

SARA A.B. FORSTER
MATERIALS LICENSING BRANCH



NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

(630) 829-9892 FAX: (630) 515-1078

TELECON & FAX TRANSMITTAL

TO: James Brand

COMPANY: West Shore Medical Center

PAGES: 4 TEL.: (231) 398-1147

FAX #: N/A

EMAIL: bra.jam@wsmed.org

CONVERSATION RECORD

|TIME |DATE
2:00 pm June 30, 2011

NAME OF PERSON(S) CONTACTED James Brand, Radiology Manager	TELEPHONE NO. (231) 398-1147	ORGANIZATION West Shore Medical Center
REPRESENTED PERSON or PERSONS John Raymond, M.D., Radiation Safety Officer		ORGANIZATION West Shore Medical Center
SUBJECT License No.: 21-16277-01		Control No.: 574613

SUMMARY

We have reviewed your requesting license renewal application and find that we are unable to continue this action until we have received information regarding the following:

(1) The application lists the mailing address and location of use as 1465 East Park Avenue, while the current license lists 1465 East Parkdale Avenue. Based on our conversation, we understand that the correct address is the currently listed Parkdale Avenue address. No additional information is required.

(2) The application limited the radioactive materials request to those authorized under 10 CFR 35.100 and 10 CFR 35.200. The 31.11 and 35.500 materials were not listed on the license. Please confirm that you wish to remove these items from the license, and provide the last date the materials were used at the facility. Include the dates of disposal and/or transfer of 31.11 and 35.500 materials from the licensee.

(a) For 10 CFR 31.11 materials: Include the date of final disposal of all such material, in addition to relevant area surveys, following disposal.

(b) For 10 CFR 35.500 sealed sources: Include the date on which the sources were transferred to an appropriate licensee. Include confirmation from that licensee that the material was received. Also include final leak tests for each Gadolinium-153 source submitted to appropriate licensee.

(3) Under 10 CFR 35.24, a licensee's management shall appoint a Radiation Safety Officer in writing. Please provide a current, signed RSO Memorandum of Understanding/Delegation of Authority, which conforms to the requirements specified in 10 CFR 35.24(b) and 10 CFR 35.24(e). No such written statement was included with the renewal application. A sample MOU/DA letter may be found in NUREG 1556, Volume 9, Revision 2, Appendix I. Per your request, please find a copy of Appendix I, attached to this record.

(4) The Occupational Dose section, found on page 8 of the application, includes an outdated reference to NUREG 1556, Volume 5. Please resubmit 8.23 Item 10 "Occupational Dose" section of the application, including an updated reference to the relevant NUREG volume, NUREG 1556, Volume 9, Revision 2.

We have requested that you submit the referenced items:

- 10 CFR 31.11 materials removal information,
- 10 CFR 35.500 Gd-153 materials removal information,
- a current MOU/DA document, and
- a revised occupational dose program statement including a current reference.

via facsimile, to (630) 515-1078. Please reference the Control No. 574613, as listed at the top of this memo. We expect to hear from you on or before July 7, 2011.

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within 7 days of this record. **Include reference control number 574613. Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file.

Please direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Sara A.B. Forster

Sara A.B. Forster 06/30/2011

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

APPENDIX I

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

Forster, Sara

From: Forster, Sara
Sent: Thursday, June 30, 2011 4:39 PM
To: 'bra.jam@wsmed.org'
Subject: FW: Lic. No. 21-16277-01, West Shore Med. Ctr. Renewal, Control No. 574613 with attachment
Attachments: 02121.574613.21-16277-01 telecon2 signed.PDF

Hi James,

Per our conversation, please see attached. Call if you have any questions.

Sara A. B. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892

