



CONVERSATION RECORD

02/09/2016

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Misbah Gulam, AMP		DATE OF CONTACT 02/10/2016	TYPE OF CONVERSATION <input checked="" type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS		TELEPHONE NUMBER (248) 473-6123	

ORGANIZATION Botsford General Hospital	DOCKET NUMBER(S) 03002077
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LICENSE NUMBER(S) 21-08892-01	CONTROL NUMBER(S) 588667
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SUBJECT
Third Request for additional information

SUMMARY

We have reviewed your letter dated August 24, 2015, and find that we will need additional information as follows:

1. It appears that your HDR program commitments and supporting information are based upon a version of HDR guidance that NRC discontinued using in 2002, when revised 10 CFR Part 35 went into effect and brought regulations for HDR for the first time. Much of your HDR program submission was extraneous and need not have been submitted, which has delayed completion of the review. And some information that we need was lacking, such as complete procedures and commitments for 10 CFR 35.610. In the future, please refrain from using outdated guidance (or "off the shelf" information based on outdated guidance) to support your licensing requests.

Please do not resubmit your HDR program commitments in entirety now. We wanted to make you aware of this issue for the future. Please only provide us with the specific information we are requesting to complete the HDR sections of your application for license renewal.

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ACTION REQUIRED (IF ANY)

Please submit a written response within 7 days of the date of this record (by February 17, 2016) or contact me to make alternative arrangements. Address your response to my attention at the address below in my signature block and reference it as "additional information to control number 588667."

Please respond directly to me for this case only; future new licensing requests should be addressed to the "Materials Licensing Branch Chief." Upon receipt of your written response we will continue our review.

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NAME OF PERSON DOCUMENTING CONVERSATION
Colleen Carol Casey

SIGNATURE
Colleen Carol Casey

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

2. Please provide brief, concise specific commitments and procedures for 10 CFR 35.610 (a)(3), (a)(4)(i) (please do not just submit the vendor's manual here), (a)(4) (ii) and (a)(4)(iii); and 35.610(2)(d), (e), (f), and (g). A "marked up" copy is attached for your convenience.

3. Please specify clearly which authorized materials are used at each location listed in Condition No. 10. Condition No. 10.A. on your current license leaves the impression that materials in Subitem Nos. 6 - 9 C. and D. are used at the main hospital location. However, your application for renewal does not support this conclusion. Please resolve this discrepancy.

4. Regarding my second request for additional information dated Feb. 5, 2016, concerning PET materials usage, please do respond in writing to clarify what appear to be discrepancies on your facility diagram for PET use. However, you do not need to submit shielding calculations for the PET use by your mobile service provider to us at this time for the renewal of your license. We are withdrawing that request.

Please be reminded that your mobile service provider for PET materials must provide appropriate shielding calculations to either NRC or its regulatory authority to demonstrate compliance with 10 CFR 20, including, but not limited to, 10 CFR 20.1301 and 20.1302. Please see the definition of "survey" in 10 CFR 20.1003 also. 10 CFR 35.80 and Appendix V in NUREG 1556, Vol. 9, Rev. 2 may also be useful, depending on exactly which services your provider renders, where patient dosages are delivered, whose staff conducts the PET studies (Botsford Hospital staff or the mobile provider's staff), etc.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this record will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Colleen
Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
(630) 829-9841 Direct
(630) 515-1078 Fax
NRC 24 HR Operations Center
(301) 816-5100

Gentle Reminders: Unless previously arranged with or requested by me directly, please do not submit any licensing requests, responses or correspondence via e-mail. Please only submit one complete, signed copy of your correspondence to us. Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance, as appropriate.

Thank you very much!

Please also note that my full-time work schedule includes every other Friday off.

Ensuring the health and safety of
our people, our nation and
our environment
<http://www.nrc.gov/>



Home > NRC Library > Document Collections > NRC Regulations (10 CFR) > Part Index > § 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

- (a) A licensee shall--
- (1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
 - (2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 - (3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
 - (4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include--
 - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.
- (c) A licensee shall post instructions at the unit console to inform the operator of--
- (1) The location of the procedures required by paragraph (a)(4) of this section; and
 - (2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in--
- (1) The procedures identified in paragraph (a)(4) of this section; and
 - (2) The operating procedures for the unit.

CONTINUED NEXT PAGE

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

Page Last Reviewed/Updated Wednesday, December 02, 2015