



November 16, 2012

Judith A. Joustra, Chief
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 U.S. Nuclear Regulatory Commission
 Region I
 2100 Renaissance Blvd, Suite 100
 King of Prussia, PA 19406-2713

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SUBJECT: REPLY TO A NOTICE OF VIOLATION.

Docket No. 03034187
 License No. 52-25361-01MD

Dear Mrs Joustra:

Find below the response for the notice of violation letter sent on October 16, 2012.

- A. 49 CFR 172.200 (a) requires each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in the manner required by this subpart. 49 CFR 172.203 (d) requires that shipping papers contain, in part, (2) a description of the physical and chemical form of the material, if the material is not in special form; (3) the activity contained in each package of the shipment; (4) the category of label applied to each package in the shipment (for example: "RADIOACTIVE WHITE-1"); and (5) the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II or RADIOACTIVE YELLOW-III labels.

Contrary to the above, the licensee transported packages and shipping papers that did not state the activity contained in the packages on June 26, 2012 and August 14, 2012, and transported a package and shipping papers on June 25, 2012, that did not contain information regarding the category of label applied to the package and the transport index assigned to the package.

1. The cause of the violation was determined to be a mishandling of an old document after a new version was printed. The shipper employee incorrectly selected and used the incomplete old version of the document when the case was shipped out. The driver assigned to deliver the case failed to identify that the document was incomplete.
2. Corrective actions implemented :
 - a. Group discussion was performed with all involved personnel.
 - b. All personnel involved in packaging and shipping were retrained on equipment use and document management and completion.

- c. Operational procedures were reviewed to assure accuracy when managing documents after a new shipping document is printed. Old document version will be immediately destroyed when a change is requested to avoid the mix up with the most recent version.

Corrective actions results: Customers are receiving accurate information on shipping documents. All shipping papers are being reviewed to assure they are completed and accurate by the assigned driver before leaving the facility. If discrepancies are found, the documents will be corrected by the pharmacist shift supervisor, before leaving the facility.

3. Corrective actions that will be taken to avoid further violation are:
 - a. Personnel retraining, review of operational procedures and review of documents before they leave the facility.
4. Date of full compliance will be achieved by December 15, 2012.

- B. 49 CFR 171.201 (e) requires that each person who provides a shipping paper must retain a copy of the shipping paper required by §172.200 (a), or an electronic image thereof, that is accessible at or through its principal place of business and must make the shipping paper available, upon request, to an authorized official of a federal, state, or local government agency at reasonable times and locations.

Contrary to the above, on September 7, 2012, the licensee did not retain a copy of a shipping paper as required. Specifically, the inspector requested the licensee to provide a copy of the shipping papers for the package containing prescription numbers XXXX610, XXXX611, and XXXX612, transported on June 25, 2012, and the licensee was not able to provide a copy.

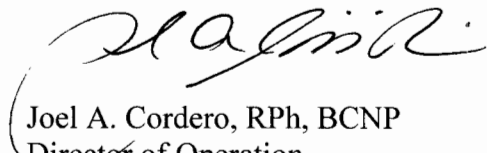
1. The cause of the violation was identified as improper handling of shipping papers before they were filed electronically.
2. Corrective actions immediately taken were:
 - a. Discussion of the violation with drivers, packaging personnel, and management.
 - b. All personnel involved were retrained in the regulatory compliance requirements governing shipping papers.
 - c. An application is currently under development to match all shipping papers that leave and return to the radiopharmacy.

Results: The complete team is aware of the importance to fulfill regulatory requirements. The discussion between management and

employees gave the opportunity to develop an application to file and organize shipping papers.

3. Corrective actions to be taken to avoid further violation are:
 - a. Implementation of the new application and to train personnel in its use.
 - b. Daily report of matching shipping papers signed by the facility. In the case of discrepancies, an investigation will be conducted and cause will be identified and resolved within 24 hours.
 - c. Documents will be scanned immediately after receiving and matched with the new application for full tracking purposes. The electronic copy will be retained for three years.
4. Date of full compliance will be achieved by December 15, 2012.

Should you have any other questions please do not hesitate to contact me.
Sincerely,



Joel A. Cordero, RPh, BCNP
Director of Operation
Lantheus MI Radiopharmaceuticals, Inc.

Reply to a Notice of Violation Docket # 03034187 - 11-16-12.docx (File: Medical Imaging Radiopharma)