UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

November 1, 2023

Patrick Charmel, President/CEO
Griffin Hospital
130 Division Street
Derby, CT 06418

SUBJECT: GRIFFIN HOSPITAL REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 636444

Dear Patrick Charmel:

This is in reference to your application dated June 12, 2023, requesting to renew NRC License No. 06-13905-01. The items below reference NUREG-1556, Volume 9, Revision 3, which can be found online at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In order to continue our review, we need the following additional information:

1. Item 5, Radioactive Material – Section 8.5. Your renewal requested approval of any byproduct material permitted by 10 CFR 35.500 sealed sources for calibration, reference, and/or transmission sources with an activity of 300 mCi per source and a total of 1000 millicuries. Since these sources exceed the limits allowed in 10 CFR 35.65, you must provide: the radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. You should include all possible alternate source models you might use to minimize the need for license amendments if you change model or vendor. Additionally, you must indicate the authorized user who is designated for the use of this material and provide documentation of their training and experience as required by 10 CFR 35.590.

2. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Section 8.8. Your renewal application did not contain the requested commitments concerning training for individuals working in or frequenting restricted areas. Therefore, please provide the following commitment concerning 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."

3. Item 9 - Facilities and Equipment – Section 8.9.1. You provided three diagrams – a more detailed, focused diagram and a broader floor plan of the premises. However, not all of the information requested under Item 9 of NUREG 1556, Vol. 9, Rev. 3 was provided. Therefore, please provide the following:

    a. Provide room numbers, if applicable, for rooms or areas where byproduct material is prepared, used, and stored.

    b. Specify which doors are access controlled (i.e., locked).

    c. Specify if you store any radioactive waste in stress or nuclear scan rooms.

    d. Please confirm that you will not perform any PET procedures at your facilities.

    e. For the in-patient I-131 room provide shielding calculations or documented surveys for radiation readings for the maximum dose administered, demonstrating compliance with the public dose limits. Additionally, provide the principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below the therapy treatment room.

    f. Confirm that I-131 will be administered in capsule form only; otherwise provide facilities and procedures that will be used to administer liquid I-131.

4. Item 9 – Facilities and Equipment – Relative to your radiation monitoring instruments and dose calibrator:

    a. Section 8.9.2. You stated that you will be using the Captus 4000e to perform the required area surveys; however, I believe you mean it will be used to count the wipe tests. Please provide the instrumentation used to conduct daily radiation surveys.

    b. Section 8.9.2 Provide the following commitment: “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”

    c. Section 8.9.3. A description of the equipment used to measure the dosages.

    d. Section 8.9.3. If you are using any alpha emitters, for measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer’s instructions to calibrate the instrument.

5. Item 10 – Radiation Safety Program-

    e. Section 8.10.2. Your application contained a commitment to either perform and document a prospective an evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of 10% of regulatory limits or you will provide dosimetry that meets the requirements listed in NUREG-1556, Vol. 9, Rev.3. However, the commitments did not mention that

you will maintain documentation for inspection. Please confirm that you will maintain documentation for inspection.

f. Section 8.10.10. Provide the following commitment: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded licensed material in storage is secured from unauthorized access or removal licensed material not in storage is maintained under constant surveillance and control records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

g. Section 8.10.11. Provide the following commitment: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67."

6. Section 1.2.3. Please indicate if your facility is conducting any human research under 10 CFR 35.6. Please note that if research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee, shall provide a written commitment that the licensee will, before conducting research: 1) obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and 2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

We will continue our review upon receipt of this information. Please reply to my attention at Robin.Elliott@nrc.gov.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5076 or via electronic mail at Robin.Elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

Robin L. Elliott

Digitally signed by Robin L. Elliott
Date: 2023.11.01 08:12:06 -04'00'

Robin L. Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-13905-01
Docket No. 030-01300
Mail Control No. 636444

cc: Christine Cooper, Radiation Safety Officer

GRIFFIN HOSPITAL REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 636444 DATED NOVEMBER 1, 2023.

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L06-13905-01.636444.RAI.docx
SUNSI Review Complete: RElliott
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NAME	RElliott (RLE)							
DATE	11/1/2023							

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