# The NRC and the ADR Process

Learning Experiences

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# 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 or the applicable agreement state.

# SCOPE

- In this presentation we will explore 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 maintained or 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 the licensee.

# 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 be licensed, and 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 such as opportunity for a hearing and judicial review in federal court.

# ORIGIN OF THE NRC AS WE KNOW IT TODAY

- 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 Regulation.

# NRC'S REGULATION PERTAINING NUCLEAR MEDICINE

- The practice of nuclear medicine is mostly regulated by the NRC in 10 CFR Parts 20 and 35.

# 10 CFR Part 20

- Part 20 pertains to standards for protection against radiation.

# 10 CFR Part 35

- Part 35 pertains with the medical use of radioactive materials.

# 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.

# RADIATION CONTROLS REQUIREMENT FOR NUCLEAR MEDICINE CLINICS

- The aim of the NRC's radiation controls regulations is safety through the minimization of radiation exposure.

# TEDE

- The NRC defines radiation dose units and then it creates 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.

# USE OF DOSIMETERS

- The regulations 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.

# HOT LABS AND OTHER SAFETY PROCEDURES

- 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 the Geiger Müller Counters 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.

# LICENSING OF NUCLEAR MEDICINE CLINICS BY THE NRC

- As part of the licensing tier the NRC first requires nuclear medicine clinic to obtain an *operating license.*

# RSO

- *Licensees are required to include in their 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.

# RADIATION SAFETY PROGRAM

- As part of the aforementioned radiation safety program, the nuclear medicine clinic must provide adequate financing and other 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.

# EMERGENCY PROCEDURES

- The clinic must establish emergency procedures; procedures for the posting and labeling of radioactive 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 USER

- 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

- 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;
- preparation of written directives.

# RECORDKEEPING AND FILING

- The third tier of the NRC's safety strategy is record keeping and filing.

# 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.

# ALSO TO KEEP RECORDS OF

- 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.

# REPORTS TO BE FILED TO THE NRC

- The NRC requires nuclear medicine clinic to file reports 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.

# WRITTEN DIRECTIVES

- 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*) regardless of whether is for diagnostic or therapeutic purposes, or any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material.

# REQUIREMENTS OF A WRITTEN DIRECTIVE

- 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 Authorized User (AU).

# WRITTEN DIRECTIVE PROCEDURE

- The Authorized User must positively verify the identity of the patient prior to the administration, 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.
- After administering the byproduct a copy of the written directive must be retained in the clinic's records.

# MEDICAL EVENTS

- According to 10 CFR 35.3045 instances of a medical event occur when:
  - the wrong byproduct,
  - dosage,
  - route or
  - treatment
- is administered to a patient or
- when the byproduct is administered to the wrong patient or
- when a sealed source implanted into a patient is leaking.
- When the difference between the prescribed and administered dose is above a determined threshold

# WHAT TO DO IN CASE OF A MEDICAL EVENT

- 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.

# ENFORCEMENT BY THE NRC OF ITS LAWS AND REGULATIONS

- Any violation of NRC's laws and regulations may entail an enforcement action on the part of the NRC.

# NRC'S ENFORCEMENT TOOLS

- 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.

# CRIMINAL PENALTIES

- Any willful violation or conspiracy to violate an NRC regulation might be pursued through criminal penalties.

# NRC'S ENFORCEMENT POLICY GOALS

- 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.

# MEANS TO IDENTIFY VIOLATIONS

- To identify violations to its regulations, the NRC uses inspections, investigations and licensee's self- identification.

# ENFORCEMENT TOOLS AVAILABLE TO THE NRC

- Administratively, the NRC has three types of enforcement tools available:
  - Notices of Violation,
  - Civil Penalties, and
  - Enforcement Orders.

# NOTICE OF VIOLATION

- 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.

# ADMINISTRATIVE ORDERS BY THE NRC

- Administrative Orders can require specific actions by licensees.
- An order might also modify, suspend, or revoke licenses.
- Orders may require additional corrective actions, such as:
  - removing specified individuals from licensed activities or
  - requiring additional controls or outside audits.

# RIGHT TO BE HEARD ON A HEARING

- Persons who are adversely affected by Orders that modify, suspend, or revoke a license, or that take other action, may request a hearing.

# SEVERITY OF VIOLATION

- The NRC assigns a gradation of severity to each violation.
- The severity level can range from IV to level I.
  - Severity Level IV is for violations of low safety significance through Severity Level I for the most significant violations.

## TO ASSESS THE SIGNIFICANCE OF A VIOLATION NRC CONSIDERS THESE CRITERIA:

- (1) actual safety consequences;
- (2) potential safety consequences;
- (3) potential for affecting the NRC's ability to perform its regulatory function; and
- (4) any willful aspects of the violation

# ESCALATED ENFORCEMENT PROCEDURE

- The escalated enforcement process starts when violations are identified through inspections or investigations.
- If a notice of violation and proposed imposition of civil penalty are issued 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 process use in cases of wrongdoing.

# THE POLICY GOALS OF THE ADR PROCESS

- To improve the effectiveness of the enforcement program,
- to promote efficient and amicable resolution of investigation findings.

# ADR IS VOLUNTARY

- 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.

# WHEN TO USE ADR

- 1. Prior to the pre-decisional enforcement conference.
- 2. After the initial enforcement action is taken.
- 3. After imposition of a civil penalty and prior to a hearing request.

# USE OF MEDIATION OF ADR PROCESS

- The ADR process involves the use of mediation.
- The mediation is an informal process in which a professional neutral mediator works with the parties to help them reach a resolution.

# FINALIZATION OF ADR PROCESS

- The terms of the ADR settlement agreement will be confirmed by order.

# PERSONAL LEARNING EXPERIENCE

- 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 innacurate 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.

# PERSONAL LEARNING EXPERIENCE

- 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 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 prior to 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 making this presentation.

# LEARNING POINTS OF THE NRC ADR PROCESS:

- It was a process that provided an effective, efficient and timely resolution in a confidential proceeding.
- It avoided a lengthy and expensive process, with reduction in levels of antagonism between the parties to a dispute by using a mediator.
- It provided more control by the parties over the outcome of their dispute than in a formal adjudication.
- Through the ADR process there was significant reduction of Civil Penalty to the Company.

# ALWAYS MAINTAIN &PROVIDE ACCURATE INFORMATION REQUIRED BY THE NRC.

- One of the forms that the NRC has to maintain security in its administrative process is that the licensees maintain and 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 maintain and 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.