



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

OCT 31 1983

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch, NMSS

THRU: William L. Axelson, Chief *WLA*
Materials and Safeguards Branch

FROM: Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

SUBJECT: CRITERIA FOR REVIEWING ADEQUACY OF RADIATION SAFETY OFFICER
FOR LICENSES OF BROAD SCOPE

During recent months, Region III has had numerous applications for amendment to or renewal of licenses of broad scope in which the proposed Radiation Safety Officer (RSO) is an outside consultant or a faculty member with major commitments other than radiation safety. We are concerned, in these cases, with the adequacy of the RSO's authority, duties and responsibilities, support staff, and availability to the institution's radiation safety program. Consequently, we propose that the following list of information be obtained from applicants and used as a basis for the standard review of these types of requests:

1. Authority

The licensee should describe the RSO's authority and position in the organization to ensure that it is sufficient to carry-out his/her duties. The RSO must have authority to immediately terminate any activity that is found to be a threat to health or property.

2. Duties and Responsibilities:

The licensee should describe duties and responsibilities equivalent to those described in Item 8.b. of Regulatory Guide 10.5 and Revision 1 of NUREG 0267 (Appendix B).

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3. Staffing support

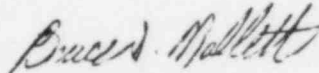
The licensee should submit a description of the resources available to carry-out the RSO's duties and responsibilities. The description should include a commitment from the Radiation Safety Committee to reevaluate these resources during annual review of the program and demonstrate that they are sufficient to carry-out the radiation safety program in a timely and thorough manner. The results of this review should be documented in the committee minutes and made available to NRC inspectors for review.

4. Availability

The licensee should submit a statement of the RSO's availability to the program. The statement should discuss availability in regard to:

- a. response to emergencies (i.e., on-site contact or time to respond)
- b. provisions for alternate, qualified RSO when RSO is unavailable

Please review this proposal and provide us with your comments/approval as soon as possible, since Region III has cases pending your decision.



Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosures: 1. Reg. Guide 10.5
2. Appendix B of NUREG 0267

cc: John E. Glenn, RI
John P. Potter, RII
Robert J. Everett, RIV
Robert D. Thomas, RV

APPENDIX B

RADIATION SAFETY TASKS INVOLVED IN KEEPING OCCUPATIONAL EXPOSURES ALARA

1. Surveys of the following radioactivity areas:
 - a. Nuclear medicine
 - b. Radiation therapy
 - c. Oncology
 - d. Pathology
 - e. Cardiology
 - f. Pediatrics
 - g. Radioactive waste disposal and storage
 - h. Other research and clinical laboratories using radioactive materials
2. Surveys of diagnostic and therapeutic machines and generators, including:
 - a. Teletherapy sources and machines
 - b. Computerized axial tomography scanners
 - c. Interlock and safety checks
 - d. Calibrations
 - e. Fluoroscopes
 - f. Radiographic x-ray
3. Personnel monitoring:
 - a. Review of personnel exposure data and reports
 - b. Preparation of reports required by regulations
 - c. Filing, collecting, and mailing personnel monitoring devices (including late and lost)
 - d. Special investigations of exposure and notifications to regulatory agencies as appropriate
 - e. Calibration of personnel monitoring dosimeters, including commercially supplied film badge service
4. Radiation safety instrument calibration and maintenance:
 - a. Calibration
 - b. Battery replacement and adjustment
 - c. Pocket chamber and IED calibration
 - d. Minor repair (electronic)
 - e. Instrument selection and distribution
 - f. Check-source calibration

5. Decontamination and waste disposal:
 - a. Collection and packaging
 - b. Surveying
 - c. Recording
 - d. Shipping arrangements
 - e. Placarding
 - f. Decontamination of surgical instruments, rooms, and laboratories
6. Leak-testing radioactive sources using the following techniques:
 - a. Wiping
 - b. Counting
 - c. Calculation
 - d. Recording
 - e. Counter calibration
7. Evaluation of internal exposure by means of:
 - a. Collection of samples, including air sampling when applicable
 - b. Radiochemical or scintillation bioassay analysis
 - c. Counter calibration
 - d. In vivo counting
 - e. Computer analysis of results
8. Special surveys of patients and rooms for implant, intracavitary, or unsealed radiopharmaceutical therapy, including:
 - a. Food preparation and protective covering
 - b. Labeling (bed, chart, door)
 - c. Nursing staff and housekeeping staff briefings
 - d. Background surveys
 - e. Source insertion and afterloading surveys
 - f. Surveys of patients in operating room and recovery room
 - g. Placing of lead barriers
 - h. Recovery of sources and wastes
 - i. Survey of room cleanup and decontamination
 - j. Instructions to patient and to family of patient as appropriate
 - k. Measurement of radiation from cadavers and briefings to pathology staff and funeral directors as appropriate
9. Administration and consultation, including:
 - a. Approval of facilities, equipment, and procedures used in areas where radioactive materials are handled
 - b. Preparation of license applications and amendments
 - c. Preparation of hazard evaluation reports for licensing
 - d. Programming of routine required surveys
 - e. Supervision of routine radiation safety operations
 - f. Revisions to radiation safety manual
 - g. Periodic radiation safety instruction for hospital staff and administration

- h. Training of residents and medical staff
- i. Conferences with physicians and other safety staff
- j. Coordination of radiation safety committee meetings and minutes
- k. Inspections and discussions with government regulatory agency representatives
- l. Professional meetings
- m. Selecting and ordering equipment and supplies
- n. Planning and budgeting
- o. Facility and shield design and meetings with architects
- p. Record maintenance and related computer programming
- q. Planning prompt effective response to incidents and emergencies involving radiation
- r. Providing instructional direction for outside persons (for example, firemen) who would respond to an emergency situation involving or potentially involving radiation
- s. Preparation of Radiation Safety Office reports to administration

The RSO should have the final authority in radioisotope matters (e.g., disposal facilities, etc.) and should be responsible for compliance in radiation protection with the NRC staff, etc., and use of the radioactive material to be used under the license. A statement should be included describing the RSO's duties, responsibilities, and authority for carrying out the radiation safety program. Radiation protection should be the primary responsibility of the RSO. The extent of the RSO's responsibility and authority will depend on the scope of the proposed program; however, the following should be considered:

- (1) General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.
- (2) Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the radiation safety committee.
- (3) Monitoring and maintaining absolute and other special filter systems associated with the use, storage, or disposal of radioactive material.
- (4) Providing consulting services on all aspects of radiation protection to personnel at all levels of responsibility.
- (5) Receiving, delivering, and packing all shipments of radioactive material arriving at the institution and receiving, packaging, and shipping all radioactive material leaving the institution.
- (6) Distributing and providing personnel monitoring equipment, determining the need for and evaluation of bioassays, keeping personnel exposure and bioassay records, and notifying individuals and their supervisors of exposures approaching maximum permissible amounts and recommending appropriate remedial action.
- (7) Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- (8) Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records and monitoring effluents.
- (9) Storing all radioactive materials not in current use, including wastes.
- (10) Performing leak tests on all sealed sources.
- (11) Maintaining an inventory of all radioisotopes at the institution and limiting the quantity of radionuclides at the institution to the amounts authorized by the license. The inventory should include the name of the person responsible for each quantity of radioisotopes, where it will be used or stored, and the date the quantity was delivered

to that person. Items are removed from the inventory by showing how and when the radioisotope was disposed of.

(12) The authority to terminate immediately a project that is found to be a threat to health or property.

(13) Maintaining other records not specifically designated above, e.g., receipt, transfer, and survey records as required by §30.51, "Records," of 10 CFR Part 30.

c. Radiation Protection Procedures

A formal set of rules, instructions, and procedures for procurement, disposal, and safe handling of radionuclides within the institution should be established by the radiation safety committee. A copy of these rules and procedures in the form in which they will be given to all personnel under the jurisdiction of the committee should be submitted.⁷ Where instructions are given with respect to an action necessary for compliance with NRC regulations (e.g., waste disposal), such instructions should be specific and not consist of a single reference to the regulations.

The written radiation protection procedures should be clear and concise and should cover the following:

- (1) Process for obtaining permission to use radioactive materials at the institution.
- (2) Care, selection, and use of protective apparel and other equipment and facilities.⁸
- (3) Limitations and conditions (special equipment, facilities, and procedures) relative to handling liquid, gaseous, finely divided, or uncontained radioactive materials⁹ and the equipment to use in working with them. For example, the types of materials and operations that should be conducted in ventilated equipment with filtered exhaust systems (i.e., chemical fume hoods or glove boxes) and the types and details of shielding and remote handling equipment to be used with hard beta- or gamma-emitting materials should be defined.
- (4) Special equipment, procedures, and precautions to be used in working with neutron and alpha-particle emitters and radionuclides that decay by spontaneous fission.

⁷ Although a specific set of rules and procedures is required as a basis for evaluating the license application, the applicant may specify that certain portions of the documents may be revised without prior notification of the NRC staff. For example, the applicant may specify in the application that the institution will make the following changes without notifying the NRC: Changes dictated by NRC rule changes, changes in internal management forms or specific dates, changes in contractors for bioassay or waste disposal services or for servicing and calibrating personnel dosimeters, or references to particular pieces of equipment, etc. By careful use of this technique, the applicant can avoid the necessity for frequent license amendments.

⁸ A complete description of respiratory protection devices and procedures for fitting, sanitizing, and repairing them should be included. Credit for respiratory protection cannot be taken unless a respiratory protection program is established pursuant to §20.103 of 10 CFR Part 20.

⁹ Those applications or operations that present unusual hazards because of the nature of the material, the quantity involved, and the type of operation and that may require specialized facilities should be covered in separate instructions rather than incorporating these instructions in the main body of the radiation protection procedures.