From: Sandra Gabriel
To: pmas@harthosp.org
Date: Wed, Jan 26, 2005 4:26 PM
Subject: Additional information needed for renewal of Hartford Hospital NRC license, mail control 135589

Reference: Hartford Hospital, NRC license 06-00253-04, docket 03001239, mail control 135589

This is to follow up to our telephone conversation. Please provide the following information within 10 days. (we discussed the first 3 items earlier today.) You may fax your response to 610-337-5269, referencing mail control 135589. Please contact Shirley Xu or me with any questions.

Thank you,
Sandy Gabriel
Senior Health Physicist
NRC Region I
Medical Branch

1) For research uses and the gas chromatograph, please complete the forms in App. C and D of NUREG-1556, Vol. 7. Describe the facility where the gas chromatograph is located.

2) Your Nuclear Associates 67-850 Sr-90 eye applicator will be listed as a separate line item on your license as "Isotope Products, Inc.Model BF90Ti series (labeled as Nuclear Associates Model 67-850)" to correspond to the SS+D listing. Your 2004 NRC inspection report said the eye applicator was in storage andyou would obtain a current calibration prior to any clinical use. What is the current status of the eye applicator; is it in storage with intent to dispose or do you intend clinical use? Who should be listed as AMP(s) if clinical or non-medical user for supervision of storage?

3) Does you have any additional information about the 35.400 Nuclear Associates model 69665-33 and 69665-66 sources? Are these in clinical use or in storage with intent to dispose? If in storage, who should be listed as non-medical user for supervision of storage?

4) Your current license does not list loading dock locations mentioned in item 3 of the application; do you need these to be listed for deliveries to be made to these locations?

5) Your current license authorizes 35.500 at the 4 satellite diagnostic facilities, but this was not requested in item 3 of the renewal application. Do you wish to retain this authorization?

6) Your application states that intravascular brachytherapy procedues are no longer requested and the devices were both returned to the supplier. For both the Cordis and Novoste devices, please licensee should submit documentation of return of devices and final sources.

7) Your application requests authorization for 200 uCi of 31.11. Your current license does not list 31.11. Most of our licensees are currently either not performing in vitro testing or are doing it under a general license. Those that do specifically list 31.11 are typically authorized for 2-5 mCi. Please review 31.11, which allows possession of up to 200 uCi of I-125, I-131, Se-75,

and/or Fe-59 at any location under a general license. Consider whether you wish to revise this request.

8) We're having difficulty identifying the location of the HDR room and hot lab in the drawing of the full Radiation Oncology department. Can you describe where these are? What is above and below the HDR vault? Is there any other radiation-producing equipment in this room? On page 40 of application, item 4 says the AMP will ensure that only one device modality is operating at a time. This is fine for a mobile device, such as a C-arm, but not what we usually see for a permanently installed unit (i.e., simulator, orthovoltage unit, or linac). We typically see engineering controls rather than administrative controls: either there is a switch allowing only one unit at a time to be energized or the keys to both units are on a single key ring.

9) Are there any separate radioactive materials use or storage areas in the Children's Medical Center Building? This building is listed separately on the license but we couldn't identify any drawings associated with facilities in this building.

10) Do you perform any inpatient 35.300 or 35.400 treatments (i.e., requiring hospitalization under 35.75)? If so, describe facilities, shielding, and emergency response equipment for 35.400. Confirm that you will provide a private room/private bath for I-131 inpatients.

11) For HDR spotchecks, please describe the method used to check the area radiation monitor and timer accuracy. What is criterion for acceptable result for timer accuracy check?

12) Attachment 9d.2 addressed the operation of mobile HDR units. This license does not appear to authorize mobile HDR. Please clarify.

13) Regarding the self-shielded irradiator, please confirm the following statements from NUREG-1556, VOL. 5:

a) Confirm that you will ensure that each area where a self-shielded irradiator is located corresponds to the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the applicable Sealed Source and Device Registratiion Certificate.

b) Confirm that the floor beneath the irradiator is adequate to support the weight of the unit, the irradiator is secured to prevent unauthorized access or removal, and the area where the irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low level radiation risk attributable to fires.

c) Confirm that operating and emergency procedures will be developed, implemented, maintained, and distributed, and will meet the criteria in the section entitled "Radiation Safety Program--Operating and Emergency Procedures" in NUREG-1556, Vol. 5, dated October 1998. Also confirm that if you change your operating and emergency procedures without amending your license, you will ensure that the changes are reviewed and approved by licensee management and the RSO; affected licensee staff are trained in the procedures before they are implemented; the changes or procedures are consistent with applicable license conditions and the procedures or commitments in the license application; and the changes do not degrade the safety of the program.

d) Confirm that you will implement and maintain procedures for routine maintenance of your self-shielded irradiator according to the manufacturer's (or distributor's) written instructions. Confirm that non-routine maintenance of your self-shielded irradiator will be performed by the irradiator manufacturer (or distributor) or other person authorized by NRC or an Agreement State to perform non-routine maintenance.

14) The non-medical user authorizations requested in item 7c of your application are somewhat different than those on your current license. We will retain the current authorizations unless you indicate specific changes to be made.

15) Please submit a copy of source documentation for your Cs-137 instrument calibrator.

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From: Sandra Gabriel

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Options

Expiration Date:	None
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