**From:** Ford, Monica
**To:** IsraelJ@uhcwv.org
**Cc:** Lanzisera, Penny; Gaskins, Farrah
**Subject:** NRC request for additional information - License renewal for United Hospital Center
**Date:** Friday, April 03, 2015 3:02:00 PM

Licensee: United Hospital Center
License No.: 47-01458-01
Docket No.: 03003375
Control No.: 585502

Dear Mr. Israel:

Please send a return email to confirm that you received this message.

This is in reference to the application dated November 24, 2014 requesting to renew Nuclear Regulatory Commission License No. 47-01458-01. In order to complete your renewal application, we need the following additional information:

1. Items 5 & 6

    a. You requested any byproduct material permitted by 10 CFR 35.300 and also Iodine -131 in any capsule form. Please note that Iodine-131 can be used under the authorization for 35.300. Please confirm if you will use Iodine-131 under this authorization and whether you wish to increase the possession limit to 3 Curies or if 1.5 Curies will be adequate.

    b. Please confirm if you currently use or possess material authorized under 10 CFR 31.11. If you wish authorization for these materials, you may wish to use the materials under a general license and file NRC Form 2.

    c. You requested use of the Nucletron Model number microselectron-HDR V2 for the High Dose Rate (HDR) Remote Afterloader. Please confirm if this is the same model as the one listed on your current license. Also, please provide the Sealed Source and Device Registry number.

    d. You are currently licensed for 600 millicuries of any byproduct material permitted by 10 CFR 35.400 (specifically Cs-137, I-125, and Pd-103). In your current application you requested byproduct material permitted by 10 CFR 35.400 – Cs-137: 280 millicuries and byproduct material permitted by 10 CFR 35.400 – I-125 and Pd-103: 150 millicuries. Please provide a current source inventory list and confirm:

        i. that these are the correct maximum quantities needed as their total is less than the maximum quantity that you are currently authorized for.

        ii. Whether the Cs-137 sources are “in storage” awaiting disposal and no longer used for patient treatments.

2. You requested for Amy Patrick, M.S. to be authorized for instrument calibrations. Ms. Patrick is not currently listed on the license for this authorization. Please

submit documentation of training and experience demonstrating that Ms. Patrick is qualified to use the types and quantities of licensed materials for the requested uses. In addition, please provide the instrument calibration procedures and calibration facility description.

3. The report issued by Physics Solutions, LLC recommends the amount and type of shielding used in the PET department and HDR suite. Please confirm that the amounts recommended were installed. The recommendations do not include shielding above seven feet high. Since public dose limits do not have a height restriction, describe the shielding installed above seven feet. Alternatively you may submit survey data to support that dose rates are below 2 mRem in any one hour above seven feet.

4. Please provide a statement that "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

5. With regard to Item 9.d HDR Remote Afterloader – Calibration and Use

    a. 10 CFR 35.643 requires that:

        i. Spot checks are performed before the first use of a high dose rate remote afterloader unit on a given day and after each source installation. Please correct your HDR Remote Afterloader Daily Checks procedure to reflect that the spot checks will also be performed after each source installation.

        ii. You must assure proper operation of clock (date and time) in the unit's computer. Please add this to the procedure and describe the acceptance criteria for checking the clock date and time on the computer.

        iii. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check in addition to reviewing the results of the spot checks within 15 days. Please add this requirement to the procedure.

        iv. You must assure proper operation of all warming lights. Please describe how lights on the HDR unit are verified and confirm that you will add this to your procedure.

    b. Please provide a description of how you will verify that the viewing and intercom system is functioning properly.

6. 10 CFR 35.610 requires detailed procedures for responding to abnormal situations when the operator is unable to place the source in the shielded position. In your application Item 10 addresses these procedures. Please:

    a. Confirm that for licensed activities where sources are placed within a patient's or human research subject's body, a licensee shall only conduct treatments

which allow for expeditious removal of a decoupled or jammed source;

b. Confirm that whole body and extremity dosimetry is provided for emergency responders; and

c. Indicate whether a suture removal kit will be available.

d. The actions specified for emergency response should give primary consideration to minimizing exposure to the patient and healthcare personnel while maximizing patient safety. Please confirm:

i. That you only permit individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room with the sources.

ii. That operators, authorized medical physicists, the Radiation Safety Officer, and authorized users will participate in drills at least annually.

7. Your application describes different areas for nuclear medicine, nuclear cardiology, and PET studies. Please list the manufacturer and model number of the dose calibrator used in each area.

8. Please indicate whether or not doses containing alpha emitting unsealed byproduct material are used. If alpha emitting unsealed byproduct material is used please include a statement that “dosages will be determined by relying on the provider’s dose label for measurement of the radioactivity and the combination of volumetric measurement and mathematical calculation.”

9. Please confirm that your procedures for the safe use of unsealed byproduct material as described in the application are “written” procedures.

10. For Iodine-131 and brachytherapy in-patient rooms, please provide calculations for maximum activity administered and average patient room design, in order to show that the public dose limit is not exceeded in the surrounding areas.

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).

You may respond to my attention in writing by letter, email (if scanned into a pdf format), or fax (610-337-5269), referencing mail control number 585502. Please ensure that your response is signed by an appropriate licensee management representative.

If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your amendment. Please feel free to contact me with any questions you may have.

Kindest regards,

**Monica Ford**

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