January 26, 1996

FOR: The Commissioners

FROM: James M. Taylor /s/
Executive Director for Operations

SUBJECT: PROPOSED STAFF ACTIONS FOR ANALYSIS OF INSTITUTE OF MEDICINE REPORT, "RADIATION IN MEDICINE:A NEED FOR REGULATORY REFORM"

PURPOSE:

To obtain Commission approval to use an operational committee and public workshop process to develop recommendations to respond to the report prepared by the National Academy of Sciences (NAS), Institute of Medicine (IOM).

BACKGROUND:

In January 1994 the Nuclear Regulatory Commission contracted with the IOM, to conduct an external review of the NRC's medical regulatory program, including a review of the basic regulatory rules, policies, practices, and procedures. There were three major goals of the study: (1) examination of the overall risk associated with the use of ionizing radiation in medicine; (2) 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 NRC was seeking specific recommendations on two major issues. First, it requested recommendations on a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate commerce for application of radiation to human beings should be allocated among Federal Government agencies and between the Federal and State Governments. Secondly, it requested recommendations on appropriate criteria to measure the effectiveness of regulatory program(s) needed to protect public health and safety.

The NAS provided NRC with a prepublication copy of the report on December 8, 1995, and issued a press release announcing the availability of the report on December 14, 1995. The NRC is providing copies of the report to all Agreement States and non-Agreement States and Territories, appropriate Federal agencies, the Conference of Radiation Control Program Directors (CRCPD), the Organization of Agreement States, Congressional Oversight Committees and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, the NRC has published a Federal Register notice and issued a press release acknowledging receipt of the report and requesting comments. The ACMUI is scheduled to meet with the staff on February 21 and 22, 1996, to discuss the report. The NAS is scheduled to brief the Commission on February 27, 1996.

The IOM report provides recommendations to Congress, the NRC, the States, and the CRCPD. Attachment 1 is a summary table of the recommendations of the report.

DISCUSSION:

The staff has developed, for Commission consideration and approval, a three-phase process for analysis of and response to the IOM report on NRC's medical use program (Attachment 2). The proposed process includes submittal of recommendations on revisions to NRC's medical use regulatory program to the Commission in December 1996.

Phase I of the proposed staff plan includes: providing copies of the report to external parties; requesting comments from affected parties and members of the public on the possible impacts and any policy, legislative, rulemaking, or guidance issues; and performing a detailed staff review of the report to discuss identified recommendations, conclusions and supporting data, as well as general implications/impacts of the findings and recommendations. This phase is scheduled to be completed in March 1996.

In phase II, the staff proposes to establish an operational committee to develop recommendations for the Commission to consider in response to the IOM report. The operational committee concept is outlined in SECY-94-264, "The Federal Advisory Committee Act and Agreement State Participation in NRC Activities," and the staff believes that the committee should include representatives of the Offices of Nuclear Material Safety and Safeguards and State Programs, the Department of Health and Human Services/Food and Drug Administration, the Agreement States, and the non-Agreement States. As described in that paper, an operational committee would be able to meet without the contraints of the Federal Advisory Committee Act. The operational committee would be primarily responsible for: analyzing the NAS recommendations; determining what approaches to revising 10 CFR Part 35 are available, either with or in the absence of concurrent actions by Congress, other Federal agencies, and the States; and providing the Commission with those approaches. During July through September 1996, the operational committee would conduct two convened, facilitated, public workshops as part of its deliberations, to gain input from a broad spectrum of affected parties and members of the public. The use of a convener/facilitator (contracted) is important to ensure that all viewpoints will be represented in a structured format. A single group of participants representing the affected Federal and State agencies, the regulated community, and members of the public would participate in both workshops. The regulated community would include not only the end-user (i.e., medical licensee), but other entities such as manufacturers, distributors, and nuclear pharmacies that are part of the medical use delivery system. The first workshop would focus on the broad policy issues in the report and other background documents. A time interval between workshops would be allowed for participants to reflect, network, and discuss issues with individuals/ groups represented by the participants. The second workshop would focus on more specific issues such as possible legislative changes and/or rulemaking. The operational committee would consider the input of the workshops in developing recommendations for Commission approval, including the policy objectives which might be implemented through legislation and/or rulemaking. The staff anticipates that the Commission will be briefed on the operational committee recommendations in December 1996. In phase III, the staff would implement the recommendations approved by the Commission.

The staff believes that the review of the IOM report should be conducted in parallel with the ongoing efforts and staff actions for broad-scope licensees, resulting from the internal contamination events at the National Institutes of Health and the Massachusetts Institute of Technology. The staff plans to make available to the operational committee the lessons learned and staff actions as a background document, and to ensure that the implications of those events are considered as part of the review process.

Most of the activities described in phase I are necessary irrespective of whether an operational committee approach is approved by the Commission for developing NRC actions in response to the report. However, the staff believes that the use of an operational committee is necessary to move from the broad recommendations in the IOM report to specific actions that can be implemented by the NRC, other Federal agencies, and the States. This approach is consistent with

the Chairman's response to the Organization of Agreement States (OAS), dated December 28, 1995, supporting the OAS resolution for Agreement and non-Agreement State involvement in the review of the IOM report.

The staff believes that because of the process described to review the overall medical use program, there is no need for the annual staff report on the NRC's medical use program which is due to the Commission in March 1996. Therefore, rather than provide a report at that time, the staff proposes that a report will be provided in December 1996 after completion of the activities described in phases I and II. The staff is available to brief the Commission on the process for review of the IOM study at the time of the NAS briefing.

The staff has identified a legally acceptable alternative to the three-phase approach. Specifically, the Commission could pursue immediate withdrawal from the medical program and develop appropriate legislative proposals based on an expedited staff evaluation of the NAS report and the NAS briefing of the Commission. This approach is not being pursued because the NAS study left unresolved issues associated with implementation of the recommendations, and it does not address NRC's need to fully confer with affected entities such as the Agreement and non-Agreement States and other Federal agencies.

RESOURCES:

The staff estimates a total of 0.75 direct staff full-time equivalent (FTE) will be necessary to complete phase I of the staff plan, which includes the ACMUI meeting scheduled for February 21 and 22, 1996. It is estimated that approximately 2.5 FTE will be expended to complete phase II. This includes the expected staff effort from NMSS, OSP, and OGC to prepare for and conduct the operational committee meetings and public workshops. The resources required to complete the first two phases of the staff plan are included within current budget allocations for the 5-year medical management plan. The estimated cost for conducting two facilitated workshops, using a contractor, is approximately $100,000 and the estimated cost for the operational committee meetings is approximately $30,000.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

RECOMMENDATION:

That the Commission approve the proposed staff actions for analysis of the NAS report.

Original signed by:

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Executive Director for Operations

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Attachments:
1. Summary Table of IOM Recommendations
2. Three Phase Process for Analysis of NAS report

cc: SECY
OGC
OCA
OPA

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ATTACHMENT 2

THREE PHASE PROCESS FOR ANALYSIS OF NAS REPORT

**Phase I - Short Term Activities Focused on Informing Parties and Commission of Staff Plan**
(estimated total FTE ~ 0.75)

Task 1 - Inform External Parties (completed January 1996)

1. Publish a Federal Register Notice and Issue a Press Release

   Indicate availability of document, and provide an opportunity for early comments.

2. Provide copies of report to the following parties (coordinate with OSP, OCA). Request comments within 90 days (comments requested on possible impacts and views on policy, legislative, rulemaking and guidance issues).

   Governors of Agreement States, Non-Agreement States and Territories
   CRCPD, OAS
   FDA, DHHS
   DVA, DoD, DA, DAF, DN
   EPA, DOT, OSHA
   Radiation Control Program Directors for Agreement and non-Agreement States

3. Provide informational copies to:

   Congressional Oversight Committees
   ACMUI
   Regions, including DNMS, RSLO/RSAO's
   OMB

Task 2 - Development of Commission paper to outline plan and seek approval for process including the formation of operational committee and conduct of facilitated workshops.

Task 3 - Detailed staff review of the NAS report to discuss identified recommendations, conclusions and supporting data, as well as general implications/impacts of findings and recommendations. The review team is comprised of representatives of NMSS, RES, and OGC. The results of this review will be forwarded to the Commission prior to the NAS brief scheduled for February 27, 1996.

Task 4 - ACMUI meeting with staff is scheduled for February 21-22, 1996.

Task 5 - Commission briefings by NAS and staff (February 27, 1996).

Task 6 - Following Commission approval of staff plan, a second letter will be sent to the parties specified in Item 2 of Task 1 informing them of the plan and soliciting participation on the operational committee. Any additional specific issues raised by the Commission will be identified for their input.

**Phase II - Activities for Operational Committee**
(estimated total FTE ~ 2.5 for completion)

Task 1 - Develop statement of purpose for operational committee. Committee will include representatives of NMSS, OSP, FDA/ DHHS, Agreement States, and non-Agreement States. OGC and NRC's Medical Visiting Fellow will serve as consultants to the committee.

Task 2 - Prepare background papers to be used for enhanced participatory process

- Staff review of the IOM report identifying recommendations, conclusions and supporting data, as well as general implications/impacts of findings and recommendations (Phase I, task 3).
- Analysis of data collected through NRC's temporary instruction for inspection of licensees' Quality Management Programs.
- Transcript and minutes of ACMUI meeting - summary of key issues and recommendations of ACMUI.
- Summary of initial inputs from commenters identified in Phase I, Tasks 1 and 6.
- Lessons learned from incidents at the National Institutes of Health and the Massachusetts Institute of Technology.

Task 3 - Initiate activities of operational committee (begin March 1996)

- Organize background documents.
- Develop strategy for possible attendance and participation/discussion of issues at professional organization and other meetings (e.g., Agreement States technical meeting, Conference of Radiation Control Program Directors, Society of Nuclear Medicine, American Association of Physicists in Medicine, American Society for Therapeutic Radiation Oncology, Radiological Society of North America).
- Work with contracted convenor/facilitator to identify a single group of participants, representing national viewpoints and perspectives, for two public workshops. Participants will include, to the maximum extent possible, representatives of specific Federal agencies, Agreement and non-Agreement States, patient advocacy groups, medical licensees (both broad and limited scope), and radiopharmaceutical, source, and device manufacturers, vendors, and distributors(1).
- Develop agenda and issues for convened, facilitated public workshops.
- Conduct 2 facilitated public workshops (mid-July, September 1996). The first workshop will focus on the broad policy issues in the report and other background documents and general discussion of issues such as implications and approaches. The time interval between workshops will allow the participants to reflect, network, and discuss issues with individuals/groups represented by participants. The second workshop will focus on more specific issues such as possible legislative changes and/or rulemaking.
- Preparation of recommendations, to include the policy objectives which might be implemented through legislation and/ or rulemaking, for Commission approval (December 1996).

Phase III - Longer Term Activities with Broad Implications for the Medical Use Program - Including Part 35 Revisions

Task 1 - Implement recommendations approved by the Commission - specific actions or time-frame will result from the operational committee recommendations and Commission direction.

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1. Invited participants would be expected to pay for their own travel to the workshops; however, NRC would fund travel in those cases where it is difficult or impossible for participants, or the participant's organization, to pay travel expenses.