports of emergencies involving unidentified radioactive material in the possession of an individual or group without an NRC or Agreement State license to EPA, in accordance with the Lead Federal Agency provisions of the draft Federal Radiological Emergency Response Plan. This track is considered closed as of September 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Conducted Meeting:	06/29/93
	Publish final guidance (Cancelled):	03/31/94
CONTACT:	NMSS/LLWM/Austin and IMOB/Combs	

Action 5. Evaluate Southwest Research's final report on the source wire failure and document the findings. Track 61.

Action Plan:

Upon receipt, the staff will review the final report and make appropriate recommendations.

Update:

The staff received the final report which confirmed the staff's hypothesis regarding the cause of the source-wire breakage. The contractor's final report was transmitted to the Commission via a memorandum dated October 27, 1993.

STATUS:	**CLOSED**
COMPLETION DATES:	Completed evaluation and Memorandum to Commission dated 10/27/93 to transmit final report .
CONTACT:	NMSS/SCDB/Haughney

ATTACHMENT 7

DATA ON 1993-1994 MISADMINISTRATIONS

MISADMINISTRATION REPORT STATUS FOR 1993 - 1994

			Verbal Notifications			Written Reports	
	Events	Patients	Referring Physician	Patient	Resp. Relative	Patient	Resp. Relative
1993	29	30	29	25	2	24	3
January - June 1994	14	14	12	14	4	12	-

Attachment 7

ATTACHMENT 8

PUBLIC PRESENTATIONS DURING FY 94

PUBLIC PRESENTATIONS DURING FY 94

The following is a list of public presentations made by staff of the 10-member Medical and Academic Section, during FY 94. The purpose of these presentations was primarily to discuss implementation of the QM rule and QM requirements, high-dose-rate remote afterloading brachytherapy, and development of the NUREG currently under development and discussed in program area 7, "Management and RSO Responsibility."

American Association of Physicists in Medicine Summer School

American Association of Physicists in Medicine - Physics Committee

American Association of Physicists in Medicine - South East Chapter

Health Physics Society - Bluegrass Chapter

Health Physics Society - North East Chapter

American Board of Medical Physics - Annual Meeting

American College of Nuclear Physicians - Mid Winter Meeting

Society of Nuclear Medicine - Annual Meeting

Radiological Society of North America - Annual Meeting

American College of Radiation Oncology - Annual Meeting

Association of Freestanding Radiation Oncology Centers - Annual Meeting

American College of Cardiology - Annual Meeting

Organization of Agreement States - Fall Meeting

Agreement State Managers Workshop - Summer Meeting

Advisory Committee on the Medical Uses of Isotopes - Nov. '93 & May '94 Mtgs.

3 Licensee Workshops to discuss the QM rule

Attachment 8