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DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
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NORFOLK, VIRGINIA 23513-2617

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From: Commanding Officer, Navy Environmental Health Center
To: Distribution List

Subj: NAVY RADIOACTIVE MATERIAL PERMIT PROGRAM

Encl: (1) NRC Information Notice No. 90-71: Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs

1. Enclosure (1) is forwarded for review by your Radiation Safety Officer (RSO) and Radiation Safety Committee (RSC).

2. The Command should ensure that the RSC maintains sufficiently detailed records to document its performance of radiation safety program functions. These functions include but are not limited to:

a. Approval of authorized users

b. Approval of minor changes to the radiation safety program as authorized by Title 10 Code of Federal Regulations Part 35.31

c. Review of the RSO's annual summary of the radiation safety program

d. Review of the ALARA program

3. Point of contact on this subject is LCDR G. I. Snyder, MSC, USN, Radiation Health Department (NEHC-311), AUTOVON: 564-4657 or Commercial: (804) 444-7575, Ext. 266.

P. J. DURFEE
By direction

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

November 6, 1990

NRC INFORMATION NOTICE NO. 90-71: EFFECTIVE USE OF RADIATION SAFETY COMMITTEES TO EXERCISE CONTROL OVER MEDICAL USE PROGRAMS

Addressees:

All NRC licensees authorized to use byproduct material for medical purposes.

Purpose:

This information notice is provided to remind byproduct material licensees of their responsibilities for ensuring that radiation safety activities are performed in accordance with license conditions and other regulatory requirements. It is expected that licensees will review this information for applicability to their programs, distribute it to members of the Radiation Safety Committee (RSC), responsible radiation safety staff, and hospital management, and consider actions, if appropriate, to prevent problems from occurring at their facilities. Hospital Administrators, Chief Executive Officers, or Presidents are urged in particular to read carefully the information contained in this notice. However, suggestions contained in this information notice do not constitute new Nuclear Regulatory Commission (NRC) requirements, and no written response is required.

Description of Circumstances:

Since the implementation of the revised 10 CFR Part 35, "Medical Use of Byproduct Material," became effective on April 1, 1987, NRC has cited numerous violations directly or indirectly related to RSC responsibilities. The violations resulted from the various RSCs failing to exercise effective oversight and control of their radiation safety programs. Many of the NRC-identified violations should have been identified and corrected during the RSC's required annual review of the licensed radiation safety program.

An analysis of the violations relating to RSC responsibilities identified four common areas of weakness. These areas are:

° Failure of the RSC to consistently meet quarterly with the required number of members present. NRC regulations require that at least half of the members be present, including the Radiation Safety Officer (RSO) and the management representative, to constitute a quorum and conduct business.

° Failure to have management actively participate with the RSC. The licensee's management must support the activities of the RSC by ensuring that sufficient staff, time, and equipment resources are allotted to the radiation safety program.

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- Failure of the RSC to review the functions of RSO, to ensure that: (1) the RSO is vested with necessary authority and independence to carry out program responsibilities; (2) the RSO does not have other duties that prevent adequate attention to the safety program; (3) the RSO has not delegated substantial responsibilities to other staff members or to consultants, such that the RSO is unaware of program status; and (4) the RSO is otherwise effective in managing the licensed program and in carrying out the responsibilities identified in 10 CFR 35.21 of the regulations.

- Failure of the RSC to perform its radiation safety program functions. NRC regulations and license conditions require the RSC to review summaries of the types and amounts of material used, all incidents involving byproduct material, the ALARA (as low as is reasonably achievable) program and occupational doses, changes in radiation safety procedures, training and continuing education for the staff, and the RSO's annual summary of the radiation safety program. Review of the program should help to identify weak areas and areas that are not in compliance with NRC regulations. Once these areas are identified, effective corrective actions should be implemented immediately to avoid violations.

Discussion:

The common weaknesses just described have resulted in numerous violations at medical institutions with ineffective RSCs. Civil Penalties were assessed against many of the hospitals where multiple violations of NRC requirements were identified, or in cases where previously cited violations were not corrected. Examples of such cases are described in Attachment 1.* The NRC enforcement policy (10 CFR Part 2, Appendix C, Section V.B.) clearly states that ineffective licensee programs for problem identification or correction are unacceptable.

The RSC may seek qualified assistance from outside consultants if the licensee staff does not possess the necessary experience or training to perform the required review and implementation of corrective actions. However, it is the licensee's responsibility to ensure that the review and corrective actions meet the regulatory requirements.

To summarize, the purpose of the RSC is to: (1) identify radiation safety problems; initiate, recommend or provide corrective actions; and verify implementation of corrective actions; (2) review, on the basis of safety, the training and experience of proposed authorized users, RSOs, or Teletherapy Physicists; (3) review and approve or disapprove minor radiation safety changes permitted by 10 CFR 35.31; (4) review quarterly a summary of occupational dose records of all personnel working with radioactive material and review recommendations on ways to maintain individual and collective doses ALARA; (5) review quarterly, with the assistance of the RSO, all incidents involving byproduct material, with respect to cause and subsequent actions taken; and (6) review annually, with the assistance of the RSO, the radiation safety program. These objectives can only be met by the RSC working closely with the RSO, authorized users, and the technical and ancillary staff.

* Full details of escalated enforcement actions against materials licensees can be found in NUREG 0940, as well as the NMSS quarterly Newsletter.

The licensee's management must actively participate in the RSC by attending the committee meetings, extending sufficient authority to the committee's decisions, and being aware of licensed activities, and regulatory and license commitments.

Hospital management must assure that the RSC is meeting as required and performing its required functions. In a few instances, medical personnel have created false records of RSC meetings due to failure of the institution to support the RSC. Providing false information to the NRC or creating a false entry in a record required by the NRC is not tolerated. Hospitals have received significant monetary penalties, authorized users have been removed from licenses and criminal investigations have been conducted as the result of false information provided to the NRC, and as a result of licensees or their employers willfully failing to meet Commission requirements.

In summary, the number of enforcement actions involving civil penalties have increased from 9 in 1987, to 13 in 1988, and 21 in 1989. It is imperative that hospital administrators be aware of the regulations described in 10 CFR Part 35 and the conditions of the hospital's license. In addition, a responsible RSO and good functioning RSC can minimize the potential for adverse NRC inspection results, and thereby avoiding civil penalties which are accompanied by subsequent press releases giving the hospital adverse publicity.

No written response is required by this information notice. If you have any questions, please telephone the contact listed below or the appropriate regional office.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

Technical Contact: Janet R. Schlueter
(301) 492-0633

Sandra Waldron, RII
(404) 331-2687

Attachments:
1. Examples of Escalated Enforcement Cases Involving RSCs at Medical Institutions
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

EXAMPLES OF ESCALATED ENFORCEMENT CASES INVOLVING RADIATION SAFETY COMMITTEES (RSC) AT MEDICAL FACILITIES

Case A:

An NRC inspection identified 24 violations covering a wide range of issues, including the failure of the RSC to meet quarterly, failure to conduct annual reviews of the radiation safety program, failure to review the training and experience of all users of radioctive material and ensure sufficient qualifications are met, and failure to determine whether current procedures are maintaining radiation exposures ALARA. Numerous other violations were cited involving other program areas, including providing adequate radiation safety equipment to the staff.

It was determined by the NRC that the root cause of the violations going undetected was that the RSO had been intentionally remiss in performance of his RSO and RSC Chairman duties. A $10,000 civil penalty was assessed.

Case B:

An NRC inspection identified 14 violations, eight of these had been cited previously, including two cited twice and one cited three times. The fundamental problem appeared to be the lack of sufficient time and attention to the radiation safety program by the RSO due to other duties assigned to him at the facility. Licensee management was not aware of the importance and needs of the radiation safety program. The RSC failed to support the RSO in ensuring that sufficient staff, time and equipment resources were alloted to the radiation safety program by management. The RSO had expressed concerns about these inadequacies to the RSC on several occasions, but the RSC failed to support the RSO in these matters. A $2,500 civil penalty was assessed.

Case C:

An NRC inspection identified 12 violations at a medical facility. No violations were identified during the previous inspection. The degradation of the radiation safety program began when two technologists terminated employment with the facility. The RSO indicated that he allowed the two technologists to implement the radiation safety program and that he had little involvement with the day-to-day activities. Of particular concern was that the licensee relied on the technologists to make the program function rather than a viable management control system. It was determined that the RSC needed to be more aggressive in their audit and review of the program, and ensure that deficiencies are promptly identified and corrected. A $4,375 civil penalty was assessed.

Case D:

An NRC inspection identified 38 violations covering a range of issues in the nuclear medicine and teletherapy radiation safety programs including the RSC's failure to review the qualifications of individuals who acted as teletherapy physicists. The lack of adequate authority vested in the RSO, inadequate involvement of the RSO and RSC in oversight of the radiation safety program, and failure of management to ensure the RSO and RSC performed as expected contributed to the violations. A $7,500 civil penalty was assessed.

Case E:

An NRC inspection identified 26 violations covering a range of issues including the RSC's failure to meet for 4 consecutive calendar quarters from 1988 to 1989. Twenty of the 26 violations occurred and continued during the year the RSC did not meet. A root cause of the violations was lack of management oversight, as well as, RSC oversight of the radiation safety program and the RSO, to ensure the functions of the RSO were carried out. A $3,125 civil penalty was assessed.

Case F:

An NRC inspection identified 19 violations involving a wide range of issues in the nuclear medicine program (16 violations) and the teletherapy program (3). The root cause of the violations appeared to be the failure of the RSO and the RSC to exercise adequate control over the radiation safety program and ensure that NRC requirements were being followed. A $5,000 civil penalty was assessed.

Case G:

An NRC investigation identified 2 violations involving the failure of the RSC to meet quarterly except for two occasions during the time interval of January 27, 1983 to September 6, 1989, and the willful fabrication of RSC minutes by a contract nuclear medicine technologist to appear that the meetings had taken place. A $6,250 civil penalty was assessed.

Case H:

An NRC inspection identified 5 violations involving the licensee's brachytherapy and radiopharmaceutical therapy program including radiation levels in unrestricted areas exceeding regulatory limits and the failure of the RSC to perform an annual review of the entire radiation safety program. A root cause of the violations appeared to be the RSO's focus on the diagnostic rather than the therapeutic portions of the licensee's program. As a result, hospital management, the RSC and RSO were not effective in aggressively monitoring and evaluating licensed activities, and in particular those activities involving the Radiation Therapy program. A $625 civil penalty was assessed.

Case D:

An NRC inspection identified 30 violations covering a range of issues in the nuclear medicine and teletherapy radiation safety programs including the RSO's failure to review the qualifications of individuals who acted as teletherapy physicists. The lack of adequate authority vested in the RSO, inadequate involvement of the RSO and RSC in oversight of the radiation safety program, and failure of management to ensure the RSO and RSC performed as expected contributed to the violations. A $7,500 civil penalty was assessed.

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An NRC inspection identified 26 violations covering a range of issues including the RSC's failure to meet for 4 consecutive calendar quarters from 1988 to 1989. Twenty of the 26 violations occurred and continued during the year the RSC did not meet. A root cause of the violations was lack of management oversight, as well as, RSC oversight of the radiation safety program and the RSO, to assure the functions of the RSO were carried out. A $3,125 civil penalty was assessed.

Case F:

An NRC inspection identified 19 violations involving a wide range of issues in the nuclear medicine program (16 violations) and the teletherapy program (3). The root cause of the violations appeared to be the failure of the RSO and the RSC to exercise adequate control over the radiation safety program and ensure that NRC requirements were being followed. A $5,000 civil penalty was assessed.

Case G:

An NRC investigation identified 2 violations involving the failure of the RSC to meet quarterly except for two occasions during the time interval of January 27, 1987 to September 6, 1989, and the willful fabrication of RSC minutes by a contract nuclear medicine technologist to appear that the meetings had taken place. A $6,250 civil penalty was assessed.

Case H:

An NRC inspection identified 6 violations involving the licensee's brachytherapy and radiopharmaceutical therapy program including radiation levels in unrestricted areas exceeding regulatory limits and the failure of the RSC to perform an annual review of the entire radiation safety program. A root cause of the violations appeared to be the RSO's focus on the diagnostic rather than the therapeutic portions of the licensee's program. As a result, hospital management, the RSC and RSO were not effective in systematically monitoring and evaluating licensed activities, and in particular those activities involving the Radiation Therapy program. A $625 civil penalty was assessed.