UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

December 4, 2014

Docket No. 03001246 License No. 06-00854-03
Control No. 584263

Robert Falaguerra
Vice President, Facilities, Support Services, and Construction
Saint Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105-1299

SUBJECT: SAINT FRANCIS HOSPITAL AND MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL TO LICENSE, CONTROL NO. 584263

Dear Mr. Falaguerra:

This is in reference to your application dated June 30, 2014 requesting to renew Nuclear Regulatory Commission License No. 06-00854-03. In order to continue our review, we need the following additional information:

1. Please provide a Sealed Source and Device certificate of registration number for the strontium-90 sealed source manufactured by Tech Ops, Model M1. Also, please indicate if this source is still in use or in storage. If in storage, please describe your disposal plans.

2. Please provide a Sealed Source and Device certificate of registration number for the strontium-90 sealed source manufactured by PTW-Freiburg, Model BR 206.

3. In support of your request to authorize Dr. Colasanto for materials permitted under 10 CFR 35.300, please provide one of the following, as applicable:

    a. Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which Dr. Colasanto was specifically named as an authorized user for 10 CFR 35.300; or

    b. Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR 35.390 (see www.nrc.gov); or

    c. Description of the training and experience identified in 10 CFR Part 35.390 demonstrating that Dr. Colasanto is qualified by training and experience for the use requested; and

    d. Written certification, signed by a preceptor physician authorized user, that the above training and experience has been satisfactorily completed and that a level

of competency sufficient to function independently as an authorized user for medical uses authorized has been achieved; and

e. If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

NRC Form 313A (AUT) (http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aut).pdf) may be used to document this information. Please note that if the board certification, or training and experience, was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

4. Please provide the correct spelling for one of the medical physicists requested – the application requests that George M. Dascolov, Ph.D. be listed while Amendment 114 of License No. 06-00854-03 lists him as George M. Daskalov, Ph.D. In addition, please confirm that you wish to remove C-14 for instrument calibration from Dr. Daskalov and Dr. Wilcox's authorization.

5. For the Nuclear Medicine, Cardiology, and PET Imaging areas, on a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-d) and describe the type, dimensions, and thickness of shielding that you will use. Figure 8.1 of NUREG-1556, Vol. 9, Rev.2 may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

   a. Use and storage of Tc-99m generators, iodine-131, and xenon-133.

   b. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as non-radioactive waste. If this area is not located within your main department, describe how you will secure the material.

   d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

6. Please provide facility diagrams, with installed shielding, of the entire PET department, including the imaging room, quiet rooms, dedicated bathrooms, and any other areas where licensed material is used and/or stored. These diagrams should also indicate adjacent areas, including above and below, and show what areas are to be restricted or unrestricted as defined in 10 CFR 20.1003. In addition, please provide details of any specialized equipment for use of the 511 keV emitters (syringe shields, L-block, emergency equipment, etc.). If your well counter is located in your hot lab, describe any additional shielding of the detector. In addition, please provide shielding calculations for your PET facility.

7. Your current license authorizes any diagnostic study or therapeutic procedure permitted by 10 CFR 35.300 and manual brachytherapy under 10 CFR 35.400. Please provide detailed information on the room(s) used for in-patient procedures involving 10 CFR

35.300 or 35.400 (floor plans or diagrams, adjacent areas including above and below the rooms). Alternatively you may confirm that you will only treat patients that are releasable in accordance with 10 CFR 35.75.

8. Please confirm your zip code; 06106-1299 or 06105-1299.

9. Your application states that calibration of survey instruments will be performed by a qualified service engineer. Please confirm that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

10. 10 CFR 35.12(b) (2) requires that licensees submit procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, as applicable. Please provide the step-by-step spot-check procedures and acceptance criteria for the items listed in 10 CFR 35.643 (e.g., electrical interlocks) for your remote afterloader.

11. With regards to your HDR facility:

    a. Please confirm if any radiation producing equipment is or will eventually be housed in the HDR treatment room. If so, please confirm the steps that will be taken to ensure that no two radiation producing units can be operated simultaneously;

    b. Please submit a facility diagram that identifies the activities conducted in all contiguous areas surrounding the area of use. Location, room numbers, and principle use of each adjacent room should be provided, including areas above, beside, and below, indicating whether the room is a restricted area as defined in 10 CFR 20.1003. Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The shield calculations should include estimated workload and hours of use. The diagram should include the exact location that the HDR unit will be used and stored. All diagrams should be to scale, indicating the scale used;

    c. Please confirm where the radiation monitor will be located (e.g., will it be visible to someone who enters the room);

    d. Please describe the warning systems and restricted area controls (e.g. locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;

    e. Please confirm where viewing and intercom systems will be located;

    f. Please describe methods used to ensure that whenever the device is not in use or is unattended the console keys will be inaccessible to unauthorized persons; and

    g. Please provide a description of emergency response equipment.

12. 10 CFR 35.610 requires, in part, that all device operators, authorized medical physicists, authorized users, and the Radiation Safety Officer participate in drills of the emergency

procedures, initially and at least annually. Please confirm that emergency drills will be done as part of the initial and annual training and specify who will participate in them.

13. We understand that you no longer conduct research activities. Please confirm our understanding and confirm that you will submit decommissioning and disposal records as a separate amendment request soon.

14. With regards to your irradiator program:

    a. Please confirm that before using licensed materials, authorized users will receive the training described in Appendix G in NUREG-1556, Vol. 5, dated October 1998;

    b. Please confirm that you will ensure that each area where a self-shielded irradiator is located corresponds to the "Conditions of Normal Use" and Limitations and/or Other Considerations of Use" on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.

    c. Please confirm that you will use radiation monitoring instruments that meet the specifications published in Appendix K to NUREG-1556, Vol. 5 and that each survey meter will have been calibrated by an authorized calibration service provider. Further, confirm that you will ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.

    d. Please confirm that physical inventories will be conducted at intervals not to exceed six months to account for all sealed sources and devices received and possessed under the license;

    e. Please confirm that if you make changes to your Operating Procedures for the irradiator without amending the license, you will ensure that: the changes are reviewed and approved by the RSO; the affected staff will be trained in the procedures before they are implemented; the changes are consistent with applicable license conditions and procedures or commitments submitted in the license application; and the changes will not degrade the safety of the program;

    f. Please confirm that Operating and Emergency procedures will be developed, implemented, maintained and distributed and will meet the Criteria in the section entitled, "Radiation Safety program- Emergency procedures" in NUREG-1556, Vol. 5, dated October, 1998;

    g. Please confirm that leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device

Registration Certificate. In addition, please confirm that leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for other licensees and according to the manufacturer's (or distributer's) and kit supplier's instructions, or as an alternative, that you will perform leak testing and adopt the model leak test program published in Appendix P to NUREG-1553, Vol. 5, dated October 1998;

h. Please confirm that you will implement and maintain procedures for routine maintenance of your self-shielded irradiators according to each manufacturer's (or distributer's) written recommendations and instructions;

i. Please confirm that you will have the self-shielded irradiator manufacturer (or distributer's) or other person authorized by NRC or an Agreement State perform non-routine maintenance.

In addition, please note that the detailed procedures for your irradiator (e.g. calculation of Blood Irradiation Cycle Time) were not required to be submitted and were not reviewed as part of your license renewal.

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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 584263. If you have any technical questions regarding this deficiency letter, please call Mr. Robert Gallaghar at (610) 337-5182.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Gregory S. Hisel, C.H.P., Radiation Safety Officer

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