The NRC and the ADR Process

Learning Experiences

By Juan Pérez Monté, MD

INTRODUCTION

Nuclear Medicine is a highly advanced and complex medical specialty that uses very sophisticated medical equipment such as the gamma camera and PET-CT scan imaging equipment. Also requires a trained nuclear medicine technologist (CNMT) and a specialized Nuclear Medicine Physician to perform and interpret the different diagnostic studies as well as therapeutic studies with I-131 Sodium Iodide for patients with hyperthyroidism and thyroid cancer. Radiopharmaceuticals are administered to the patient to help referring physicians make a diagnosis in the different medical fields such as the cardiovascular system, endocrine, musculoskeletal, genitourinary, gastrointestinal, thoracic, etc.; as well as for therapeutic uses. These radiopharmaceuticals are mostly composed of radioactive isotopes, thus containing small doses of radiation for diagnostic studies, as well as, higher doses of radiation for the therapeutic doses. Therefore, these radiopharmaceuticals are highly regulated by several agencies including the U.S. Nuclear Regulatory Commission (NRC). Thus, this specialty in addition of being regulated by general laws and regulations that apply to the practice of medicine is also regulated by the NRC.

In this article we will discuss the regulations and requirements of the NRC in the practice of Nuclear Medicine. Among the regulations and requirements we will discuss the record keeping requirements and the information to be provided to the NRC regularly and during inspections. Also we will examine the tools and methods that the NRC has to its disposal to remedy any discrepancies with licensees and finally the alternate methods that the NRC provides to solve any dispute between it and licensees.

HISTORY OF THE NRC

The U.S. Nuclear Regulatory Commission's is a federal regulatory agency that oversees the civilian use of nuclear energy. The NRC's primary mission is to help ensure that public health and safety are protected in the many different peaceful uses of nuclear energy. Established in 1974 to

replace the Atomic Energy Commission (AEC), the NRC was given a mandate to take over from the AEC the responsibility for regulating various commercial, industrial, academic, and medical uses of nuclear energy.

The NRC licenses the construction and operation of nuclear reactors and other facilities and the ownership and use of nuclear materials. It issues standards, rules, and regulations for the maintenance of licenses, and it regularly inspects nuclear facilities such as a nuclear medicine laboratory, to ensure compliance with public health and safety, environmental quality and national security.

SOURCES OF NRC'S AUTHORITY

The main sources of the NRC's authority are the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974. The Atomic Energy Act of 1954 was created by the United States Congress to promote and regulate the use of nuclear energy. On this act Congress declared its nuclear energy policy as follows: "the development, use, and control of atomic energy shall be directed so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise." This law requires that private uses of nuclear energy and materials to be licensed, gives authority to the NRC to regulate and enforce its provisions in order to protect health, safety and minimize the danger to life and property. This act provides due process safeguards as opportunity for a hearing and judicial review in federal court.

As stated above, The Energy Reorganization Act of 1974 created the NRC and gave it the authority to regulate civilian use of atomic energy and materials.

Using the authority given to the NRC by the above mentioned statutes, this agency has enacted various regulations regarding the production, handling and use of nuclear energy and materials. These regulations are contained on Title 10 of the Code of Federal Regulations (CFR).

NRC'S REGULATION PERTAINING NUCLEAR MEDICINE

The practice of nuclear medicine is mostly regulated by the NRC in 10 CFR Parts 20 and 35. Part 20 pertains to standards for protection against radiation. Part 35 pertains with the medical use of radioactive materials.

RULES AND REGULATIONS

Now let's discuss the most salient provisions of 10 CFR. Reflected in the regulations are four strategies to minimize radiation exposure: radiation controls, licensing, recordkeeping and enforcement. The aim of the NRC's radiation controls regulations is safety through the minimization of radiation exposure. To do that, the regulations related to radiation controls first define radiation dose units and then they create the concept of total effective dose equivalent (TEDE) as the sum of the deep dose equivalent for external exposures, and the committed effective dose equivalent for internal exposures[1]. They establish the dose limits for employees and the general public. In order to monitor the dose limits for employees the use of dosimeters is required to determine their total radiation exposure. Also, personal monitoring is required for people who are likely to receive doses in excess of 10 percent of an applicable annual limit. To limit the radiation exposure to the general public the use of lead shielding of walls might be necessary. To protect work areas the use of equipments to detect radioactive spills, such as Geiger Müller counter are required to perform periodic surveys of those areas. To protect patients and employees a nuclear medicine clinic has to designate restricted areas, such as the commonly known as "hot lab". A hot lab is the designated place to keep radioactive materials such as unused radiopharmaceuticals, radiation sources and radioactive wastes that are put to decay. This place requires lead shielding for radiation protection and is strictly restricted to limit the access to radioactive materials to authorized personnel.

As part of the licensing tier the NRC first requires nuclear medicine clinics to obtain an *operating* license. Licensees are required to include in their

[1] 10 CFR part 20 Subpart A

license the names of the professionals to be included as Radiation Safety Officer "RSO" and authorized users "AU".

Among the responsibilities of the RSO are to establish together with management and administer the clinic's comprehensive radiation safety program. Also, along with management, the RSO will be responsible for the clinic's compliance with the NRC's regulations through supervision, monitoring and audits. The RSO serves as well as the clinic's liaison with the NRC.

As part of the aforementioned radiation safety program, the nuclear medicine clinic must provide adequate financing and other material resources (including space, equipment, personnel, time, and, if needed, contractors) to the Radiation Protection Program to ensure that patients, the public, and workers are protected from radiation hazards. The clinic must establish emergency procedures; procedures for the posting and labeling of radioactive materials areas; establish protocols for receiving and opening packages containing radioactive materials and for disposing of contaminated waste. All of these, under the supervision of the RSO.

Authorized Users "AU" are usually Nuclear Medicine professionals whose name are included in the clinic's NRC license and are the persons authorized to handle and use the radioactive material. The responsibilities of the AUs involve the following: administration of a radiation dose or dosage and how it is prescribed; direction of individuals under the AU's supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material and preparation of written directives.

The third tier of the NRC's safety strategy is record keeping and filing. Then as part of the record keeping requirements, a nuclear medicine clinic must keep records of radiation and contamination surveys, individual monitoring, and planned special exposures, doses to members of the public and waste disposal. As part of the report filing component the regulation requires nuclear medicine clinics to file reports to the NRC by for a variety of events, including: the theft or loss of licensed material, decommissioning of radioactive materials, incidents in which specified dose

limits may be exceeded, actual exposures or concentrations in excess of the limits, and planned special exposures, and annual reports on individual occupational doses to workers in nuclear medicine facilities. The records will, in part, identify all areas where licensed materials are (or were) used, stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread), and leakage of sealed sources, if any.

Two of the record keeping requirements intimately associated with nuclear medicine clinics are **Written Directives(WD)** and the reporting of **Medical Events.**

Written Directives are documents required by 10 CFR 35.40 prior to the administration of I-131 sodium iodide greater than 1.11 MBq (30 µCi) or regardless of whether it is for diagnostic or therapeutic purposes, any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. A written directive must be dated and signed by an Authorized User prior to the administration and among other things, must contain the name of the patient, the dosage of the byproduct material to be administered, route of administration and signature of the AU. After administering the byproduct a copy of the written directive must be retained in the clinic's records[2]. As part of the written directive procedure the Authorized User must positively verify the identity of the patient prior to the administration[3], and then the activity of the radiopharmaceutical dosage or radiation dose must be recorded before the administration. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator.

---

[2] 10 CFR 35.2040

[3] Examples of positive patient identity verification include at least 2 independent means such as examining the patient's driver's license, and/or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.

According to 10 CFR 35.3045 instances of a medical events occur when the wrong byproduct, dosage[4], route or treatment is administered to a patient or when the byproduct is administered to the wrong patient or when a sealed source is leaking when implanted into a patient. In case of such an event, the clinic must notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event and submit a written report to the appropriate NRC Regional Office.

TYPES OF VIOLATIONS AND PENALTIES

The fourth tier of the NRC strategy is enforcement. For this the NRC has various enforcement tools at its disposal. First, any violation of the above mentioned requirements may entail an enforcement action on the part of the NRC. Among the enforcement tools that the NRC has at its disposal are the ability to obtain injunctions to prevent violations, the authority to impose civil penalties for violations, or revoke a license for a violation. Any willful violation or conspiracy to violate the NRC regulation might be pursued through criminal penalties. The NRC's policy goals for enforcement are to use it as a deterrent in order to emphasize the importance of compliance with regulatory requirements, and to encourage prompt identification and timely, comprehensive correction of violations. To identify violations to its regulations, the NRC uses inspections and investigations.

Administratively, the NRC has three types of enforcement tools available: Notices of Violation (NOV), Civil Penalties, and Enforcement Orders. A Notice of Violation identifies a requirement and how it was violated, requires corrective action and often a written response. A Civil Penalty is a monetary fine.

Finally, Orders can require specific actions by licensees. An order might also modify, suspend, or revoke licenses[5].

---

[4] When the difference is above a determined threshold.

[5] Orders may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. Persons who are adversely affected by Orders that modify, suspend, or revoke a license, or that take other action, may request a hearing.

The NRC assigns a gradation of severity to each violation. The severity of level can range from IV to level I. Severity Level IV is for low safety significance violations through Severity Level I for the most significant violations. To assess the significance of a violation the NRC considers these criteria: (1) actual safety consequences; (2) potential safety consequences; and (3) potential for affecting the NRC's ability to perform its regulatory function; and (4) any willful aspects of the violation.

ENFORCEMENT PROCEDURE

The enforcement process starts when the NRC issues a written Notice of Violation and Proposed Imposition of Civil Penalty. Then the licensee has 30 days to respond in writing, by either paying the penalty or contesting it. If the penalty is contested, the licensee can request a hearing.

The NRC issues a press release with a proposed Civil Penalty or Order. All Orders are published in the Federal Register.

THE ADR PROCESS

One of the alternatives that the NRC provides to expedite the resolution of the enforcement procedure is the Alternate Dispute Resolution[6] process. The policy goals of the ADR process stated by the NRC are to improve the effectiveness of the enforcement program, to promote efficient and amicable resolution of investigation findings.

The ADR process is completely voluntary any party may withdraw from the negotiation at any time. The parties remain all through the ADR process in control of the decision on whether to participate and whether to agree to any resolution.

The ADR may be used by the parties at three distinct points: 1. Prior to the decisional enforcement conference. 2. After the initial enforcement action is taken. 3. After imposition of a civil penalty and prior to a hearing request.

The ADR process usually involves the use of mediation. The mediation is an informal process in which a professional neutral mediator works with the

[6] ADR

parties to help them reach a resolution. The terms of the ADR settlement agreement will be confirmed by order.

We were personally involved in the ADR process after the NRC alerted us of some recordkeeping inaccuracies involving written directives. After an NRC inspection.

We were alerted that written directives for diagnostic uses of I-131 Sodium Iodide in excess of 30 uCi, were unaccounted for. After the notice of violation we provided inaccurate information to the NRC claiming that missing labels found were the written directives. Even though these labels contained the information regarding the patient name, dosage, and the administration date these labels did not constitute written directives since these were not signed and dated by the authorized user prior to administration. This prompted an NRC investigation process. After the investigation we learned that a document to be a written directive has to be signed and dated by the authorized user before the administration of the dosage. Thus, when we provided the missing labels containing correct information regarding the patient name, dosage, and the administration date we provided inaccurate information to the NRC because the label weren't signed and dated by the Authorized User before the dosage administration. As a matter of fact, the signature and dating by the authorized user was placed when the labels where found after the notice of violation. As part of the Alternate Dispute Resolution (ADR) process we clarified to the NRC that the signature and date on the labels was incorporated after the NOV. After that admission we settled the administrative process initiated with the investigation. The NRC allowed me to remain as an authorized user, but I agreed to remove myself of any RSO duty for two years and to disseminate our experience to my peers and colleagues regarding the ADR process and the need to provide and maintain required accurate information and recordkeeping to the NRC. This is one of our reasons for writing this article.

LEARNING POINTS OF THE NRC ADR PROCESS:

1. It was a process that provided an effective, efficient and timely resolution in a confidential proceeding.
2. It avoided a lengthy and expensive process, with reduction in levels of antagonism between the parties to a dispute by using a mediator.
3. It provided more control by the parties over the outcome of their dispute than in a formal adjudication.
4. Through the ADR process there was significant reduction of Civil Penalty to the Company.
5. Always provide accurate information to the NRC.
6. One of the forms that the NRC has to maintain security in its administrative process, is that the licensees provide accurate information at all times; and the only way to achieve this is developing trust between the NRC and the licensees. If trust is lost between the NRC and the community that is regulated it becomes impossible to achieve its standards and goals and comply with their regulations.
   I have learned how important and fundamental is to provide accurate information to the NRC. If this is not done all the Nuclear Medicine industry is in jeopardy; as well as all the benefits that it provides to its patients and the general public.
   My best advice to all authorized users and RSO's is to be meticulous and consistent to comply with all the NRC regulations and if in doubt not to be afraid to consult with the agency and to always tell the truth.

REFERENCES:

1. ATOMIC ENERGY ACT

2. ENERGY REORGANIZATION ACT

3. 10 CFR PART 20

4. 10 CFR PART 35

5. NRC ENFORCEMENT POLICY

6. THE NUCLEAR REGULATORY COMMISSIONS POST-INVVESTIGATORY ADR PROGRAM NUREG/BR-0317 JANUARY 2005

7. WINSTON & SHAW LLP, NUCLEAR REGULATORY FUNDAMENTALS