

From: [Nathan Bryant](#)
To: staff@nuclearstresstest.net
Subject: Request for Additional Information
Date: Friday, November 1, 2024 4:19:00 PM
Attachments: Incredible Heart, LLC..pdf

Good afternoon,

This email is in response to the new license application dated September 6, 2024. Upon review of your request, there were areas identified that requires additional or clarifying information in the attached document.

Additionally, a pre-licensing site visit will be required for this new license application. I will be accompanied by Jason Kelly, Health Physicist. We have the following dates we are available to perform the visit: November 14th or 21st at 3:00 p.m. or November 15th or 22nd 10 a.m. to 12 p.m. If these times don't work, please let me know at your earliest convenience to discuss additional availability.

Please provide a management signed response by November 28, 2024. As you will not receive a hardcopy of this request for additional information, please confirm that you have received this email.

Thank you,

Nathan Bryant
Health Physicist
RIII/DRSS/MLB
630-829-9861



Incredible Heart, LLC.

1. [Table C-1 of Appendix C of NUREG 1556, Vol. 9 Rev.3](#) illustrates an acceptable format for describing the requested radioactive material and provides a purpose of use.

Radionuclide	Form or Mfr/Mod No.	Max Qty	Purpose of Use
Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
Any radionuclide in excess of 30 mCi for use in calibration, transmission, and reference sources. List radionuclide: _____	Sealed source (Manufacturer _____, Model No. _____)	___ mCi	For use in a Manufacturer _____, Model No. _____ for calibrations and checking of licensee's survey instruments.

Your request for authorized use did not align with the guidance. In particular, your request for transmission or reference sources may not be applicable unless you are requesting sources with an activity exceeding 30 mCi.

Please indicate if you require authorization for any sealed sources with a quantity exceeding 30 mCi. If applicable, please provide the radionuclide, manufacturer / distributor name of the sealed source and device, and activity.

2. Section 8.7.1 of NUREG 1556 Vol. 9 Rev. 3 lists acceptable formats in identifying a Radiation Safety Officer in accordance with [Title 10 of Code of Federal Regulations \(10 CFR\) 35.50](#).

Your request included an incomplete copy of the Florida Radioactive Materials License No. 4072-5 Amd. 22.

Please provide a complete copy of the Florida RAM license in which Armando Clavero was listed as RSO to provide verification that the authorized uses as described in Items 6,7,8 of the Florida license are applicable with those requested.

3. Section 8.7.1 of NUREG 1556 Vol. 9 Rev. 3 provides further guidance on Radiation Safety Officer requirements. It is unclear if proposed RSO is an outside consultant. Please clarify if proposed RSO is an outside consultant or in-house representative. If proposed RSO is an outside consultant, the following items will need to be addressed:
 - a. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO, as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the size of the program).

- b. Identify an in-house representative who will serve as the point of contact during the RSO's absence.
- c. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

If applicable, please provide the above information for your proposed RSO.

4. Please provide applicable contact information for the proposed RSO, including the following as applicable:
 - a. office phone number
 - b. mobile phone number
 - c. fax number; and
 - d. e-mail address.
5. Section 8.7.2 of NUREG 1556 Vol. 9 Rev. 3 provides guidance on acceptable verification of Authorized Users. The following items were identified:

Upon reviewing the board certification, it has been identified that the application is lacking certification from any of the NRC recognized specialty boards that meet NRC requirements in 10 CFR 35.290 "Training for imaging and localization studies." Upon reviewing the classroom training certificates, the submitted certificate has a completion date of 8/10/2016, which does not meet the 10 CFR 35.59 "Recentness of Training" requirement that states training must be obtained within 7 years preceding the date of the application. More recent training will be required.

If applicable, please submit one of the following:

- a. The Medical Uses Licensees Toolkit web page provides [NRC Form 313A \(AUD\)](#) to be used to document training and experience. Please provide a completed NRC Form 313A (AUD) that includes appropriate recentness of training.
- b. Alternatively, it is noted that correspondence with the Certification Board of Nuclear Cardiology was included in the application. If certification was obtained since the submission of this application, please provide the CBNC certificate as an acceptable verification of authorized use.

6. In the following areas, you have provided more information than what is required in Appendix C of NUREG 1556 Vol 9. Rev 3. By doing, you may be over committing, and you will be subject to the more restrictive procedure when inspected. You may keep these sections as they are but will still need to provide the following statements listed:

a. Please provide the following statement regarding training for individuals working in or frequenting restricted areas:

“We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.”

b. Your statement in your application did not provide all the information specified in guidance. Therefore, please provide one or both of the following statements regarding radiation monitoring instruments:

i) "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

and/or

ii) "We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."

c. Please provide one or both of the following statements regarding occupational dose:

“We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in [10 CFR §20.1502](#);

or

“We will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety Program–Occupational Dose’ in NUREG–1556, Vol. 9, Rev. 3, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees;”