

From: Donna Janda
To: Jgiardina@petroneassoc.com
Date: Tue, Apr 18, 2006 10:29 AM
Subject: Additional information needed for Christ Hospital

Licensee: Christ Hospital
License No. 29-12644-01
Docket No. 03002556
Mail Control No. 138505

Subject: Additional information needed for license amendment request

Dear Mr. Giardina:

In order for us to continue our review of Christ Hospital's request for HDR authorization under 10 CFR 35.600, we need the following additional information:

1. Christ Hospital requested a possession limit of 21 curies for iridium-192 permitted by 10 CFR 35.600. Item 8 on your license will state "2 sources, 1 source not to exceed 12 curies and one source not to exceed 9 curies." Please confirm that this is acceptable.

2. In order to continue our review of Christ Hospital's request to add Julie Lo, M.S., as an authorized medical physicist (AMP), please provide the following information:

a) a description of the training and experience demonstrating that Ms. Lo is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested; and

b) a written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved; and

c) a description of the training and experience specified in 10 CFR 35.51(c) demonstrating that Ms. Lo is qualified by training in the types of use for which she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system; and,

d) if Ms. Lo's training and experience were not obtained within the last 7 years, provide a description of Ms. Lo's recent related continuing education and experience as required by 10 CFR 35.59.

Please note that the preceptor AMP must meet the requirements of 10 CFR 35.51, or equivalent Agreement State requirements for an AMP for each type of therapeutic medical unit for which Ms. Lo is requesting AMP status.

3. In order to continue our review of Christ Hospital's request to change your Radiation Safety Officer (RSO) to Julie Lo, M.S., please provide the following additional information:

a) a description of the training and experience specified in 10 CFR 35.50(b) demonstrating that Ms. Lo is qualified by training and experience as applicable to the types of uses for which you seek approval of Ms. Lo to serve as RSO; and

b) a written attestation, signed by a preceptor RSO, that Ms. Lo has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which you seek approval and that Ms. Lo has achieved a level of radiation safety knowledge sufficient to function independently as an RSO; and

c) a description of the training and experience specified in 10 CFR 35.50(e) demonstrating that Ms. Lo is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of uses for which you seek approval of Ms. Lo to serve as RSO.

d) if Ms. Lo's training and experience were not obtained within the last 7 years, provide a description of Ms. Lo's recent related continuing education and experience as required by 10 CFR 35.59.

4. Please provide a diagram which clearly depicts the location, including the room number, of the high dose rate remote afterloader (HDR) unit during use and storage. On this diagram, provide the location of area radiation monitoring equipment that indicates the presence of radiation to an individual entering the treatment room and the location of other radiation producing equipment housed within the same or adjacent rooms. In addition, depict the room numbers and location of adjacent areas, including those areas above and below, of the HDR treatment room and storage area. Indicate whether each room or area is restricted or unrestricted as defined in 10 CFR 20.1003. Figure 8.1 of NUREG-1556, Volume 9 may be helpful in describing adjacent areas.

5. Provide shielding calculations, with information about the type, thickness and density of all shielding materials, including walls, floor, and ceiling to enable independent verification of shielding calculations. Include information on the maximum "on time" per hour and per week and occupancy factors used for all adjacent areas. Additionally, include the location and dimensions of any portable shields used for remote afterloader treatments. Shielding calculations must demonstrate compliance with the limits specified in 10 CFR 20.1301.

6. Describe the method(s) used to secure the HDR unit in the treatment room when not under constant surveillance (e.g., stored in a locket closet). In addition, describe the method used to secure the HDR treatment room (e.g., door physically secured with a lock) when not in use.

7. Please confirm that you will periodically test the radiation monitor backup battery. Provide the frequency (e.g., monthly, quarterly, semi-annually) that you will perform this test.

8. Please describe the method used to ensure that, whenever the HDR unit is not in use or is unattended, the console keys will be inaccessible to unauthorized persons (e.g., in a locked cabinet in the physics office).

9. Attachment 5 of Christ Hospital's application states that the authorized user and either the medical physicist or the RSO must be physically present for all patient treatments. Please confirm that an authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the HDR unit. In addition, please confirm that 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, will be physically present during continuation of all patient treatments involving the HDR unit.

10. Attachment 5 of Christ Hospital's application provides a general checklist for spot-checks to be performed prior to use of the HDR unit. 10 CFR 35.12(b)(2) requires, in part, that licensees submit procedures, including acceptance criteria, for periodic spot checks for the HDR unit in accordance with 10 CFR 35.643. Please provide your detailed spot-check procedures to be performed before the first use of the HDR unit on a given day and after each source installation to assure proper operation of the following:

- 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 system;
- d. emergency response equipment;
- e. radiation monitors used to indicate the source position;
- f. timer accuracy (including the duration of source exposure);
- g. clock (date and time) in the unit's computer; and
- h. decayed source activity in the unit's computer.

11. Please confirm that if the results of the periodic spot-checks indicate the malfunction of any system, the control console shall be locked in the "off" position and shall not be used except as may be necessary to repair, replace, or check the malfunctioning system.

12. Attachment 6 of Christ Hospital's application describes emergency procedures to be implemented in the event automatic retraction and emergency retraction of the source is not possible. 10 CFR 35.610(a)(4)(i) and (ii) requires that these procedures include the names of the individuals responsible for implementing corrective actions and the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally. Please confirm that you will update your emergency procedures to include this information.

Please note that the response to these items must be reviewed and submitted (i.e., signed) by a management representative of Christ Hospital. You may **not** provide your response by email. You may fax your response to my attention at 610-337-5269. Please place Mail Control No. 138505 on your response. If you have any questions regarding these items, please call me at 610-337-5371.

Thank you very much for your attention to this matter.

Sincerely,

Donna Janda
Health Physicist, Medical Branch
Division of Nuclear Materials Safety
U.S. NRC Region I

Mail Envelope Properties (4444F7B8.783 : 8 : 55404)

Subject: Additional information needed for Christ Hospital
Creation Date: Tue, Apr 18, 2006 10:29 AM
From: Donna Janda

Created By: DMJ@nrc.gov

Recipients

petroneassoc.com
Jgiardina (Jgiardina@petroneassoc.com)

Post Office

Route

petroneassoc.com

Files	Size	Date & Time
MESSAGE	12501	Tuesday, April 18, 2006 10:29 AM

Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard