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5 ROLE OF PHYSICIAN AUTHORIZED USERS AND SUPERVISED INDIVIDUALS

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5.1 Introduction

In addition to the RSO, other workers assume responsibility for the safe use of licensed material in daily operations by adhering to the policies and procedures established as part of the radiation safety program. Among these individuals are physicians authorized to use licensed material (physician authorized users), physicians (such as residents) working under the supervision of an authorized user, nuclear medicine and radiation oncology technologists, dosimetrists, pharmacists, health and medical physicists, radiation safety technical staff, and nurses and other trained individuals responsible for the care of patients undergoing therapeutic procedures. Also included in the category of supervised individual is anyone who, as part of his/her assigned duties, is responsible for handling licensed radioactive material and patients who have been administered licensed material. Each category of individual will be discussed in terms of the role played in the day-to-day operations of the radiation safety program. This chapter does not address researchers (authorized users who are not physicians) who are employed in most broad scope programs.

5.2 Physician Authorized Users

The discussion herein applies to physicians who are authorized to use licensed materials and any other physicians working under the supervision of a physician authorized user, such as residents, who are responsible for administering licensed material to patients. Licensee management should ensure that authorized users possess the necessary training and experience to handle licensed material safely and to effectively oversee individuals working under their supervision. For example, authorized users will need training with respect to policies and procedures specific to the licensed program, will need to instruct individuals who are responsible for performing certain tasks related to radiation safety under their supervision, and will need to periodically review the supervised individual's work. The goal is to have an adequate system of instruction and supervision in place, including a feedback mechanism, to ensure that the supervised staff knows the proper procedures to follow in the absence of the authorized user, and how and when to contact the authorized user or RSO. Additionally, it is in the best interest of the authorized user to monitor implementation of these procedures. The complexity and formality of this monitoring system differ from facility to facility, depending on a facility's size and the scope of its

program, and the responsibility for implementing this system lies with the authorized user. Additionally, although the authorized user may delegate specific tasks associated with the medical use of radioactive material to supervised individuals, the responsibility for its safe use cannot be delegated. Therefore, if a supervised individual, through misunderstanding, negligence, or omission, acts contrary to the requirements of the license or regulations, the licensee remains responsible.

Generally, authorized users have two major areas of responsibility for the safe use of licensed material. First, they are responsible for the safe use of licensed material in humans by prescribing a radiation dose or dosage to be administered to the patient for diagnosis or treatment. More generally, authorized users are responsible for ensuring the safe use of licensed material throughout a department, such as nuclear medicine or radiation therapy, and perhaps throughout a facility, if the physician who is the authorized user is also a member of the RSC or is designated as RSO.

With respect to the safe use of licensed material in medicine, the direct involvement of the authorized user with the procedure may be dependent upon the complexity of, or safety risk associated with, the patient study or medical treatment. For example, when conducting diagnostic procedures, technologists under the supervision of an authorized user typically perform the patient study, with minimal direct involvement by the authorized user. Patient procedures are successfully performed because the authorized user has established policies and procedures for the safe diagnostic use of the licensed material and has instructed the technologists in these procedures, and because the supervised individuals adhere to the procedures. Typically, the authorized user defines acceptable ranges for patient dosages for specific studies in a diagnostic clinical procedures manual to which technologists refer when conducting diagnostic studies. Authorized users should ensure that technologists know and understand the information contained in the manual and know when to contact the authorized user or RSO if a discrepancy exists between what is indicated by the patient or referring physician and what has been prescribed or administered. NRC does not typically review the appropriateness of the prescribed radiation dose; rather, NRC relies on the self-policing of physician authorized users to ensure that the prescribed dose is appropriate for a specific patient. It is also important to recognize that when new radiopharmaceuticals or procedures are employed, supervised

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Enforcement conferences are held for violations assessed at Severity Levels I, II, or III, and may be held for violations assessed at Severity Level IV if increased management attention is warranted (e.g., for repetitive or numerous violations). An enforcement conference is a meeting between the NRC and the licensee to (1) discuss the apparent violations, their significance, the reason for their occurrence, including the apparent root causes, and the licensee's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information that will help the NRC determine the appropriate enforcement action. The decision to hold an enforcement conference does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. In accordance with the enforcement policy, enforcement conferences are normally closed to the public. On July 10, 1992, the Commission implemented a two-year trial program to allow certain enforcement conferences to be open to public observation.

Following the enforcement conference, the regional office prepares the proposed enforcement action. All Severity Level I and II cases and some Severity Level III cases are sent to NRC headquarters for processing and approval. Routine Severity Level III materials cases and Severity Level IV and V matters are issued directly from the regional office.

In the absence of mitigating circumstances, civil penalties are normally issued for Severity Level III or higher violations and may be issued for violations at Severity Level IV if the violations are repetitive or similar to previous Severity Level IV violations. In addition, a civil penalty may be issued for any willful violation.

If a civil penalty is to be proposed, the base value of the penalty should first be determined. The base value is derived from the type of licensed activity, the type of licensee, and the severity level of the violation. Once the base value is determined, a number of factors are considered that may either escalate or mitigate the amount of the civil penalty, depending on the unique circumstances of the case. These factors are: (1) whether NRC or the licensee identified the violation, (2) whether the corrective action was prompt and extensive or untimely and only marginally acceptable, (3) the past performance of the licensee, (4) whether the licensee had prior notice of similar events or other indications that should have alerted management, (5) whether there were multiple examples of the violation, and (6) whether the violation existed over a long duration.

If a civil penalty is to be proposed, a written "Notice of Violation and Proposed Imposition of Civil Penalty" is issued and the licensee has 30 days to respond in writing, by either paying the penalty or contesting it. The NRC considers the response, and if the penalty is contested, may either mitigate the penalty or impose it by an order.

If the civil penalty is to be imposed by order, the order is published in the *Federal Register*. Thereafter, the licensee may pay the civil penalty or request a hearing.

Orders may be used to modify, suspend, or revoke licenses. Orders that modify a license may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. The NRC issues a press release with a proposed civil penalty or an order.

Deliberate Misconduct Rule

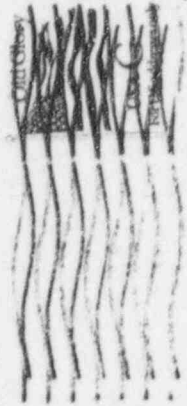
On September 16, 1991, the Commission implemented a new rule concerning orders issued to unlicensed individuals. This new rule called the "Deliberate Misconduct Rule" applies to an employee of a licensee, a contractor, or subcontractor, who knowingly provides components or any other goods or services that relate to licensed activities. This rule prohibits (1) engaging in deliberate misconduct that causes, or but for detection would have caused, a licensee to be in violation of any NRC requirement, or (2) deliberately submitting to NRC, a licensee or contractor, or subcontractor, information known to be incomplete or inaccurate in some respect material to the NRC. Deliberate misconduct means an intentional act or omission that the person knows would cause a violation or is a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee or contractor, whether or not the person knew a resulting violation of NRC requirements would occur.

An order issued under the deliberate misconduct rule might order the wrongdoer to remain out of licensed activities for a specified period, to notify the NRC before resuming involvement in licensed activities, or to inform any prospective employer of the issuance of the order. The order might require the employer to remove or confirm the removal of an employee from licensed activities, require the employer to advise prospective employers of the existence of the order when they call for reference checks, or require notice to the NRC if a licensee employs or desires to reemploy a wrongdoer in licensed activities.

you should also mention your unaltered policy of announcing NUV to the local popular press even before the true state of affairs is determined

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