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Porter Memorial Hospital ATTN: Gregg Bechtold Assistant Administrator 814 LaPorte Avenue Valparaiso, IN 46383

Gentlemen:

Enclosed is Amendment No. 16 renewing your NRC License No. 13-17073-01 in accordance with your request.

Please note that in accordance with 10 CFR 35.999, the regulations in Part 35 supersede your procedures described in application dated April 1, 1987 in the event they conflict. You must comply with Part 35 regardless of your procedures unless the license document contains a specific exemption paragraph to the contrary. In order to obtain an exemption to the regulations you must provide adequate justification and submit alternate procedures. All requests for exemptions are reviewed by NRC national headquarters staff and are not usually routinely granted. We will consider exemptions for unusual circumstances.

Several areas in your application currently conflict with Part 35 and specific exemptions have not been granted at this time. Therefore, you must comply with Part 35 in the following areas:

- a. 10 CFR 35.315 "Safety Precautions" for radiopharmaceutical therapy states in paragraph 35.315(8) that the licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 (this includes capsules as well as liquids) within three days.
- b. 10 CFR 35.70(f) states a licensee shall conduct surveys so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute. Item 17, page 24 of your procedures do not appear to meet this requirement.
- c. 10 CFR 35.92(a)(1) states waste must be held for a minimum of ten half-lives before it is discarded. Your procedures contained on page 25 do not meet this regulation.

If you wish to pursue a request to be exempted from these regulations, please submit a written request explaining any unusual circumstances as to why you cannot meet the regulations, a justification and alternate procedures. When responding you may state that your response is additional information to Control No. 83423.

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Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

- Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- Possess radioactive material only in the quantity and form indicated in your license.
- Use radioactive material only for the purpose(s) indicated in your license.
- 4. Notify NRC in writing of any change in mailing address.
- 5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.
- 6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
- 7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed By Evelyn R. Matson Mate: This Licensing Section

Enclosure: Amendment No. 16

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