



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 21, 2011

Docket No. 030-38331
Control No. 573262

License No. 34-32780-02

Willie Regits, Ph.D.
Director, Health Physics, Nuclear Pharmacy Services
Cardinal Health Nuclear Pharmacy Services
Quality and Regulatory
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: CARDINAL HEALTH NUCLEAR PHARMACY SERVICES, APPLICATION FOR
WITHHOLDING PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE,
CONTROL NO. 573262

Dear Dr. Regits:

By letter from Cardinal Health 414 LLC dated February 15, 2011, and affidavit dated February 15, 2011, you submitted an application for a license and requested that it be withheld from public disclosure pursuant to 10 CFR 2.390. We have reviewed your February 15 application, and the material submitted with letters dated July 23 and August 5, 2010, and February 23, 2011. For the following reasons, we have determined that the submitted information sought to be withheld, in whole or in part, does not contain proprietary information.

- 1) Much of the information is the same as, or similar to, information that is already available to the public because it was submitted in letters to the NRC for License Nos. 34-29200-01MD and 04-26507-01MD, and was not requested to be withheld pursuant to 10 CFR 2.390 at the time of submission. This includes information such as the organization chart, persons responsible for the radiation safety program and authorized users, the training and qualifications of persons who will work in the restricted areas, training and qualification programs, the radiation safety program and procedures, radiation safety equipment and its calibration, waste disposal methods and procedures, and other similar information.
- 2) Much of the information is the same as, or similar to, information which is listed on the license or contained in NRC guidance documents, which are available to the public. This includes information such as the persons responsible for the radiation safety program and other authorized users, some sealed source requirements and procedures, and certain waste disposal methods and procedures.
- 3) Some of the information is a description of compliance with the regulations. This includes information such as descriptions of the packaging and labeling that is required in order to be in compliance with Department of Transportation regulations.

- 4) Some of the information is provided to your customers, such as information for return of packages and materials to your facility, and is therefore already available to the public.
- 5) Some of the information is available to the public through the internet. This includes information such as the manufacturer's information about the cyclotron and its safety systems, and many of the containers used for shielding, packaging and transport of your products.

As we discussed during the telephone conversation on March 18, 2011, the following information will be returned to you under separate cover: the applications submitted with the letters dated July 23, 2010 and February 15, 2011; and the letters dated August 5, 2010 and February 23, 2011. We will retain the letter dated July 23, 2010, which initiated this licensing action, and the letter dated February 15, 2011 with the affidavit. These letters will be released for public disclosure.

Because you are an operating accelerator and required to obtain an NRC license due to changes in the NRC regulations pursuant to the Energy Policy Act of 2005, we will keep this licensing action open, and you must submit a replacement application within 30 days of the receipt of this letter. You should submit the application in accordance with the guidance in NUREG-1556, "Consolidated Guidance About Materials Licenses" Volume 21, "Program-specific Guidance About Possession Licenses for the Production of Radioactive Material Using an Accelerator" (NUREG-1556, Volume 21). Please note that Chapter 8 and Appendix C do not require all of the information that was provided in your original applications, but offer alternate submission of commitments to procedures that meet the minimum criteria specified in the guidance document. Be sure that the replacement application addresses the pertinent issues that were specified in our Request for Additional Information dated August 24, 2010.

Please note that the NRC is required to withhold from public disclosure, information that is described in 10 CFR 2.390(a). This includes sensitive information such as facility diagrams and other information related to the security of the facility.

If you believe that some sections of your replacement application are proprietary information, you must submit a request for withholding and new affidavit, and the following:

- a. Provide a non-proprietary version of the application, with brackets showing where the proprietary information has been deleted, and provide a proprietary version of the application that is marked clearly on the first page of the document, and on the top of each page that contains proprietary information, to indicate that information falls under the claim of proprietary information. On each page that contains information to be withheld from public disclosure, use adjacent markings to indicate clearly which portions of the page are to be withheld, and specify the reason(s) for withholding that particular information.
- b. Alternately, if the portions of information requested to be withheld can be separated in their entirety from the remainder of the application, you may submit the application that contains most of the information required by NUREG-1556 Volume 21, and a separate document that contains only the information you are requesting to be withheld from public disclosure. The publicly-available

application must indicate the areas for which information will be found in the second document for which withholding is requested.

Withholding documents from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the basis for withholding information from public disclosure changes such that the information could be made available for public inspection, you should notify the NRC. You should understand that the NRC may have cause to review determinations to withhold information in the future (for example, if the scope of a Freedom of Information Act request includes withheld information). In all review situations, if the NRC makes a determination that information will not be withheld, you would be notified in advance of any public disclosure.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; Regulations, Guidance, and Communications**. 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of the replacement application. Please reply to my attention at the Region I Office and refer to Mail Control No. 573262. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040 or send email to elizabeth.ullrich@nrc.gov.

Sincerely,

Original signed by Elizabeth Ullrich

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

cc:

Dan Hill, Radiation Safety Officer
James Matthews, Manufacturing Radiation Safety Officer

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