UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

June 22, 2012

Docket No. 03017125 License No. 44-19196-01
Control No. 577274

Melvyn Patashnick
Chief Executive Officer
Copley Hospital
528 Washington Highway
Morrisville, VT 05661

SUBJECT: COPLEY HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 577274

Dear Mr. Patashnick:

This is in reference to your application dated March 26, 2012 requesting to renew Nuclear Regulatory Commission License No. 44-19196-01. In order to continue our review, we need the following additional information:

1. Section 8.5 on Page 1 of your application listed your request for three types of radioactive material: byproduct material permitted by 10 CFR 35.100, byproduct material permitted by 10 CFR 35.200, and sodium iodide iodine-131, 25 microcuries per capsule, for thyroid uptake procedures. Please note that oral administration of up to 30 microcuries of sodium iodide iodine-131 for thyroid uptake procedures is regulated under 10 CFR 35.100 and it is unnecessary to list this separately on your license

   Section 8.9 on Page 2 of your application stated that you are not applying for 10 CFR 35.300 and will forego the use of iodine-131 in quantities greater than or equal to 30 microcuries. This section also stated that your radiologists wish to remain as authorized users (AUs) of 10 CFR 35.300, specifically for up to 33 millicuries of sodium iodide iodine-131 for treatment of hyperthyroidism.

   NRC licenses list the institution's authorizations in Item 6, authorized uses in Item 9, and the AUs' authorizations in Item 12B. NRC policy is to authorize AUs only for uses included in the institution's authorizations in Item 6 and the institution's authorized uses in Item 9. Please clarify which of the following two options you wish to pursue:

   a. Retain your current institutional authorization in Item 6 for "iodine-131 permitted by 10 CFR 35.300," authorized use in Item 9 for "any iodine-131 study or procedure permitted by 10 CFR 35.300 in quantities less than or equal to 33 millicuries," and AU authorizations for Drs. Neel and Bennum in Item 12B for "Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries;" or

b. Remove the current institutional authorization for iodine-131 permitted by 10 CFR 35.300 and the corresponding user authorizations for Drs. Neel and Bennum.

If you choose to retain the current iodine-131 authorization, please confirm that you wish to retain the maximum possession limit (100 millicuries) that is currently listed on your license or provide a different possession limit.

2. Regarding your facilities:

   a. Please indicate room numbers (if any) for all areas of byproduct material use or preparation for use (e.g. hot lab). Please be aware that information (including diagrams) that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 2.390."

   b. You stated that there is no second floor. Please provide a description of the areas below the areas of use, if any.

   c. Attachment 8.24, Item 10A(2) – Area Survey Map, shows a treadmill in the nuclear medicine scanning room. However, Attachment 9.1.2 – Imaging Room Layout and Attachment 8.24, Item 10B(2) – Wipe Test Map seem to be the same nuclear medicine scanning room, but do not include a treadmill. Attachment 8.24, Items 10A(4) – Area Survey Stress Lab and 10B(4) – Wipe Test Map seems to be the stress lab room and includes a treadmill. Please clarify the exact location of the treadmill if it is an area of radiopharmaceutical use.

3. With regard to your response for occupational dose in Section 8.23, Item 10 of your application, please confirm that all personnel dosimetry provided will meet the requirements listed under 'Criteria' in Section 8.23, Item 10 of NUREG-1556, Vol. 9, Rev. 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'

4. The statement you provided in Section 8.25, Item 10 regarding safe use of unsealed licensed material did not indicate that the procedures will be written. Please revise this commitment by stating: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

5. In order to facilitate future communications, please provide a current contact e-mail address, telephone and fax number for your RSO and President/Senior Management.

6. Please note that several procedures were not required to be submitted, were not reviewed in detail, and will not be included as a commitment in your license. These items will be reviewed during a future inspection of your licensed activities. A cursory review of these procedures, however, identified a concern:

   Section 8.21, Item 10 – Radiation Protection Program, states that your Radiation Safety Committee (RSC) membership is comprised of at least an authorized user (AU). Although you are currently not required to establish a RSC in accordance with 10 CFR 35.24 (f), please note that if your program expands to require the

establishment of an RSC, the committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer (RSO), a representative of the nursing service, and a representative of management who is neither an AU nor an RSO.

Please revise your procedures accordingly.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, See our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 577274. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5090.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Please note that the office of the Region I USNRC Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Thank you for your cooperation.

Sincerely,

Original signed by Sandra Gabriel

Maryann Abogunde
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Bradley P. Collette, Radiation Safety Officer

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