UNIVERSAL IMAGING, INC.

MAKING TODAY'S TECHNOLOGY AFFORDABLE

UNIVERSAL IMAGING
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Fixed & Mobile
- CT
- MRI
- Nuclear Medicine

August 22, 1996

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III
801 Warrenville Road
Lisle, IL 60532-4351

ATTN: Hubert J. Miller
Regional Administrator

Re: UNIVERSAL IMAGING, INC. NRC License No. 21-26532-01

Response to NOV Dated 8-2-96 received 8-7-96

A

1. Failure to maintain the required system for ordering and receiving radioactive materials.

Reason: A system of ordering radiopharmaceuticals existed at the time of the misadministration. The system consisted of:

> The schedule book was reviewed to determine the studies to be performed for the day. The prescribed dosage list was then referenced to determine what radiopharmaceutical and what amount should be ordered for the study. The order for radiopharmaceuticals was then placed using this information. A purchase order number and / or the name of the individual taking the order was recorded to indicate that an order had been placed for the radiopharmaceuticals for the studies listed in the schedule book.

Corrective Steps: On April 29, 1996, we created and implemented a new system for ordering radiopharmaceuticals which lists the facility, the supplier, the radionuclide, the chemical form, the amount, and the number of doses. This form also allows documentation of the verification of the receipt against the order.

Steps Taken to Avoid Further Violations: This new system will be used at all of our licensed facilities and will only be revised to improve effectiveness.

Date of Full Compliance: April 29, 1996

2. Failure to verify material received was the material ordered.

Reason: The technologist receiving the material did not question why she received material which was not listed on the Prescribed Dosage List for the facility. We believe this error to be due to overconfidence on the part of this technologist.

Corrective Steps: On April 29, 1996, we created and implemented a new system for ordering radiopharmaceuticals which lists the facility, the supplier, the radionuclide, the chemical form, the amount, and the number of doses. This form also allows documentation of the verification of the receipt against the order.

Steps Taken to Avoid Further Violations: We have also issued and posted a memo to All Nuclear Medicine Personnel that instructs them to contact management before proceeding if they receive a radiopharmaceutical that is not on the Prescribed Dosage List or that is not normally used.

Date of Full Compliance: April 29, 1996

3. Failure to provide the required training to an employee before they assumed duties.

Reason: Training was provided by our Chief Nuclear Medicine Technologist at the time in question. To the best of the Chief Nuclear Medicine Technologist's knowledge the new employee completely understood all operating and imaging procedures. However, documentation of this training was either not completed or was subsequently lost.

Corrective Steps: Our new Chief Nuclear Medicine Technologist has developed a new training program which includes competency training of all technologists.

Steps Taken to Avoid Further Violations: All technologist will complete a performance based training program before being allowed to work unsupervised.

Date of Full Compliance: July 1, 1996

B

1. Administration of greater than 30 uCi of NaI-131

Reason: The technologist who administered the dosage failed to adhere to the prescribed dosage list. We believe that this was due to overconfidence of the technologist and an unwillingness to ask questions when in doubt.

Corrective Steps: We have issued and posted a memo to All Nuclear Medicine Personnel that instructs them to contact management before proceeding if they receive a radiopharmaceutical that is not on the Prescribed Dosage List or that is not normally used. Our written order sheets state "Do Not Order NaI-131". Our license has been amended to restrict possession of NaI-131 or NaI-125 to less than 30 uCi.

Steps Taken to Avoid Further Violations: Our license has been amended to restrict possession of NaI-131 or NaI-125 to less than 30 uCi.

Date of Full Compliance: August 5, 1996

2. Failure of the RSO to spend 4 hours per week at Northwest X-ray Clinic

Reason: This was a commitment made voluntarily by the RSO in good faith and with good intentions. We, Universal Imaging, did not request the four hours per week and were unaware that he was not meeting this obligation.

Corrective Steps: In order to provide better supervision of the radioactive material program for the future, we have hired a new RSO, a Nuclear Medicine Technologist with extensive experience. He has been made responsible for the direct supervision of the use of radioactive materials. He makes contact with all the technologists at least weekly, often daily. Our license has been amended to name him as our new Radiation Safety Officer.

Steps Taken to Avoid Further Violations: Our Vice-President meets with the new RSO frequently to ensure that he is overseeing all of the facilities.

Date of Full Compliance: August 5, 1996

C. Failure to notify the NRC within 24 hours of discovery of a misadministration

Reason: The licensee's contracted physicist discovered the misadministration during a review of the facility records. Thus the licensee's oversight prevention mechanism worked properly and resulted in identification and subsequent notification regarding the misadministration. The administering technologist failed to provide any information regarding this misadministration to the licensee management.

Corrective Steps: The NRC was notified within 24 hours after the licensee and RSO became aware of the misadministration. Our new RSO is in frequent contact with all of the Nuclear Medicine Technologists. An occurrence such as this will not go undetected with this new system.

Steps Taken to Avoid Further Violations: Our new ordering procedures and increased supervision of our program work to prevent further misadministration and to prevent a similar occurrence from going undetected.

Date of Full Compliance: July 1, 1996

D. Failure to submit a written report of the misadministration within 15 days of discovery

Reason: This was a simple error to mail the report in the time required.

Corrective Steps and Steps Taken to Avoid Further Violations: We have appointed one individual to handle all written correspondence with the NRC. In this manner, we will avoid confusion as to whether correspondence has been submitted or not.

Date of Full Compliance: July 1, 1996

Please contact me if you have any further questions regarding this matter.

Sincerely,

Phil Young

Phil Young
President

cc: Ms. Tracy King
Medical Physics Consultants, Inc.