

NOTE

- The following presentation on "Insights on Identifying Medical Events During Inspections" provides information on causes of medical events and gives some past case examples and the causes of each event.
- Please note that current NRC inspection guidance, policy, and regulation, calls for less prescriptive and more
 performance-based inspections, in order to determine whether or not a licensee's program activities are executed in
 a manner that ensures public health and safety.
- Due to feedback received from the webinar training on December 2, 2014, and in an effort to avoid confusion, the case examples on Permanent Implant Brachytherapy that were discussed have been removed. Please be aware that these incidents were identified prior to issuance of the current Interim Enforcement Policy in *Federal Register* Notice (FRN) "Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting" (78 FR 41125), and as such, enforcement discretion may be exercised for reporting certain similar events, subject to criteria specified in the NRC Enforcement Policy, revision dated July 9, 2013 (ML13228A199).

Reference

NRC Enforcement Policy, Section 9.2 "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting under 10 CFR 35.3045", Revision dated July 9, 2013 (ML13228A199)



- This presentation will provide you with insights on how to identify medical events during inspections.
- The slides used during this presentation do not contain a lot of information. Please listen to the presentation more than focusing on the slides. When the presentation is finished, the slides will be made available to include the notes which have most of the information in this presentation.

-Of course, the insights provided are not all inclusive.

-Each inspector has his/her own inspection techniques and you are encouraged to find what works best for you.

-Please hold questions until the end of the presentation. The answers to some questions identified early in the presentation may be answered based on information that will be provided later in the presentation.

-You can gain insights on how to identify medical events by noting the causes of previous medical events.

Effort to identify medical events during inspections is consistent with NRC IP 87132 (Brachytherapy Programs)

NRC IP 87132 states:

"During the inspection, some records that are more closely related to health and safety (e.g., ...medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation of the radiation safety program for that particular element of a focus area."

AND

"If during the inspection, a previously unidentified medical event is identified, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 2) follow the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection."

AND

For Sr-90 eye applicators: "During the conduct of the inspection, the inspector should verify that the licensee is using the most recent calibration results. The inspector should note that a medical event has occurred if: 1) the licensee, in prescribing a dose and planning its delivery, does not use the most recent calibration results available to it at the time; and 2) the administered dose, calculated from the most recent calibration results available at the time of dose prescription, differs from the prescribed dose by greater than 20 percent.



If this presentation had to be taught with one slide, this cliché would be it.





Identification of medical events during inspections is usually not fast and easy, especially with more complex modalities such as high dose rate remote afterloader brachytherapy (HDR), prostate implants, and gamma stereotactic radiosurgery (GSR).

Licensees' processes and procedures vary and understanding their differing processes and procedures is one of the challenges.



Observe applicable staff plan, conduct, and verify medical administrations or demonstrate how they have done it.

(Share story of observing licensee staff loading a low dose rate applicator incorrectly prior to administration)

If a licensee rarely does an administration requiring a written directive, look deeper because there is a higher potential for a medical event.

Before observing administrations of licensed material or treatments using licensed material, ask the licensee to obtain patients' permission for you to observe the administrations or treatments.

Have licensee staff demonstrate the licensee's treatment planning computer software features used to verify that doses were delivered to the treatment site and the organs or tissues in accordance with the written directives and the treatment plans. Doing so familiarizes you with the licensee's software and procedures. Do not operate the licensee's equipment!

Work with knowledgeable staff member(s) and have the staff member help you understand what you see.



Familiarize yourself with the licensee's treatment device (e.g., GSR, HDR) and have the staff member help you understand what you see.

Doing so gives you more opportunity to identify vulnerabilities that may have resulted in a medical event.

For example:

-treatment device settings information transfers from the treatment planning system to the HDR device are done manually rather than electronic transfer; **(seen it)**

-the sizes of applicators are not readily apparent when they are removed from the storage area;

-the color coding on brachytherapy sources is faded/hard to discern; (seen it)

-the Perfexion GSR software display/printout that indicates the size of the collimator (e.g., "8" for 8 mm collimator vs. "B" for "blocked collimator) where the "B" and the "8" are hard to discern **(seen it)**

-the licensee posts a note on the dose calibrator that indicates the wrong dose calibrator potentiometer setting for a beta emitting radionuclide **(seen it)**



Observe the licensee demonstrate how it verifies if administrations are in accordance with the written directives and treatment plans. Note vulnerabilities that could result in a medical event.

When reviewing records of selected cases, verify that identified vulnerabilities did not result in a medical event.

Look for vulnerabilities for errors such as:

-not doing <u>independent verification of written directives</u> (e.g., dose/dosage, treatment site, radionuclide, radioactivity, etc.)

-not doing <u>independent verification of patient identification</u> (e.g., official picture ID, birthday, etc.)

-not doing <u>independent verification of pre-treatment plan</u> parameters prior to administration (e.g., dose/dosage, treatment site, radionuclide, radioactivity, time of exposure, number and type of source(s), source(s) position(s), applicator (type, size, length), dwell times, default settings that could result in problems when a unique treatment is done requiring entering other than the default parameter, etc.)

-not doing <u>independent verification of treatment site(s)</u> (e.g., right versus left, medial versus lateral, superior versus inferior)



-not doing <u>independent verification of pre-treatment device set up parameters</u> (e.g., time of exposure, source(s) position(s); applicator type, size, and length; default settings that could result in problems when a unique treatment is done requiring entering other than the default parameter, etc.)

-not doing independent <u>verification of pre-treatment device parameters (what</u> <u>was set) relative to post-treatment parameters (what happened during the</u> <u>treatment</u>) (e.g., dose/dosage, treatment site, radionuclide, radioactivity, time of exposure, source(s) position(s), applicator type and size, step size, default settings that could result in problems when a unique treatment is done requiring entering other than the default parameter, etc.)

If you identify a medical event, promptly notify the licensee, spend some time to see if other similar medical events occurred, and request the licensee to conduct an "Extent of Condition Review" to determine if other similar medical events occurred and to report the results back to you. Doing this will provide the licensee opportunities to identify information that could result in better corrective actions to prevent similar events, and allow the licensee to take actions to mitigate potential adverse consequences of the medical events sooner, if possible.



Case 1:

During an inspection to review two medical events that were reported, the inspector identified three additional patients that had similar treatments as those that resulted in the reported medical events, and one of those additional patients exhibited observable side effects.

Five GYN cesium-137 brachytherapy treatments resulted in medical events.

Three of the patients developed skin lesions on the upper thighs from radiation doses to the skin of the upper thigh, an unintended treatment site.

The <u>root cause</u> of the medical events was the use of radioactive sources that had a smaller diameter than that specified in the instructions distributed

with the brachytherapy applicator, which allowed the sources to move from their intended position within the applicator (spring) to a position that resulted in the unintended doses to the skin of the patients.



Contributing causes were:

1. The instructions provided by the manufacturer of the applicator were inadequate because the instructions did not provide adequate caution statements regarding the physical dimension requirements of sources to be used in the applicator.

Specifically, the instructions did not provide sufficient specificity regarding the physical dimension requirements of the sources to be used; and

The instructions permitted the use of other manufacturers' sources, but did not provide cautions regarding the use of sources that were of a smaller diameter than those from the specified source manufacturer.



2. The licensee provided poor supervision of contract medical physicists.

Specifically, the licensee relied on contract medical physicists to self-instruct and familiarize themselves with the applicator prior to its use.

A contract medical physicist involved in the five brachytherapy treatments was not familiar with the use of the particular applicator and did not recognize that the two sets of brachytherapy sources possessed by the licensee were physically different in a critical dimension; and

Neither the licensee nor the authorized user provided specific instructions to the contract medical physicists regarding technical limitations associated with the use of the applicator.



3. Licensee staff failed to read the instructions provided with the applicator and therefore, did not follow the instructions.

The instructions specified the use of sources manufactured by 3M and the applicator was marked with the appropriate source dimensions; however, during each of the 5 medical events, the contract medical physicist selected G.E. Healthcare sources for use in the applicator because he assumed that all of the sources were manufactured by 3M and did not recognize that he had selected sources from a different manufacturer.

The physicist did not recognize that the difference in source dimensions could impact their use in the applicator. Therefore, since he failed to thoroughly read the instructions and failed to recognize that the licensee possessed two sets of sources that were different in a critical dimension, he used G.E. Healthcare sources in the applicator that were too small in diameter.



4. The licensee's procedures for manual, low-dose-rate brachytherapy administrations were inadequate.

Specifically, the licensee 's procedures did not require verification that the sources used with the applicator were appropriate to administer the treatment as prescribed on the written directive; and

The licensee's procedures referenced obsolete requirements that existed prior to the April 2002 revision of 10 CFR Part 35.

Note: If a medical event occurs, it is likely that a violation of 10 CFR 35.41 occurred. Specifically, if the licensee: (1) did not fully implement its procedures to provide high confidence that each administration is in accordance with the written directive; or (2) fully implemented inadequate procedures to provide high confidence that each administration is in accordance with the written directive, then it is likely that a violation of 10 CFR 35.41 oCFR 35.41 occurred.



Low Dose Rate Brachytherapy Cs-137 GYN Medical Event



5. The Radiation Safety Officer (nuclear medicine informed) provided poor oversight of the brachytherapy radiation safety program which significantly reduced his ability to: (1) ensure that radiation safety activities were performed in accordance with regulatory requirements; (2) identify radiation safety problems; (3) initiate, recommend, or provide corrective action; and (4) stop unsafe operations.

Specifically:

The licensee relied on the contract medical physicists to monitor activities relative to the licensee's brachytherapy radiation safety program; however, the contract medical physicists were also delegated the responsibility for the day-to-day implementation of the brachytherapy radiation safety program.

As a result, the licensee missed opportunities to identify precursors associated with five medical events and to promptly identify and report those medical events (e.g., limitations on the sources that should be used with the applicator, a contract medical physicist's unfamiliarity with the two types of sources possessed by the licensee)



Take Always:

-Does the licensee take action to ensure that the brachytherapy applicator/source apparatus is adequate to deliver the radiation dose prescribed on the written directive? For example, do they do acceptance testing to ensure that sources stay in position within the applicator?

-Does the licensee ensure that the dummy sources are the same physical size as the sources used for brachytherapy?

-If the licensee uses a Wang applicator, how does it ensure that the sources cannot move down the center of the spring?

-Does the RSO oversee all aspects of the radiation safety program, including those that he/she is less knowledgeable about?

If the licensee contracts technical staff (e.g., medical physicists) assess vulnerability due to a potential lack of licensee oversight of contracted staff. (Especially if the RSO is not technically knowledgeable in an aspect of the radiation safety program)



An inspector identified an HDR medical event that occurred during the licensee's administration of three treatment fractions administered to a patient.

An NRC Medical Consultant concluded that the medical event resulted in: (1) an overdose to the vaginal vault that is unlikely to cause vaginal necrosis; and (2) an under dosage to the inferior-posterior vaginal wall (which contained cancer) that increases the risk of cancer recurrence.

While reviewing selected HDR treatment records with a medical physicist, including written directives, treatment plans, pre-treatment HDR device settings, and post-treatment HDR device settings, the inspector noted that one of the treatments had an error involving entering the wrong step size into the HDR unit that was used for the treatment.



Root Cause: Error in entering the step size into the HDR unit.

Contributing Causes:

- (1) licensee failure to instruct an Authorized Medical Physicist (AMP) on written directive (WD) procedures;
- (2) AMP's failure to read the licensee's WD procedures until the inspection;
- (3) inability to transfer the treatment data electronically to the HDR unit for the treatment;
- (4) the AMP's perceived sense of urgency to complete the treatment because of the patient's discomfort;
- (5) the licensee staff's failure to check that the step size data was properly transferred to the HDR unit prior to the treatment; and
- (6) Use of an HDR unit's default step size setting of 2.5 millimeters when 5 millimeters was normally used by the licensee (BIG VULNERABILITY!)

The licensee lost an opportunity to identify the medical event because a staff member failed to check that the step size that was actually used for the treatment was in agreement with the treatment plan after administration of the treatment.



Corrective Actions:

- Changed the HDR unit's default step size setting from 2.5 millimeters to 5 millimeters because 5 millimeters is normally used by the licensee. (Less Vulnerability)
- (2) Had the AMP/RSO discuss the licensee's WD procedures with all applicable licensee staff and licensee management to ensure that they are aware of the WD procedures and that they will review them with new staff and ensure that the new staff understands the WD procedures prior to participation in licensed activities;
- (3) had the AMP review and implement its WD procedures and subsequently revise them to include dual verification that the parameters in the HDR unit console used for patient treatments are the same as those developed in the treatment planning computer, including step size, dwell times, and number of dwell positions; regardless of the means of transferring the treatment parameters from the treatment planning computer to the HDR;
- (4) worked with the HDR unit manufacturer to resolve the difficulty it had transferring the data electronically to the HDR unit;
- (5) made changes in patient handling methods to reduce the time patients must wait for treatments after applicators are inserted into the patients; and



(6) planned to expand physics staff coverage from three to five days per week to permit more thorough preparation work on procedures and equipment prior to treatments and periodic, independent review of the work.

Take Always

Default settings can be a vulnerability, especially when the default setting is not used most often.

Failure to conduct dual verification of parameters in the treatment device used for patient treatments to ensure they are the same as those developed in the treatment planning computer, including step size, dwell times, and number of dwell positions was a vulnerability.

Long waiting times between when the applicators are inserted into the patients and when they are treated is a vulnerability because patients are more uncomfortable and that can result in licensee staff rushing to treat the patient which increases the risk of errors.



<u>Case 4.</u>

Describe Savi applicator for HDR breast treatments.



A medical event occurred as a result of mispositioning of the iridium-192 HDR source in the patient's body.

<u>Root Cause:</u> Human error in that the licensee did not accurately reconstruct the applicator in the treatment planning computer for 8 of 10 fractions.

Explain the toggled images for an illustration of what happened!

Point out that the source dwell positions are illustrated as lavender dots.

Toggle the images by using the up/down arrows and note that the image showing reconstruction starting at the connector end is <u>what was</u> <u>administered</u> (see this page), and the image showing reconstruction starting at the tip end <u>is the intended plan</u> (see next page).



Contributing Causes:

(1) the licensee's practice of starting applicator reconstruction during treatment planning at the connector end for all HDR treatments except breast treatments combined with the need to change the treatment planning computer default from, "start at connector end" to "start at tip end" for all HDR breast treatments (another example of using a default when it is not applicable for all types of treatments done by the licensee)

(2) difficulty with identifying if the "start at" selection was correct for applicator reconstruction during use of the treatment planning system (i.e., printouts from the treatment planning software did not clearly indicate the "start at" position; therefore, the user could not easily detect a potential error in the "start at" position if not correctly switched to "tip end" for breast treatments by means of the printed treatment plan. In order to identify if the "start at" selection was incorrect for multiple catheter HDR treatments, the licensee had to view the three-dimensional (3D) image of the reconstructed applicator and use visual indicators to determine if the applicator was in the proper orientation. The visual indicators for SAVI® applicators were: (1) pink coloration and flattened catheter ends showing the connector end of the applicator; (2) rounded catheter ends showing the tip end of the applicator; and (3) whether or not the numbers of each catheter increased in the counterclockwise direction while viewing the tip end of the applicator.



Corrective Actions:

- 1. Adding a step to the procedure for multi-catheter HDR breast treatments to verify that the applicator is properly oriented in the three-dimensional image;
- 2. Revising its written directive form to add a checkbox indicating "tip end selected" as a means of reminding staff to change the default from "start at connector end" to "start at tip end" during applicator reconstruction;
- 3. Training staff about the revised written directive form; and
- 4. Committing to train applicable staff on the requirements in 10 CFR 35.3045.



Take Always:

-Verify if licensee's accurately reconstruct the applicator in their treatment planning computers.

-Verify that default settings are changed when appropriate.

-Verify if medical events resulted incident to the use of defaults.

-Verify if the licensee's treatment planning system has weaknesses that make it difficult to identify important information to prevent errors. (If so, inform the vendor!)



Case 5:

Discuss HDR catheters using the above pictures.

A medical event under dose occurred.***

<u>Cause:</u> The patient's treatment catheters were incorrectly connected to the HDR unit. Specifically, the patient's treatment catheters were connected to onemeter long transfer tubes that were connected to the HDR unit, instead of being directly connected to the HDR unit per the manufacturer's instructions.

As a result, the treatment site did not receive any dose during the treatment because the radioactive source remained outside the body and delivered an estimated dose of 1.8 rad to the patient's skin on the patient's left shoulder and upper arm.



<u>Root Cause:</u> The licensee's written procedures failed to ensure that the patient's treatment catheters were appropriately connected to the HDR unit such that the administration would occur in accordance with the written directive. A violation was identified involving licensee failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41).

Corrective Actions:

The licensee:

- (1) revised its written procedures to require the physicist and an independent staff member to review and verify the correctness of the connections to the HDR unit (dual independent verification)
- (2) provided training to all affected users on the revision to the written procedure;



(3) developed a comprehensive manual that includes narrative descriptions and photographs of treatment set-ups of all types of HDR treatments that are in accordance with the manufacturers' instructions; and

(4) trained other qualified staff to perform the secondary check to confirm the correctness of all connections to the HDR unit.

Take Away

Failure to do dual, independent verification of key information is a vulnerability.



Discuss the helmet, and other hardware.

Discuss the collimators too.



Fiducial is defined as "a standard of reference".

Show where the stereotactic frame is and why it is attached to the fiducial box as a means of correlating 3-D patient anatomy with the imaging and treatment planning systems.



Show where the stereotactic frame is and why it is attached to the fiducial box as a means of correlating 3-D patient anatomy with the imaging and treatment planning systems.



Generic Issue - Excerpted from NRC Information Notice

Following the attachment of the frame to the patient's skull, the licensee performed imaging and localization studies using Magnetic Resonance Imaging (MRI) with the frame attached to the patient's skull and a fiducial box (box) installed on the frame.

The frame and box were used to align the patient along the X, Y, and Z axes and to provide markers on the MRI images corresponding to the X, Y, and Z coordinates. This information allowed for precise target site localization with the three coordinate system, and the X, Y, and Z coordinates of each site were ultimately documented on the written directive authorizing the treatment.

However, the licensee inadvertently positioned the box on the frame 180 degrees backwards (i.e., the front of the box faced the back of the patient, and the back of the box faced the front of the patient).

The box positioning error did not effect the X and Y coordinates; however, it resulted in the Z coordinates being inverted. Since the Z coordinates were inverted, the GSR treatment resulted in prescribed doses that were delivered to unintended anatomical areas.



The box was designed with a safety feature to prevent inadvertent wrong positioning of the box onto the frame. Specifically, the box had four pins that, when positioned correctly, would seat into corresponding holes in the frame. One of the pegs was larger than the other three, and one of the holes was larger than the other three. If the box was incorrectly positioned, the larger pin would not seat in the smaller holes, thus preventing the box clamps from latching.

The licensee noted resistance while fastening the box onto the frame. The licensee attributed this resistance to the fact that the box might have been in contact with the top of the patient's head which, in turn, would not let it lower to the point where the box clamps could fasten onto the frame. However, the resistance was due to the fact that the box had been positioned incorrectly.



The resistance was actually the result of the large box pin not seating in one of the frame's smaller holes due to the erroneous box position. The licensee applied sufficient force to clamp the box to the frame even though the large pin had not seated in the smaller hole.

The safety feature, intended to prevent incorrect attachment of the box to the frame, failed because the unseated, large pin was too short, and this allowed the plastic clamps to flex enough to latch to the frame. After attachment, the licensee didn't notice that the large pin on the box was not seated in the smaller hole in the frame. Authorized staff were aware of the safety feature and assumed that there was no way the box could be attached to the frame incorrectly.

Failure of the safety feature was a contributing factor to the event.

Take Aways

-Is the GSR X, Y, and Z hardware labeled to avoid confusion during patient setup?

-How do they assure that the fiducial box is properly positioned on the stereotactic frame prior to MRI?

-Is the fiducial box marked legibly?



-Verify that the written directive has the required information (e.g., compare with applicable regulation)

-Verify that the correct material was administered (e.g., review dosage packing slip)

-Verify that the correct activity was administered (e.g., record of measured dosage activity by licensee and/or supplier)

-Verify that the administration was given to the correct patient (e.g., record of patient identification ID verification, such as photos, etc.)

-Verify that the route of administration was correct (e.g., record of route of administration)



<u>Case 6:</u>

Medical events typically have a root cause and contributing causes/factors.

A medical event occurred as a result of inadvertent loss of about 66 percent of a prescribed samarium-153 lexidronam dosage before the remaining 34 percent of the prescribed dosage was administered to the patient.

Samarium-153 lexidronam is used to treat bone pain incident to metastatic prostate cancer.

The root cause of the medical event was that the syringe containing the dosage started to slip out of the syringe shield during an attempt to connect the shielded syringe to the intravenous connector, resulting in inadvertent dosage loss when the Authorized User attempted to stop the syringe from slipping completely out of the syringe shield.



Contributing causes to the medical event included:

- (1) the dosage's high specific activity (larger loss of activity per unit volume lost);
- (2) the licensee's removal of the needle from the syringe without first pulling the material out of the needle and into the syringe (lost activity contained in the needle);

(3) the Authorized User's lack of experience with the syringe shield affixed to the syringe (example of increased error potential when a person does administrations infrequently);

(4) The inability of the syringe shield to secure the syringe within it;

(5) the Authorized User's lack of training on how to prevent the syringe from disengaging from the syringe shield;



(6) the decision to continue preparation for, and administration of, the dosage after identification of potential dosage leakage without first assessing the dosage radioactivity that was spilled; and

(7) the failure to include in the licensee's written procedure: response to potential leakage identified prior to dosage administration, the technique used to prevent syringe disengagement from the syringe shield, and response to syringe disengagement from the syringe shield.

These causes provide insights on how you can identify vulnerabilities for medical events.

The inspector identified a violation involving the licensee's failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41).



Corrective actions included:

 immediately established that only therapists with more experience connecting shielded syringes to the IV connector will do this until long-term corrective actions are developed and implemented;

Actions done infrequently increase vulnerability for mistakes!

(2) began examining alternative syringe shield designs and ways to better secure the syringe in the syringe shield;

(3) began re-evaluating when to stop and assess the situation before administering dosages when there is indication of a potential problem that could result in a medical event; and

(4) began to contemplate what revisions it would make to the procedure



<u>Case 7:</u>

Expect the unexpected when looking for medical events

Look for potential trip wires for mistakes

-Licensee ordered I-131 dosage

-NMT received the dosage, looked down into the container, and saw a capsule in it

-NMT measured the container with the capsule inside with a dose calibrator and the measured dosage was as prescribed

-The licensee inverted the container and administered the capsule to the patient

-The residual waste (e.g. vial shield, inner container, etc.) was returned to the radiopharmacy

-The radiopharmacy did surveys of the incoming radwaste package and identified abnormally high readings

-The radiopharmacy found that the inner container had an I-131capsule inside, resulting in an under dose medical event

-Causes: The dosage included **two** I-131 capsules with a desiccant pad positioned between them. The bottom capsule was invisible when the NMT looked into the container and it was wedged with the desiccant pad at the bottom of the container such that it did not drop from the container when inverted.



Beware of potential incorrect measured radioactivity for beta emitters

-Verify that that written directive has the required information (e.g., compare with applicable regulation)

-Verify that the correct material was administered (e.g., review dosage packing slip)

-Verify that the correct activity was administered (e.g., record of measured dosage activity by licensee and/or supplier)

NOTE: Vulnerability with measuring beta emitters with dose calibrators

Typical Dose Calibrator Potentiometer Setting Procedure: (1) assay NIST traceable reference standard of Y-90 solution that is provided by the pharmacy (same type of container as with dosages, same volume of material as with the dosages); (2) adjust potentiometer until the reading is equivalent to the known reference sample activity; (3) repeat the measurements 3 times and verify that the measurements are within plus or minus 5% of the decay-corrected activity; and (4) document and label the potentiometer setting on the dose calibrator for future use

-Verify that the administration was given to the correct patient (e.g., record of patient identification ID verification, such as photos, etc.)

-Verify that the route of administration was correct (e.g., record of route of administration)



Case 8:

-Patient was prescribed 3 mCi of Tc-99m sulfur colloid for lymphoscintigraphy

-Patient received 25 mCi of Tc-99m methylene diphosphonate (MDP) subcutaneously

-The administration resulted in a dose > 50 rem to tissue and skin which meets the medical event criteria in 10 CFR 35.3045(a)(2)(i) (The licensee did not anticipate any long-term medical effects on the patient as a result of the medical event, because the injection sites were excised – as is standard for a lymphoscintigraphy procedure)

-Root cause of the medical event was failure to verify the dosage against the patient's prescription



QUESTIONS?