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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 21, 1993

COMSECY-93-004

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: RESPONSE TO SRM ON COMIS-92-026 - REVIEW OF THE REGULATION OF THE MEDICAL USE OF BYPRODUCT MATERIAL

In the subject SRM, the Commission requested that the EDO nominate, for Commission approval, a senior NRC manager to perform a management review of the existing medical use regulatory program. I am hereby nominating Dr. Carl J. Paperiello, Deputy Administrator for Region III, as the manager to perform this review. Dr. Paperiello, who is the team leader for the IIT investigation of the Indiana, Pennsylvania medical misadministration and related matters, will be available for this management review after completion of the IIT report, due to the EDO on January 29, 1993. If the Commission approves the selection of Dr. Paperiello, he will conduct this review independently of the program offices and will report directly to the EDO. A schedule for completion of this review will be developed by Dr. Paperiello after approval of his selection by the Commission. As requested in the SRM, he will solicit the views of ACMUI as he conducts his review.

In the SRM, the Commission also requested that the EDO propose, for Commission approval, a charter and proposed members for an outside group to conduct an in-depth review of the existing medical use regulatory program to assess whether it is appropriate to fulfill the NRC's statutory responsibilities for public health and safety.

The staff has considered various outside groups to perform this work, and has concluded that the only reasonable approach is to contract with the National Academy of Sciences (NAS). The staff feels that this is the only group with the prestige and level of independence required for a study of this nature.

On January 7, 1993, members of the NRC staff met with Dr. Kenneth Shine and other members of the NAS to explore whether the NAS is interested in conducting such a review. The NAS expressed keen interest in this project, however they did specify that they will not agree to NRC right of approval of the membership of the committee that NAS selects to conduct the review.

The NAS is only available through a sole source contracting process. Upon Commission approval to issue a sole source contract to the NAS, certain agency actions will ensue. Specifically, parallel letters will be sent to OMB and the SBA noting the importance of this study, and requesting exemption from the requirement to place a notice in the Commerce Business Daily. Upon receipt of this exemption, we will proceed to place a sole source contract with the NAS.

Based upon our discusssions with OMB and SBA, we expect it will take approximately two to four weeks to receive approval to waive the CBD requirement. During this time, the staff will continue to develop the statement of work for the project.

SECY, please track.

James M. Taylor
Executive Director
for Operations

cc: SECY
OGC

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Carl [illegible] 4L from Dr. [illegible] 3:45 p.m 3/19/93

REVIEW OF NRC REGULATION OF RADIATION MEDICINE ACTIVITIES

I. URGENT ACTIONS - These Tasks Should be Started Now and Not Wait for My Review

A. Statement of Work for National Academy of Sciences -DONE

B. Radiation Therapy Event Followup Procedure - Regional Inspectors Need an inspection procedure for the followup of misadministration reports and other radiation therapy events. Attachment A presents an outline of such a procedure.

C. Revise licensing guidance for High Dose Rate Brachytherapy and review existing guidance for all other therapy programs and ensure it is current.

D. Ensure the availability of current inspection guidance for High Dose Rate Brachytherapy and all other therapy programs.

II. Review Of Misadministrations and Current QM Rule.

Determine if the QM rule is likely to reduce the number of misadministrations. Determine the adequacy of the information on medical misadministration events. Determine if the NRC has adequate assurance that licensees are implementing the QM rule. Determine if there are other changes in NRC requirements that might reduce misadministrations in a cost-beneficial manner.

USING EXISTING INEL CONTRACT - TASK INITIATED

A. Using available data and reports review misadministrations to identify common causes. Determine if there are correlations among causes and severity.

B. Determine if the current Quality Management Rule if properly implemented could have prevented these events.

C. Determine if any licensees have had repetitive misadministrations and why. Determine if corrective actions for prior misadministrations should have prevented the additional misadministrations.

INTERVIEW REGIONAL AND NMSS STAFF

D. Determine what Regions have done to follow-up on reported misadministrations. How many misadministrations have resulted in enforcement actions. Look at the results of the QM Review Committee.

E. Determine the status of implementation of the QM rule by licensees and verification of implementation by the NRC. QUIZ Regions and NMSS.

SPECIAL TASK FORCE

F. Establish Special Task Force to Look at I-131 diagnostic-

therapeutic misadministrations. Determine if any additional actions beyond QM rule are likely to reduce misadministrations. Consider a requirement to color code I-131 capsules or caps on bottles of liquid doses. Diagnostic range doses would be green and therapeutic doses red.

III. Staffing and Organizational Effectiveness

Determine the skill levels in NMSS and the Regions with respect to Radiation Medicine. Review Regional and HQ organizations to assure maximum efficiency and work load distribution.

SELF AND PERSONNEL

A. Identify NRC staff including management background in radiation medicine. Review training and adequacy of MC 1245.
B. Review training provided to staff when rules change.
C. Review NMSS and Regional Organizations to ensure maximum efficiency and equitable work load distribution.

IV. Review Licensing and Inspection Program Implementation and the Effectiveness of the National Program Review. This task would be accomplished by a combination of survey questionnaire and personal interviews.

Determine if there are problems because of deficiencies in existing programs, policies and procedures or because existing programs, policies and procedures are not understood or followed.

INTERVIEWS OF NMSS AND REGIONAL STAFF

A. To what degree does the medical inspection program depth and frequency reflect risk.
B. To what degree does the medical inspection program depth and frequency reflect licensee performance.
C. To what degree are license conditions needed to impose safety related requirements in lieu of regulations. (i.e. Part 35 Statements of Consideration state the NRC intent not to use tiedown conditions)
D. Determine the basis of the 5 year license.

REVIEW THE RESULTS OF THE ANNUAL NATIONAL PROGRAM REVIEW

E. How adequately are the Regions implementing the medical inspection program and what additional helpful guidance have they provided to their staff.
F. To what degree do inspection procedures address current regulations and the spectrum of licensed medical programs.
G. Determine the number and age of the medical inspection backlog.
H. Determine regional adherence to NMSS licensing guidance.

REGIONAL INTERVIEWS

I. Determine the adequacy and currency of licensing Regulatory Guides and other NMSS Guidance to license reviewers for Medical

uses.

J. Determine the clarity and usefulness of Regulatory Guides to Medical Licensees.

V. Review of Enforcement Program

Determine the degree to which the enforcement program contributes to compliance and safety in the medical area. Determine if there are changes in the enforcement policy that might improve safety and/or lower NRC resource costs. Determine the adequacy of civil penalty size.

REVIEW ENFORCEMENT RECORDS, FIVE-YEAR PLAN AND STAFF DISCUSSIONS

A. Determine the causes of escalated enforcement in the medical area.
B. Determine the percentage of therapeutic events that result in civil penalties.
C. Determine from a review of repetitive civil penalties if enforcement results in deterrence.
D. Determine the level of resources needed to process an escalated enforcement case.
E. Determine the appropriateness of civil penalty sizes.

VI. Regulations

Determine the overall quality and consistency of NRC medical regulations. Determine if they are cost beneficial. This may be best accomplished through the materials regulatory impact survey.

ASSIGNMENT UNDETERMINED

A. What requirements are imposed on medical licensees through commitment to regulatory guide procedures?
B. What requirements are based on convention and not a fundamental measure of risk? (i.e. daily surveys, quarterly meetings, quarterly inventories) Which of these have little safety payoff.
C. Are there requirements counter productive to safety?
E. What areas does the NRC regulate that overlap with other federal, state or local regulatory bodies in the medical area? How does FDA regulate medical devices?
F. Review all proposed rules and the status of petitions for rule making in the medical area.

VII. Reporting

Determine what is done with event information received from medical licensees. Determine how the NRC responds to events. Determine the management and retrievability of information. This could be accomplished through interviews of NMSS, AEOD and Regional staff; reviews of agency procedures; and review of the information used by the Commission in establishing Abnormal Occurrence criteria.

INTERVIEW NMSS AND AEOD

A. Determine which offices in the NRC review reports from medical licensees.
B. Determine what data bases are maintained of medical licensee reports.
C. Determined what procedures exist for review and analysis of these reports.
D. Evaluate the basis for classifying medical events as Abnormal Occurrences.

VIII. Medical Consultants

The Medical Consultant's report may form the basis for or make a major contribution to the basis for a regulatory action. The NRC may have to legally defend the consultant's work. There needs to be a mechanism for the periodic evaluation of medical consultants. This task might best be reviewed and commented on by ACMUI. However, the use of ACMUI members, some of whom are NRC medical consultants, may result in a conflict of interest.

CONSULT WITH ACMUI AND OGC

A. Determine the basis for appointing medical consultants.
B. Determine the basis for reviewing medical consultant performance.
C. Determine what instructions have been provided to medical consultants. Is there a code of conduct? Conflict of interest?
D. Determine the liability of the NRC and the Consultant if the Consultant's medical advice results in a patient injury.
E. How are disagreements between licensee physicians and NRC physician consultants resolved?

IX. Agreement States

Determine the degree of compatibility of NRC and state medical regulations. Determine if there are mechanisms for ensuring uniformity of medical radiation regulation policy on a national basis. Determine if differences in requirements affect the reporting statistics on misadministrations. Determine if there is bias in the reporting of Co-60 teletherapy misadministrations vs. electronic teletherapy misadministrations. On a practical basis is nuclear medicine or radiation therapy practiced any different n an agreement state vs. NRC licensed state.

INTERVIEW OSP, VISIT AN AGREEMENT STATE MEDICAL LICENSEE, CONSULT WITH ACMUI

A. What are NRC requirements for compatibility in the medical area?
B. How many states have misadministration rules? How similar or dissimilar are state rules? Do States use medical consultants? How do States follow up on misadministration reports? Are misadministration reports limited to byproduct material or are all radiation therapy misadministrations reported.
C. Does OSP review misadministration reports during the state program review? Does the NRC have a policy of the States notifying the NRC on misadministrations? How do the states ensure patients are notified?
D. How compatible are agreement state medical regulations as compared to

the NRC's?

E. Do States issue civil penalties to medical users for program breakdown? Some States claim they achieve safety and compliance results as good as or better than the NRC without resorting to civil penalties. How accurate is this and what are these methods?
F. Determine what mechanisms exist for establishment of uniform national policy on medical radiation regulation.

X. Enumerate and Review Major Issues Raised in the Medical Area.

Identify major issues that might not have been reviewed above.

A. Review all ACMUI minutes and transcripts for the past 5 years.
B. Review IG and GAO audits of materials and medical areas.
C. Review Commission Papers on Medical regulation since 1975.
D. Review NMSS Medical Management Program.

Attachment 1

FOLLOWUP ON THERAPEUTIC MISADMINISTRATION REPORTS

SCOPE: Applies to all events resulting from therapy misadministrations or any other medical event resulting in an unplanned or unexpected dose to the patient in excess of Revised Part 20 incident limits. (25 rem effective whole body, 75 rem eye, 250 rads to the skin or an organ).

I. INVESTIGATION TASKS
- A.)Determine Sequence of Events
- B.)Determine Immediate and Root Causes
- C.)Determine Compliance with Quality Management Rule
- D.)Determine Compliance with Misadministration Rule
  - 1.)Notification of NRC - 24 hour
  - 2.)Notification of NRC - 15 days
  - 3.)Notification of Referring Physician and Patient - 24 hours
  - 4.)Written Notification of patient - 15 days
- E.)Review by NRC Medical Consultant
- F.)Review of enforcement options by - NMSS, OE and Region
- G.)Review by OGC for classification as misadministration

II. STAFFING
- A.)Inspector Qualifications
  - 1.)Senior GG-14 or above
  - 2.)Training in Teletherapy, Brachytherapy, Nuclear Medicine
  - 3.)Accident Investigation Training
- B.)Medical Consultant
- C.)NMSS Coordinator
  - 1.) Same qualifications as A.
  - 2.) Capable of performing dose calculations and evaluations.
  - 3.) Maintains file of all medical investigation reports.
  - 4.) Coordinates review of event by OGC for final determination of status as misadministration.

III. MEDICAL CONSULTANT ROLE
- A.)Review Event
- B.)Independent Analysis of Cause
- C.)Determine Dose to Patient
- D.)Determine likely medical consequences
- E.)Determine adequacy of licensee report to the NRC and the patient
- F.)Determine likely medical followup needed
- G.)If the patient was not notified, determine the validity of the justification.
- H.)Provide Medical support to licensee and referring physician if requested.

IV. REPORTS
- A.)The Investigation Report Package will include the inspector(s)' report, the Medical Consultant's report and the Licensee's report to the NRC.

Final report is due 15 days after receipt of licensee's and consultant's report.

B.)NRC Investigation Report Distribution

1.)Licensee
2.)Referring Physician
3.)Patient or whomever notified by referring physician
4.)ACMUI
5.)NMSS Medical Event Coordinator

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