



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

The U.S. Nuclear Regulatory Commission has enclosed two documents describing our current efforts to develop a NUREG on "Management of Radiation Safety Programs at Licensed Medical Facilities," for distribution to medical licensees during calendar year 1994. The documents are:

1. A Status Report of NRC Efforts for Development of the NUREG; and
2. Questions on effective management of radiation safety programs.

NRC is interested in obtaining comments on the questions contained in Enclosure 2 from individuals experienced in management of radiation safety programs at licensed medical use facilities. We appreciate responsible replies and will consider the information received for incorporation into the NUREG, when appropriate. Please submit your response to either individual listed below by mail, facsimile, or telephone by August 30, 1993. NRC staff appreciates your time and effort in responding to these questions.

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NUREG TASK FORCE CHARTER  
MANAGEMENT OF LICENSED PROGRAM AT  
MEDICAL USE FACILITIES

I. BACKGROUND

NRC and Agreement State staff conclude through licensing, inspection and enforcement activities that licensee executive management does not always fulfill its responsibility for oversight of the licensed program. For example, licensee management is not always familiar with the scope of the licensed program, resources necessary to effectively manage the program, role of the RSC and RSO, or necessary qualifications for an effective RSO. Additionally, in some cases, the RSC does not take an active role in providing oversight of the program and feedback to licensee management and the RSO. This can be due in part to a lack of familiarity with the requirements, available time to focus on radiation safety issues, commitment by management, and poor communication with the RSO. Further, some individuals authorized as RSO are unaware of their full responsibilities, unwilling to accept them, unable to secure adequate resources from licensee management to adequately perform their duty, or unable to dedicate the necessary time to successfully perform their duties because of other assigned duties. The principal reason for this deficiency is that there is a broad spectrum of licensed medical use programs and licensees do not always fully understand the respective role of all three key components.

The Office of Nuclear Materials Safety and Safeguards (NMSS) is interested in developing a NUREG on the management of radiation safety programs for licensed medical use facilities. The NUREG will be designed for medical facilities of varying size and scope ranging from the small, limited specific program to the large, broad scope program. Resources will include, but will not be limited to: NMSS; Office of State Programs; Office of Enforcement; NRC regional staff; two representatives from Agreement States; input from professional organizations and the NRC's Advisory Committee on the Medical Uses of Isotopes; and contract support for the conduct of a literature search and technical review of the NUREG in draft.

This Task Force will develop a profile in which the NRC will identify: 1) the spectrum of information to be presented in the NUREG, and its format; 2) the magnitude of responsibilities for RSOs, Radiation Safety Committees (RSC) and licensee management for the administration of medical radiation safety programs; 3) necessary qualifications of the RSO; 4) the type of individuals that best meets these qualifications for each size of program, i.e., authorized physician user, medical physicist, consultant, chief technologist; 5) survey data needed on program size including necessary radiation safety staffing to provide as information to readers; 6) suggested mechanisms to provide reasonable assurance that RSOs are familiar with the contents of the NUREG; 7) the Statement of Work for contract support, if deemed necessary; and 8) a mechanism to obtain information and data from professional organizations, if deemed necessary.

Members of the Task Force will examine current regulations and regulatory guides, standard review plans, the Inspection Manual and procedures, and information collected from resources. The final product of the Task Force efforts will be a NUREG which addresses the management of radiation safety programs for medical facilities by clearly defining the duties, functions, and responsibilities of the RSO, RSC, and licensee management. The Task Force also will evaluate the need to revise current NRC regulations to address this issue.

## II. LICENSEES

A survey of exemplary licensees of varying sizes and materials uses may be necessary to gain insight into sufficient resources needed to conduct an adequate radiation safety program. Clearly, broad-scope programs with an active Radiation Safety Committee (RSC) will provide one end of the spectrum. In contrast, private practice physicians with a single authorized user and few employees will provide the other end of the spectrum. Types of licensees to be considered may include medical use licensees with authorization for diagnostic and therapeutic use of radiopharmaceuticals; brachytherapy including remote afterloader procedures, when possible; teletherapy; and licensees with small and large human research facilities.

The Task Force must determine which licensees should be considered within the scope of this review, and what mechanisms should be used for evaluation. The review will include an analysis of program size, staffing levels, etc. In addition, licensing and compliance information for licensees with inspection histories ranging from good to poor will be reviewed on a case-by-case basis to more clearly identify institutional radiation safety management and the role of the RSO and RSC.

### III. TASK FORCE MAKEUP

The Task Force is chaired by Larry W. Camper, Section Leader, Medical and Academic Section, Office of Nuclear Materials Safety and Safeguards. The Project Manager for the development of this NUREG is Janet Schlueter, Medical and Academic Section. The Task Force members include: representatives from NRC Headquarters' and the five Regional offices, having experience in licensing and inspection of medical, academic, and research programs; and two representatives from Agreement States Program. These task force members are expected to communicate with other NRC and Agreement State staff for their views on subjects such as: current qualifications for RSOs; management of the radiation safety program to include supervision by licensee management, RSC, RSO and authorized users; additional skills necessary to effectively function as RSO; the content of radiation safety program audits that are required to be performed by the Radiation Safety Committee, with the assistance of the RSO; and inspection findings where violations related to failure of the RSO to adequately perform their responsibilities have been cited.

### IV. TASK FORCE SCHEDULE

The Task Force began its activities during the month of April 1993 and has scheduled three, two-day meetings, approximately once each quarter, for the remainder of this calendar year. Meeting dates for 1994 are to be determined. It is also expected that the activities of the Task Force and contractor, if applicable, will conclude during mid calendar year 1994.

### V. EXPECTED PRODUCT

By the conclusion of its efforts, the Task Force will produce a NUREG that contains sections encompassing:

1. major components associated with radiation safety program management at a licensed medical use facility, and their relationship and interaction with RSC and the RSO;
2. the role of licensee management and RSC in facilitating the responsibilities of the RSO;
3. a description of the necessary duties, functions and responsibilities of the RSO;
4. the required training and experience criteria for RSOs;
5. additional factors for consideration by licensees in selecting an individual as RSO, i.e., necessary managerial skills, attention to detail; what category of professional might best fill this role, i.e., authorized physician user, medical physicist, consultant, chief technologist;
6. use of consultants, those which are identified and function as RSO and those which augment the RSO;
7. sample data on radiation safety staff levels for a variety of sizes of licensed programs;
8. how to perform and contents of required audits, such as ALARA, quality management program, annual audit of radiation safety program;
9. suggested mechanisms to provide reasonable assurance that RSOs have read and are familiar with the contents of the NUREG and license commitments; and
10. observations of typical problems encountered in management of radiation safety programs.



STATUS REPORT OF NRC EFFORTS TO DEVELOP NUREG ON  
MANAGEMENT OF RADIATION SAFETY PROGRAMS AT  
LICENSED MEDICAL FACILITIES

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NRC and Agreement State staff conclude through licensing, inspection and enforcement activities that licensee management does not always fulfill its responsibility for oversight of the licensed program at medical use facilities. The principal reason for this deficiency is that there is a broad spectrum of licensed medical use programs and as a result, licensee management, members of the radiation safety committee (RSC) and the radiation safety officer (RSO) do not always fully understand their respective roles. Specifically, licensee management may not be familiar with the scope of the licensed program, resources necessary to effectively manage the program, role of the RSC and RSO, or necessary qualifications for an effective RSO. Additionally, in some cases, the RSC does not take an active role in providing oversight of the program and feedback to licensee management and the RSO. This can be due in part to a lack of familiarity with the requirements, available time to focus on radiation safety issues, commitment by management, or poor communication with responsible parties. Further, some individuals authorized as RSO are unaware of their full responsibilities, unwilling to accept them, unable to secure adequate resources from licensee management to adequately perform their duty, or unable to dedicate the necessary time to successfully perform their duties because of other assigned duties.

The U.S. Nuclear Regulatory Commission's Office of Nuclear Materials Safety and Safeguards has established a task force for the development of a NUREG, entitled, "Management of Radiation Safety Programs at Licensed Medical Facilities." This document will be made available to medical use licensees upon completion in mid calendar 1994. The NUREG will clarify the role of licensee management, the RSC and RSO to effectively manage the radiation safety program at medical facilities with licensed programs of various size and scope. Each responsible party is a key component for effective management of the licensed medical use program. Personnel resources for development of the NUREG include two representatives from the Medical and Academic Section at NRC Headquarters', one representative from each of the five NRC Regional Offices, and two representatives from Agreement States. Additionally, the staff is seeking input from professional organizations through meetings, the NRC's Advisory Committee on Medical Uses of Isotopes, and contract support for the conduct of a literature search and technical review of the NUREG while in draft. The task force held initial meetings during April and May 1993, and is in the early stages of developing the format and drafting the NUREG and securing contract support.