To: Patrick Grusenmeyer
Senior Vice President
From: Lester Tripp
NRC Region 1
Licensee: Christiana Care Health Services, Inc.
Docket No. 03001303
Control No. 582765
License No. 07-12153-02
Date: 05/07/2014

This is in reference to your application dated December 17, 2013, requesting renewal of your Nuclear Regulatory Commission License No. 07-12153-02. In order to continue our review, we need the following additional information:

1. With regard to Item 10.3 of your renewal application, please confirm that you will develop, implement and maintain ***written*** procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.

2. Describe the emergency response equipment available for manual brachytherapy facilities. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials labels.

3. Please describe areas above and below the Cyberkife/HDR room 1166 at the Cancer Center and any shielding required.

4. Please identify any locations of penetration through shielded barriers (e.g., HVAC ducts or cable pass-throughs) surrounding the proposed HDR treatment room and describe the shielding of the penetrations.

5. Please identify the locations of HDR radiation monitors used for your current and proposed HDR rooms to indicate source exposure and indicate whether they will be visible to an individual that enters the treatment room during source exposure. In addition, please confirm that back-up battery testing will be performed on treatment days before patient treatments.

6. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an unretracted or stuck HDR source.

7. Please provide your HDR periodic spot-checks procedures. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot-checks for remote afterloader units required by 10 CFR 35.643. Please provide *detailed step-by-step* procedures that describe how you will perform each test below and the criteria for acceptable results:

    a. Electrical interlocks at each remote afterloader unit room entrance;

    b. Source exposure indicator lights on the remote afterloader unit, on the

control console, and in the facility;

c. Viewing and intercom systems (except for low dose-rate remote afterloader facilities);

d. Emergency response equipment;

e. Radiation monitors used to indicate the source position;

f. Timer accuracy;

g. Clock (date and time) in the unit's computer; and

h. Decayed source(s) activity in the unit's computer.

In addition, please confirm that if spot-check results indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

8. Please confirm the methods to secure the treatment room door and console keys whenever the unit is not in use or is unattended. Specifically, describe how and where the HDR keys will be secured.

9. With regard to your HDR program, please note that 10 CFR 35.615(f)(2) requires that:

   a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

   b. An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

Please confirm that you will comply with 10 CFR 35.615(f)(2).

10. Please confirm that the HDR patients administration will be performed in accordance with the written directive.

11. For Y-90 microsphere use:

    a. Please commit to manufacturers' procedure for assaying patient dosages;

    b. Please confirm that if the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU will document such changes in the written directive within 24 hours after the completion or termination or the administration. The modification to the written directive must include the reason for not administering the intended dose/activity, the date, and the signature of an AU for yttrium-90 microspheres;

c. Please confirm that the written directive shall include the patient or human research subjects name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide including physical form (Y-90 microspheres); the prescribed dose/activity; the manufacturer; and if appropriate for the type of microspheres used, the statement, “or dose/activity delivered at stasis”;

d. Please confirm that the administration of Y-90 microspheres will be performed in accordance with the written directive;

e. Please confirm that you will follow the manufacturer’s procedure for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternate methods.

12. Please confirm that for radium-223, unit doses only will be used or if you plan to use other than unit doses, please provide the following statement: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation";

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. 582765. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5358.

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.

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