

From: Sandra Gabriel
To: WButler@WheelingHospital.com
Date: Fri, Apr 1, 2005 3:28 PM
Subject: NRC license amendment request for Wheeling Hospital, mail control 136537

Reference: Wheeling Hospital, Inc., 47-05322-02, 03012570, mail control 136537

Wayne Butler, Ph.D.:

Please provide the following additional information regarding your amendment request dated February 10, 2005. Please respond in writing within 30 days. You may fax your response to my attention at 610-337-5269, referencing mail control 136537. Please contact me by e-mail with any questions.

Please confirm that you received this message.

1) Please confirm that the only change in your HDR program will be the upgraded afterloader and source models. Confirm that there will be no changes to the facility information, safety systems, emergency procedures, and operating procedures submitted in your renewal application dated May 28, 2003 and letter dated August 17, 2004.

2) It is NRC's understanding that the FDA currently limits medical use of HDR devices to those containing 10 Ci of Ir-192. In order to obtain authorization for medical use of sources containing greater than 10 Ci, please provide evidence from the manufacturer that this higher activity has been approved by the FDA for medical use (e.g., 510K describing the Nucletron HDR device with a 13 Ci source activity). Otherwise your license will be written to allow possession of a source up to 13 Ci for storage and to allow installation at 10 curies. We will set your total possession limit for HDR sources to "2 sources, 1 not to exceed 13 curies and 1 not to exceed 10 curies."

3) 10 CFR 35.12(b)(2) requires licensees to submit the procedures for the periodic spot-checks for remote afterloader units described in 10 CFR 35.643. Your renewal application dated May 28, 2003 included some, but not all, of the information required by 10 CFR 35.643(d). Please confirm that your daily spot-check procedures include assurance of proper operation of: emergency response equipment, timer accuracy, clock (time and date) in the unit's computer, and decayed source activity in the unit's computer. Also provide your detailed procedure for daily timer accuracy checks, including criteria for acceptable results.

Thank you for your attention to these issues. You may wish to call or e-mail me at the time you fax your response so that I can retrieve it rapidly.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182

Mail Envelope Properties

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Creation Date: Fri, Apr 1, 2005 3:28 PM

From: Sandra Gabriel

Created By: SLG2@nrc.gov

Recipients

WheelingHospital.com

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Post Office**Route**

WheelingHospital.com

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