

From: Donna Janda
To: CTurchin@wvhcs.org
Date: Wed, Nov 23, 2005 11:09 AM
Subject: Request for additional information for WVHCS renewal

Licensee: WVHCS-Hospital
License No. 37-16170-01
Docket No. 03010942
Mail Control No. 137313

Dear Ms. Turchin,

Thank you for providing your email address. In order to continue our review of WVHCS-Hospital's license renewal application, we need the following additional information:

1. Item 5 of your application requested, in part, possession and use of any byproduct material identified in 10 CFR 35.400. Please provide the radionuclide(s) and the sealed source manufacturer and model number for each radionuclide requested.
2. You requested Mallinckrodt Model CI L BV sealed sources for use in a Nucletron Corporation Model Selectron High Dose Rate Remote (HDR) Afterloader Brachytherapy Device. Please note that this model number is no longer available. The correct model number for this HDR afterloader device is Nucletron Model 096.001, which is manufactured by Mallinckrodt Medical or AEA Technology, Inc. Please provide the correct sealed source model number for your HDR afterloader device.
3. You are currently licensed to possess and use phosphorus-32 sealed sources in a Guidant Corporation VI Model GALILEO intravascular brachytherapy remote afterloader unit. Your renewal application does not request this authorization. If you still require it, please submit a specific request for this authorization. If you do not require this authorization, please provide documentation of transfer or disposal of the sealed sources.
4. Please describe areas and/or rooms which are located above and below the rooms where byproduct material is prepared, used, administered and stored in your Nuclear Medicine Department. Please note the location of the Stress Lab on your diagram of the Nuclear Medicine Department.
5. Provide facility descriptions, including surrounding areas and shielding, for rooms where patients will be housed if they cannot be released under 10 CFR 35.75.
6. Please describe the survey instrumentation you will use to detect stray low energy or low activity (e.g., I-125, Pd-103) seeds.
7. The diagram for the Radiation Oncology facility, which was submitted with your application, does not identify the location where the HDR unit will be used and/or stored. Please provide the location where the HDR unit will be used and/or stored and describe adjacent areas and rooms, including those above and below, the HDR room. In addition, please provide the current shielding calculations to ensure 10 CFR Part 20 limits are met.
8. Please describe the method used to secure the HDR room, HDR unit, and console keys. In addition, describe signs, warning lights, and alarms for the HDR room.
9. Emergency procedures for the HDR unit must include all items in 10 CFR 35.610(a)(4). Please re-submit your updated emergency procedures which include the information required by 10 CFR 35.610(a)(4). In addition, please confirm that your emergency response equipment includes wire cutters and associated equipment to surgically remove applicators if necessary.
10. Item 9 of your application states that you have developed and will implement and maintain

written survey meter calibration procedures. You are not currently authorized to perform these duties. If you are requesting authorization to conduct survey meter calibrations in-house, please provide the manufacturer name, model number and activity of the calibration source you will be using. In addition, provide the training and experience of the individuals who will be performing the calibrations and a diagram of the area where the calibrations will be performed. If you will not be conducting survey meter calibrations under your NRC license, please confirm that you will use a person qualified to perform survey meter calibrations for radiation monitoring instruments.

11. Attachment Item #1 of your application provides the policy/procedure for periodic spot checks for the HDR unit. This policy/procedure provides a general checklist and does not include the step-by-step procedures for the periodic spot checks. 10 CFR 35.12(b)(2) requires, in part, that licensees submit procedures 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 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 systems;
- 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.

Please submit your response to this email by December 16, 2005, by fax to my attention at 610-337-5269. Please include Mail Control No. 137313 in your response. If you have any questions regarding this email, please call me at 610-337-5371.

Thank you for your cooperation.

Sincerely,

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

CC: Penny Lanzisera

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