Pre-decisional Enforcement Conference - January 18, 2024

COMMUNITY HEALTH NETWORK

NRC LICENSE NUMBER 13-06009-01

Introduction

Radiation Safety Officer- Erin Bell, MHP, DABSNM

- 2014 to present

Bachelor's degree in Environmental Health/Health Physics- Purdue University

Master's degree in Radiological Health Physics- Oregon State University

Board Certification in Nuclear Medicine Physics and Instrumentation- American Board of Science in Nuclear Medicine

Routine Inspection- December 2022

Three “apparent violations” are being considered for escalated enforcement, in part due to the previous violation from 2021 as detailed below:

Previous Violation- Severity Level III violation from Y-90 incident in November 2021

- Notice of Violation issued April 3, 2023
- Unannounced follow-up inspection Debora Piskura, November 13, 2023
- Inspection report received and dated December 1, 2023
  - No violations were identified
  - Previous violations closed

Apparent violations- decision letter received November 9, 2023

Three apparent violations being considered for escalated enforcement:

1) Licensee failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and did not require the use of individual monitoring devices by adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in 10 CFR 20.1201(a)(2)(ii.)

2) Licensee's failure to prepare written directives that were dated and signed by an authorized user before administration of iodine-131 sodium iodide greater than 1.11 MBq (30 uCi) as required by 10CFR35.40(a)

3) Security-related violation

Recommendations to be discussed:

Dosimetry apparent violation:

- Recommend no violation, calculation determined that this physician does not meet the 10% rule requiring dosimetry

Written Directive apparent violation:

- Recommend Severity Level IV violation

Apparent Violation #1- extremity dose monitoring

Inspector observed inconsistent extremity dose records on a Y-90 authorized user and asked the RSO to do a dose estimate.

Mirion supply chain issues, so badges from 11/20/2021 wore longer than normal one month wear period.

Two sets of badges were used to do an extremity dose estimate:

- One extremity badge worn 7/20/2021-8/19/2021- only worn during Y-90 procedures
- One extremity badge worn 11/10/2021-1/20/2022- worn during both Y-90 and interventional radiology procedures

Badges used for dose estimate

Wear period	#Y90 cases	mrem	Mrem/case	notes
7/20/2021-8/19/2021	2	35	17.5	Badge only worn during Y-90 procedures
11/10/2021-1/20/2022	9	889	98.78- *not accurate for Y-90, includes interventional cases*	Badge worn during both Y-90 and fluoro cases after discussion with MD

Because patient doses and length of procedures vary, it is expected to have some variability in exposure readings. When reviewing Sirtex package insert, it estimates 32 mrem per patient to the hands of the physician. For the purposes of our dose estimate, we will conservatively estimate 40 mrem per patient to the hands.

Estimate using 40 mrem/Y90 procedure

Wear period	# y-90 cases	Mrem y90	Mrem fluoro	Total mrem
11/10/2021-1/20/2022	9	360	529	889
2021	43	1720 (43 * 40)	3174 (529*6)	4894
2022	37	1480	3174	4654

Both years are less than the 10% rule of 5000 mrem to the extremities requiring dosimetry. Along those lines, however, all physicians are very compliant with their whole-body dosimetry and wear lead glasses to protect the lens of the eyes.

10CFR20.1201- Occupational dose limits for adults

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under 20.1206, to the following dose limits.

- 1) An annual limit, which is the more limiting of–
  - i) The total effective dose equivalent being equal to 5 rems; or
  - Ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv.)
- 2) The annual limits to the lens of the eye, the skin of the whole body and the skin of the extremities, which are:
  - i) A lens dose of 15 rems, and
  - Ii) a shallow-dose equivalent of 50 rem to the skin of the whole body or the skin of any extremity.

…

(c) … The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent and shallow-dose equivalent may by assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of the individual monitoring are unavailable

Compliance

The physician in question and all our interventional radiologists are very compliant with wearing their whole-body dosimeters. The dosimeters used during the period in question were Mirion dosimeters, which report out whole body, lens dose, and shallow dose, all the required areas in 10CFR20.1201. Looking at the volume of exams and the doses measured, the numbers align and show the physician is compliant with wearing their whole-body dosimeter.

Due to the complexity and wide variety of cases performed by these physicians, I would argue that the shallow dose calculated by Mirion off the collar badge worn outside the apron, is a good average representation of the dose received by various parts of the extremities.

	# exams	Deep dose equivalent	EDE webster single	Lens dose equivalent	Shallow dose equivalent
2021	1140	3926	1186	4022	4639
2022	1364	6219	1873	6403	6488
2023 (through 9/19/23)	974	3152	953	3112	3375

Discussion

Because of the nature of interventional radiology and the way that the c-arm fluoroscopy unit works, the head of the fluoro tube moves in a 360 degree fashion. The machine is not stationary and the equipment that our interventional radiologists use also performs cone beam CT, in which the tube completes a full 360-degree rotation around the patient.

With the movement of this equipment, and the fact that the vast majority of cases these physicians perform do not involve radioactive material, but mainly the use of the c-arm, the area receiving the highest exposure is incredibly difficult to determine. For this reason, I believe that the shallow dose estimate provided by the external reading on the radiation badge is a good, reproducible estimate of the shallow dose to these physicians.

Recommendation for consideration

I would argue that this is not a violation, the shallow dose equivalent was being monitored during the period reviewed.

10CFR20.1502 requires monitoring if the area could receive 10% of the annual limit, and the calculations performed using two sets of badges worn by the physician in different situations demonstrate that the estimated dose was below 10% of the annual limit.

The physician in question performs 95% of our Y90 procedures and still is receiving less than 5000 mrem to the extremities in a year, much less than the 50,000 mrem limit.

Apparent violation #2- Failure to complete a Written Directive

The second apparent violation is a failure to prepare written directives that were dated and signed by an authorized user before administration of iodine-131 sodium iodide greater than 1.1 MBq (30 uCi) as required by 10CFR35.40(a.)

Inspector observed a note by a nuclear medicine technologist that they switched from I-123 to I-131 for a diagnostic whole-body scan prior to an I-131 therapeutic treatment. She asked the technologist to pull any records in which this occurred, and it appeared to happen seven times with five patients over the prior two-year time review period. The RSO was unaware of this practice. In discussion with the technologists, this would occur when an I-123 dose did not show up for administration, most often due to a shipping delay.

Practice was only being done at one hospital, no other Nuc Med departments were switching isotopes.

Review

When researching this practice, I asked if this practice could be discontinued. Because these administrations are part of a several day, time limited procedure, in which the patient is receiving daily thyrogen injections, the physicians did not want to stop the process and wait for the dose to be available. It would require the patient to start the process over again, causing a physical hardship for the patient and excess expense as thyrogen is a costly pharmaceutical.

The process is as follows:

Day 1- Thyrogen injection #1 by nursing staff
Day 2- Thyrogen injection #2 by nursing staff
Day 2- 2 hours after thyrogen the patient returns to take the I-123 capsule
Day 3- 24 hour whole body I-123 scan and uptake with thyroid probe

Physician will determine if treatment will occur, determine I-131 dose and order/schedule administration

NMT process for switching radiopharmaceuticals

When the dose did not arrive, the technologist would call an I-131 authorized user and get a verbal approval to switch from I-123 to I-131 as well as the prescribed dose. The prescribed dose of I-131 for the whole-body scan and the physician who approved it were documented in NucTrac as approved by the AU, however a physical Written Directive was never completed, as the technologists were under the mistaken impression that Written Directives were only for therapeutic procedures, not diagnostic.

The inspector did review these doses and saw that they had always contacted an appropriate authorized user. The inspector also spoke with one of these AUs who confirmed that he did in fact give approval for these substitutions but did not complete a written directive.

Discussion

I agree that this is a violation, and it was my responsibility as the Radiation Safety Officer to discover and correct this practice.

During my quarterly audits, I review at least 30 days of prescribed doses and assay amounts, but do not routinely review every single patient dose, so I did not catch the seven administrations over the past two years.

Corrective action:

1) Immediately after this discovery, I reached out to all nuclear medicine technologists to remind them of this regulation. I asked if any other sites were doing this and it was only occurring at our North hospital, which does the majority of our network I-131 patients.

2) I developed a written directive training and retrained all nuclear medicine technologists as well as the I-131 authorized users to remind them of the regulations and requirements.

3) I developed a new generic written directive for use by these individuals and distributed them to our technologists and placed a copy on our Teams page.

4) I also plan to have one of our part-time nuclear medicine physicists do at least one audit at each site per year, to have another set of eyes on each site. Two sites have been audited so far and it has proven valuable.

Summary

Community Health Network has established a long history of compliance with the regulations, quick corrective action when issues arise, and has worked amiably with the Nuclear Regulatory Commission over the years.

We request discretion in your determination of these apparent violations, and specifically request the following:

- Extremity dose monitoring- no violation
- Written Directives- Minor violation or Severity Level IV violation

Thank you

If you have further questions or concerns, please do not hesitate to reach out to me.

Erin Bell, MHP, DABSNM

Email: ebell2@ecommunity.com

Office: 317.355.5528

Cell: 317.313.0406