

Parker, Bryan

From: Hughes, Rick (GE Healthcare) <Rick.Hughes@ge.com>
Sent: Thursday, February 27, 2014 3:15 PM
To: Parker, Bryan
Cc: Mullady, Peter (GE Healthcare); Poisson, Emile (GE Healthcare)
Subject: RE: Request for Additional Info re: NRC license renewal
Attachments: App reply Feb 2014.pdf

Importance: High

Bryan,

Please see attached responses to the questions sent concerning the GEHC St Louis RAM renewal application. Discussion was held with Pete in the St Louis site to help generate the response.

Concerning question 3 on the iodine room, please note no air vents are tied into the iodine room. The only flow of air is that being drawn from the Patriot hood, from under the door of iodine room and then up the stack and out.

If you have any questions please feel free to contact me on my cell phone. Thank you for the help in this matter.

Rick Hughes
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February 27, 2014

Bryan A. Parker
Health Physicist
U.S. Nuclear Regulatory Commission - Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Radioactive Materials License No. 24-32462-01MD
Docket No. 030-36453
Control No. 582100 (License Renewal)

Dear Mr. Parker:

Pursuant to your email correspondence dated 26 February 2014, the following responses are provided to the questions outlined in your email. The questions have been restated for ease of reference.

- 1. In Item 5, please indicate the reason(s) for the significant increases in possession limits, specifically with Subitems A (BPM 1-83) and E (I-131).**

GE Healthcare would like to increase the possession limits noted in Sub-Item A (BPM 1-83) and Sub-Item E (I-131) as specified in the radioactive materials license application renewal. The increase in the possession limits is warranted due to the growing demands of the radiopharmacy business in the area.

- 2. In Item 5, Subitems I and J, you request continued authorization to redistribute 35.400 sources and a new authorization to redistribute 35.500 sources. Please provide confirmation that:**
 - A) the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements; and**
 - B) the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.**

(This is similar to the information provided by you in Item 10.3 under Distribution Operations for other sources.)

GE Healthcare confirms all sealed sources for brachytherapy or diagnosis to be redistributed to authorized licensees will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74, or

under equivalent Agreement State requirements. GE Healthcare further confirms, the manufacturer's packaging, labeling, and shielding will not be altered. Redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document providing radiation safety instructions for handling and storing the sources.

3. In Item 10.6 under Section B of Precautionary Measures for Handling Millicurie Quantities of Radioiodine, you describe airflow, exhaust, etc. Please verify that the room exhaust does not exceed the hood exhaust to prevent backflow into worker breathing zones.

Also, please indicate the height of your stack above the roof and the distance of the stack from any other intake points.

Lastly, please verify that ventilation systems ensure that effluents are ALARA, and are within constraints for air emissions established under 10 CFR 20.1101(d).

GE Healthcare verifies the Iodine Room exhaust does not exceed the volatile materials fume hood exhaust, thereby preventing backflow into the worker breathing zones. Please note the entire iodine room is maintained under negative pressure at all times due to lack of HVAC ventilation into the room. As stated in the radioactive materials license application in Item 10.6 of Precautionary Measures for Handling Millicurie Quantities of Radioiodine, ventilation keeps the fume hood at negative pressure with respect to the rest of the Iodine Room. The design of the fume hood precludes releases into the room and prevents the operator from disrupting the airflow.

The height of the volatile materials fume hood exhaust stack above the roofline is maintained at a minimum of 6.0 feet (1.83 meters) and the distance of the exhaust stack release point is maintained at a minimum of 32.81 feet (10.0 meters) from any other potential intake points.

GE Healthcare also verifies the facility ventilation system design ensures air effluent releases are ALARA and within the constraints for air emissions established under 10 CFR 20.1101(d).

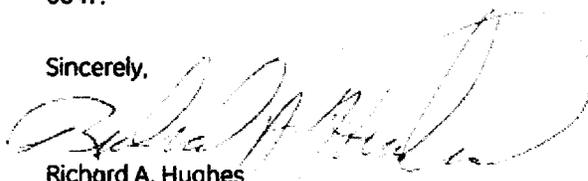
4. In Item 11.1 under Procedures for Retrieving Waste from Customers, you indicate that "GE will pick up for disposal only those items which contain or are contaminated with radiopharmaceuticals supplied by GE Healthcare." (emphasis added)

It further indicates that the customer is responsible for other waste; however, it is not clear what that statement above entails. Therefore, please clarify that you only retrieve syringes and vials supplied by you and do not retrieve any other waste from the customer.

The GE Healthcare St. Louis radiopharmacy will only retrieve syringes and vials originally supplied by GE Healthcare. The GE Healthcare St. Louis radiopharmacy will not retrieve any other waste from customer/licensees.

If you require any addition clarification or information pertaining to the GE Healthcare St. Louis radiopharmacy radioactive materials license application renewal please do not hesitate to contact me personally at (609) 514-6647.

Sincerely,



Richard A. Hughes
Corporate Radiation Safety Officer
GE Healthcare - Life Sciences - MDx