**From:** Nguyen, Janice
**To:** "kkassel@alliancehealthcareservices-us.com"
**Subject:** NRC Request for Additional Information for Alliance HealthCare Services, Inc. (Mail Control Number 589378)
**Date:** Thursday, December 17, 2015 12:45:00 PM

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**PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL**

Licensee: Alliance HealthCare Services, Inc.
License No. 47-25570-01
Docket No. 030-35774
Control No. 589378

Dear Ms. Kassel;

This is in reference to your letter dated October 13, 2015, requesting to amend Nuclear Regulatory Commission License No. 47-25570-01. In order to continue our review, we need the following additional information:

1. All correspondence should be signed by a senior management representative from Alliance HealthCare Services, Inc. (rather than the Corporate Radiation Safety Officer). Please submit a letter signed by senior management indicating that they have reviewed the letter from Alliance HealthCare Services, Inc. dated October 13, 2015, and concur in the statements and representations contained therein.

2. You have requested to add the use of a Bracco CardioGen-82 Infusion system. With the use of this system, there are two instances in which it is not possible to meet the current NRC regulatory requirements: (1) the medical use calibration requirements for the radiation detectors associated with Rb-82 generator systems and (2) the inability of users of those systems to determine the dosage of the Rb-82 before medical use. Enforcement Guidance Memorandum EGM-13-003 was issued on April 18, 2013 to provide guidance for dispositioning inspection findings related to a licensee's implementation of calibration requirements for rubidium-82 (Rb-82) activity measurement systems in accordance with 10 CFR 35.60; and the requirement to determine the Rb-82 dosage before medical use in accordance with 10 CFR 35.63. In order to be considered for future enforcement discretion, please make the following commitments:

   a. Please confirm you have written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications. Please confirm that you will perform these tests, at least every 12 months (and repeated after repair or replacement), and maintain records documenting the performance and results of these tests. The radiation detector specifications are compared to the values obtained during tests of the detector's electronics and the response to a radiation source in the static mode. You may use documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and radiation detector test.

      Note: If in the future the manufacturer were to develop a calibration procedure

(i.e., accuracy, linearity and geometry evaluations of the detector), then such calibration must be performed for the detector as opposed to the electronic and radiation function tests, as currently used.

b. Please confirm that all authorized users (AU) for medical uses under 10 CFR 35.200 who will be using Rb-82 chloride, as well as the Radiation Safety Officer for your facility, have successfully completed training specific to the manufacturer and model of generator and infusion cart being used.

Such training must include: (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedures for the clinical use of Rb-82 chloride.

Until the manufacturer develops static or dynamic calibration procedures for calibrating the radiation detector in the infusion cart, the quality control procedures must include: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer.

This training requirement is met by satisfactory completion of a training program, which addresses all of these required topics, provided by the manufacturer. The licensee must maintain documentation that all AUs using Rb-82 and the RSO have satisfactorily completed such training.

c. Please confirm that you will record the activity of each dosage administered, as provided by the infusion cart.

d. Please confirm that you will follow the manufacturer's instructions contained in the CardioGen-82 Quality Control Procedures.

3. Please confirm that all Bracco CardioGen-82 generator waste with residual Sr-82 and Sr-85 will be held for a minimum of ten half-lives and surveyed to be indistinguishable from background levels of radiation prior to disposal.

4. In your application, it is not clear whether or not the storage location in Owasso, MI is controlled by an entity other than yourself. If so, please provide documentation of a clear, contractual agreement 1) designating the space for use by Alliance; 2) documenting that only Alliance will have keys; and 3) allowing Alliance to access the waste storage location in Owasso, MI for the purpose of decontamination or removal of licensed material in the event of disharmony between you and the owner entity. This documentation should consist of signed certification from both parties. Alternatively, you may confirm that the entire building is owned by Alliance HealthCare Services, Inc.

5. Please confirm that the Bracco CardioGen-82 generator will remain on the mobile van, and provide any additional shielding during its use.

6. Please confirm that there is nothing below the waste storage closet located in

Owasso, MI.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 589378. If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your application. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;**then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you in advance for your help.

Sincerely,

*Jan Nguyen*

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