



Barbara Park
Maryland Department of the Environment
Radiological Health Program
Radioactive Materials Licensing
1800 Washington Boulevard, Suite 750
Baltimore, MD 21230-1720

Our reference:
103.002 SS&D to Elekta dba Nuc

Your reference:
MD-0497-S-113-S

Date:
February 21, 2012

Dear Ms. Park:

In conjunction with the letter dated January 30, 2011, notifying the Department of the acquisition of Nucletron Corporation by Elekta Inc on or about March 1, 2012, please amend the above Sealed Source and Device registry at that time to reflect the new distributor as:

Elekta, Inc.
d/b/a Nucletron Corporation
7021 Columbia Gateway Drive
Suite 200
Columbia, MD 21046

According to NUREG 1556 Vol. 3, Rev 1, information required concerning this change is as follows:

1. *Delineate the facility's name and location where the products are manufactured.*

The products are manufactured by: Nucletron B.V.
Waardgelder 1
3905 TH Veenendaal
The Netherlands

The products are fabricated by: Isotron Isotopentechnic
Robert-Rössle-Str 10
13125 Berlin, Germany

2. *Specify the serial number of the last unit that was distributed by the old company prior to name/address change, and the number of completed units that were transferred to be distributed by the old company to the new company.*

These seed sources are not serialized. They seed orders are identified by three factors: sales order number, purchase order number and Patient ID. The sales order number and purchase order number of the last batch of sources distributed by Nucletron Corporation prior to the name change to Elekta Inc. d/b/a Nucletron Corporation was SO12-01007 and PO#33213725-0-WL,

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www.nucletron.com
www.elekta.com

Nucletron - An Elekta Company
7021 Columbia Gateway Drive Suite 200 | Columbia, MD 21046 | U.S.A.
Tel 1-800-336-2249 | Fax 1-443-769-1570 | www.nucletron.com

Registered 30085856 | V.A.T. No.: NL 005076511 B 01 | RBS / Account No.: 58.72.04.575 / IBAN: NL91RBOS0587204575 / BIC: RBOSNL2A



respectively. This corresponds to the customer number XXXXX0863. There were no completed orders ready for distribution to be transferred for distribution by Elekta Inc. d/b/a Nucletron Corporation.

3. *Change of ownership information discussing transfer of products, records custody, and servicing arrangement for products previously distributed*

The software system for financial data storage is being changed from AXAPTA to MOVEX, all systems remain the same. There will be no change to the records custody for the sources previously distributed. All records, except for financial records storage, will continue to be maintained as established before the name change to Elekta Inc. d/b/a Nucletron Corporation. As these seeds are permanent implants, they are not subject to source exchanges. Service support will continue to be performed by previously trained Nucletron engineers. These engineers will become Elekta Inc. employees as of March 1, 2012.

4. *Provide a new label for the devices indicating the new company name and the effective date of the label change.*

Labels reflecting the change in distributor are forthcoming.

5. *Confirm that no changes were made to the product since its initial registration or last amendment*

Nucletron Corporation hereby confirms that no changes have been made to the product since its last amendment. Please see attached letter from Elekta Inc. confirming they also have made no changes to the product since its initial registration or last amendment.

6. *Verify that there are no changes to previous commitments that have been made by the old company*

See attached letter from Elekta Inc verifying that there are no changes to the previous commitments that have been made by Nucletron Corporation. (Attachment 1)

7. *Provide details regarding the quality assurance program at the new location.*

There have been no changes to the quality assurance program and the location has not changed. The company quality system remains unchanged due to the company name change only. Elekta Inc is 'doing business as' Nucletron Corporation thus following the same quality system as previously established.

Should you need clarification or have any questions, please do not hesitate to contact me at 443-545-2220 or debra.bensen@us.nucletron.com

Sincerely,

A handwritten signature in blue ink that reads "Debra Bensen".

Debra Bensen
RSO

Enclosure: As stated