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

June 12, 2012

Docket No. 03038544 License No. 34-31473-01
Control No. 577398

Willie Regits, Ph.D.
Director, Health Physics, Nuclear Pharmacy Services
Cardinal Health
Borschow Hospital & Medical Supplies, Inc., a Cardinal Health company
c/o Cardinal Health 414, LLC(Nuclear Pharmacy Services)
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: BORSCHOW HOSPITAL & MEDICAL SUPPLIES, INC., A CARDINAL HEALTH COMPANY, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 577398

Dear Dr. Regits:

This is in reference to your application dated April 9, 2012 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. In Item 5.I of the application you requested authorization for a possession limit of 100 millicuries for unsealed byproduct material with atomic number 1-83 for analytical samples. Possession of some radionuclides with atomic number 1-83 in that quantity will require that you establish financial assurance in accordance with 10 CFR 30.35. If you do not intend to possess any of the radionuclides requiring financial assurance, please request a license condition which will limit possession of unsealed byproduct material of half-life greater than 120 days in the following or similar manner: "If only one such isotope is possessed, the quantity possessed will be maintained at quantity less than or equal to $10^3$ times the applicable quantity in Appendix B of Part 30. For a combination of such isotopes, where R is defined as the sum of ratios of the quantity of each isotope to $10^3$ times the applicable quantity in Appendix B of Part 30, R shall not exceed 1 (unity rule)."

2. In Item 7 of the application you requested authorization for any Authorized Nuclear Pharmacist (ANP) listed on license 34-29200-01MD and who also has a Puerto Rico Board of Pharmacy license. Based on the information you provided, the new license Borschow will have no connection to the existing Cardinal license. It is therefore necessary that you specifically identify the qualified individuals whom you want to name as an ANP on the new Borschow license. For each person to be named on this license provide either a) the name and license number on which they may already be listed as an ANP or provide the required supporting information for each person, as described in section 8.7.2 of NUREG 1556, Vol. 13, Rev. 1.

3. Also in item 7 of the application, you requested authorization for any non-pharmacist authorized users (AU) listed on license 34-29200-01MD. As stated above regarding ANPs, it is necessary that you specifically identify the qualified individuals whom you want

to name as an AU on the new Borschow license, and provide the statement for each person regarding what other license on which they may already be listed as an AU. Please identify by name the people you want listed as an AU on the license and provide the required supporting information for each person, as described in section 8.7.2 of NUREG 1556, Vol. 13, Rev. 1.

4. Also in item 7, in the section describing the Radiation Safety Officer (RSO), you reference qualifications requirements for the local pharmacy RSO and have included a "sample blank" memo delegating authority to the pharmacy RSO. The application does not identify the proposed pharmacy RSO. Please identify by name the person you want listed as the pharmacy RSO on the license and provide the required supporting information for each person, as described in section 8.7.1 of NUREG 1556, Vol. 13, Rev. 1.

5. In item 9, section 2 you state that Borschow has leased space for use as a radiopharmacy. Has the facility described in the application been constructed and is it ready for occupancy?

6. Provide a copy of the registration or license from the Puerto Rico Board of Pharmacy for the new Borschow pharmacy, as required by 10 CFR 32.72.a. On page 10-15, section 12 of the application you stated that a copy of the license was attached, however it was not included in the package.

7. With regard to the submitted drawings of the facility layout:

    a. Please resubmit drawings of the facility layout which are marked to indicate the scale or dimensions used.

    b. For drawings that indicate exact location of materials or depict locations of specific safety or security equipment, provide copies that are marked in accordance with 10 CFR 2.390 indicating, "Security-Related Information – Withhold Under 10 CFR 2.390".

    c. Section 2.I of your application defines the "elution" area as being where generators are stored. No area of the provided floor plan is labeled as the "elution" area. Please identify the elution area on the floor plan, and mark it appropriately in accord with 10 CFR 2.390.

    d. Identify the uses of the spaces outside the walls of the pharmacy, such as whether they are other leased spaces or parking lots.

8. The note at the bottom of the drawing on page 9-10 of the application states that the additional scrubber, identified in the drawing as object "O", is optional. Please confirm the design will comply with 10 CFR 20.1301 and the ALARA requirements of 10 CFR 10.1101(d) If the scrubber is omitted

9. In Item 9, on page 9-15 of the application you reference attached Cardinal Health worksheets for both beta correction factors and alpha correction factors. However, neither of these correction factor worksheets were included in the application package. Please provide copies of both of these worksheets as required by section 8.10.8 of NUREG 1556, Vol. 13, Rev. 1

10. Item 10, section 16 provides information on shielding for radioactive drug products. You provide tables with values labeled as "typical" activity and resulting "typical" exposure rates for specific shielding pigs. Please provide the following additional information for these containers as required by section 8.10.12 of NUREG 1556, Vol. 13, Rev. 1.:

    a. For each radionuclide, the maximum potential activity for each type of container to be used.

    b. Indicate the maximum radiation level expected at the surface of each transport radiation shield when the drug container is filled with the maximum activity.

The title page of your application contains a label referring to the application which states, "Confidential and/or proprietary information notice". However, please note that the NRC will not withhold information as confidential for proprietary or business reasons unless you submit the request for withholding in accordance with 10 CFR 2.390. Please note that the NRC will withhold personal privacy-related information or information which the NRC determines should be withheld for security-related reasons, without a request from the licensee.

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. 577398. If you have any technical questions regarding this deficiency letter, please call Todd Jackson at (610) 337-5308.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Dan Hill, Technical Contact

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**SUNSI Review Complete:** EUllrich

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