

From: [Torres, Roberto](#)
To: ["David Theel"](#)
Subject: NRC request for additional information
Date: Wednesday, June 16, 2021 7:32:00 AM
Attachments: [Pages C-28 and C-29.pdf](#)

Mr. Theel:

Thank you for your response letter dated June 15, 2021. A few items are still pending. Please provide your response in a signed and dated letter (in pdf format) by reply email.

Provide the following commitments.

1. "Mountain View Hospital commits to develop, implement and maintain written procedures for the safe use of unsealed Lu-177 permitted by 10 CFR 35.300 that meet the requirements of 10 CFR 20.1101 (Radiation protection programs) and 10 CFR 20.1201 (Occupational Dose Limits for Adults)."
2. "Mountain View Hospital commits to develop, implement and maintain written waste disposal procedures for Lu-177 and detectable quantities of Lu-177m in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."
3. Confirm that the licensee has not undergone a change of control and that the licensee's legal entity name is "Mountain View Hospital".

For items #1 and #2, please note that the NRC medical licensing guidance (see attached NUREG-1556, Volume 9, revision 3, pages C-28 and C-29) provides medical licensees with the flexibility to "develop, implement and maintain written procedures" for the safe use of licensed material and for waste management. You have developed procedures that will need to be implemented and will need to be maintained by making revisions to these procedures internally as the program change. Not having these commitments in place will force you to submit a license amendment request every time that you make any kind of changes to these procedures.

Thank you for your cooperation.

Roberto J. Torres, M.S.
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76011-4511
817-200-1189

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

OR

- A statement that the applicant will implement the model leak test program of the appendix of the appropriate NUREG-1556 volume for the type of use. For instance, if an applicant possesses a self-shielded irradiator, the applicant may state, "We will implement the model leak test program published in Appendix N of NUREG-1556, Volume 5, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses."

OR

- If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

Item 10: Area Surveys

Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

Item 10: Safe Use of Unsealed Licensed Material

Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

Item 10: Mobile medical service

- Review the guidance in Appendix V of this NUREG to determine the response required.

Item 10: Minimization of Contamination

A response is not required under the following condition: The NRC will consider that the criteria have been met if the information provided in the applicant's responses satisfies the criteria for the following sections in this NUREG: Sections 8.9, 8.9.1, 8.10, 8.10.5, 8.10.12, and 8.11 on the following topics: facilities and equipment, facility diagram, radiation safety program, spill and contamination procedures, area surveys, and waste management.

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 11: Waste Management

Provide the following:

- A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

AND

- Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration or compaction.

From: [David Theel](#)
To: [Torres, Roberto](#)
Subject: [External_Sender] Re: NRC request for additional information
Date: Tuesday, June 15, 2021 3:04:34 PM
Attachments: [01_NRC Request for Info.pdf](#)

?Mr. Torres,

Please find attached the response to your request for additional information. I hope that I have left nothing out, but if I have, please feel free to reach out to me via email or the phone number listed below.

Thank you,
David Theel, DABR
Radiation Safety Officer
208-221-8322

From: Torres, Roberto <RobertoJ.Torres@nrc.gov>
Sent: Monday, June 14, 2021 8:55 AM
To: David Theel; David Theel - IFCH
Subject: [External Email] NRC request for additional information

Mr. Theel:

The NRC has received your amendment request for the use of Lu-177 for medical use and additional information is needed. Lu-177 will be included in item 6.C. of the license (any byproduct material permitted under 35.300). Please provide your response in a signed and dated letter (in pdf format) by reply email addressing the items described below.

1. Mountain View Hospital, NRC license number 11-35120-01, commits to:

A. follow the NRC licensing guidance for the medical use of Lu-177 described in memorandum dated June 1, 2018 (ML18136A824),

B. develop, implement and maintain written procedures for the safe use of unsealed Lu-177 permitted by 10 CFR 35.300 that meet the requirements of 10 CFR 20.1101 (Radiation protection programs) and 10 CFR 20.1301 (Radiation dose limits for individual members of the public),

C. only allow physicians authorized for the use of any beta emitter or any photon emitting radionuclide with a photon energy less than 150 keV under 10 CFR 35.390, to administer Lu-177, and

D. develop, implement and maintain written waste disposal procedures for Lu-177 and detectable quantities of Lu-177m in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part

20, Subpart K, and of 10 CFR 35.92.

1. The individuals (maintenance and department supervisor) who will have access to the key of the outbuilding (new waste storage area) will need to receive radiation safety training commensurate with their duties. Commit to provide 10 CFR Part 19 and Part 20 required radiation safety training to all the individuals who will have access to the outbuilding (new storage area) at 1550 Hoopes Avenue, Idaho Falls, Idaho.

1. The amendment request letter dated May 24, 2021, makes reference to the licensee's name as "Mountain View Hospital" as well as "Idaho Falls Community Hospital". Confirm the legal entity name and indicate if a change of ownership of the licensee has occurred. Indicate if the licensee's name need to be modified to reflect a dba (doing business as) if this is the case, and request the licensee's name to be amended.

1. Will there be a need to increase the possession limit in item 8.C. in the license as a result of using Lu-177? Request that item 8.C. be amended and provide a new maximum possession limit or indicate that no change is needed for item 8.C.

Thank you for your cooperation.

Roberto J. Torres, M.S.
Senior Health Physicist
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1600 East Lamar Boulevard
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817-200-1189

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Mr. Roberto Torres
USNRC/DNMS Region IV

Thank you for the review of Mountain View Hospital request for amendment dated 5/24/2021.

This amendment request is for only:

Mountain View Hospital
Lic# 11-35120-01
2325 Coronado Street
Idaho Falls, Idaho 83404

Currently, according to Lic# 11-35120-01 listed in item 10:

10. A. Licensed material in Subitem No. 6.D. may be used at the licensee's facilities located at Mountain View Hospital, 2325 Coronado Street, Idaho Falls, Idaho.
B. Licensed material in Subitem Nos 6.A. through 6.C. may be used at the licensee's facilities located at Teton Cancer Institute, Radiation Oncology, 1550 Hoopes Avenue, Idaho Falls, Idaho.

The amendment request is to allow the possession and therapy for 10 CFR 35.300 (Subitem No. 6.C.) to additionally occur at the parent facility Mountain View Hospital address at 2325 Coronado Street.

The Authorized Users and the clinical administration staff that currently perform the administration at the Teton Cancer Institute will also be performing the administration at the parent facility of Mountain View Hospital. We have already conducted training for the nursing staff in the unit where the procedure will be performed. What will determine the location of the administration is a stratification of patients into Low to High Risk for abnormal retention and elimination of the isotope in the hours following the administration. Low Risk to Medium Risk patients who are not likely to need additional medical intervention or the medical care of an inpatient setting will receive their administration at Teton Cancer Institute, an outpatient facility with no inpatient capacity. High Risk patients will receive their administration at Mountain View Hospital, with the approval of the amendment, to accommodate any overnight stays for medical observation of patients with insufficient kidney function or other medically necessary interventions.

The conditions listed in the paragraph above are NOT related to "RG 8.39 Rev 1 C.1. Release Criteria," but instead are related to medical conditions that the patient may have that interfere with the patient's ability to eliminate the radioisotope through excretion at a rate that is commiserate with the published studies conducted regarding Lu-177 that describe doses to other tissues. In order to prevent higher doses to those tissues due to atypical retention, the physicians may decide to admit the patient for observation and administration of diuretics or other interventions that the physician may deem medically necessary.

The Release Criteria for Lu-177 has been calculated and applied to the standard therapeutic unit dose of 200 mCi using "RG 8.39 Rev 1 C.1.3 Release of Patients Based on Patient

Specific Dose Calculations” that is to be used when the administered isotope is not presented in Table 1 of the same document. The patient are released with the calculated 0.25 Occupancy described in RG 8.39 Rev 1 Equation 1, and given release instructions to insure the safety of the public and care providers. These instructions are acknowledged by the patient prior to the administration of the isotope.

In dealing with the metastable product, Mountain View Hospital has established a pay service with Thomas Gray and Associates to remove the low-level Lu-177m waste contaminate that remains following the 70 day primary decay as noted in the NRC Memo dated June 1, 2018 addressed to Director James Trapp.

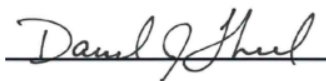
The policies and procedures that we used for administration of Lu-177 at Teton Cancer Institute have been expanded to include the new inpatient setting at Mountain View Hospital.

The occupational dose, radiation safety, and administration policies of Mountain View Hospital remain in place and require no updating to accommodate the addition of the 2325 Coronado address for 10 CFR 35.300 procedures.

Anyone with Hot Lab access is required to complete a minimum of a Radiation Package Receipt module in Health Stream that covers safe handling practices and exposure expectations with package labeling. This same module will be used in training the staff members allowed access to new decay storage box located in the outbuilding at the 1550 Hoopes Avenue address. Those records are administered and maintained by the education department with annual oversight by the RSO.

We do not anticipate the need to increase the possession limit with Lu-177 because the program numbers will not change. The only thing that will change is the location of the administration and the possibility of inpatient stay for medical necessity not related to procedures for radioactive patient release.

If you have any other questions, please do not hesitate to contact me.
David Theel, DABR
Radiation Safety Officer
Mountain View Hospital
Idaho Falls, Idaho



06/15/2021