



Nucletron

AN ELEKTA COMPANY

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

Our reference:
105.002 SS&D to Elekta dba Nuc

Your reference:
MD-0497-S-107-S

Date:
February 21, 2012

Dear Ms. Park:

In conjunction with the letter dated January 30, 201²~~1~~, 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: Mallinckrodt Medical B.V.
Westerduinweg 3
NL-1755 LE Petten
The Netherlands
OR
QSA Global, Inc.
40 North Avenue
Burlington, Massachusetts 01803

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.*

The serial number of the last source distributed by Nucletron Corporation prior to the name change to Elekta Inc. d/b/a Nucletron Corporation has not yet been determined. Sources are still being manufactured primarily by QSA and they do not have the final serial number projection for March 1, 2012 as yet. This information will be forwarded to the MDE on March 1, 2012.

Human Care Makes the Future Possible

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 30085858 | V.A.T. No.: NL 005076511 B 01 | RBS / Account No.: 58.72.04.575 / IBAN: NL91RBOS0587204575 / BIC: RBOSNL2A



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

There will be no change to the records custody or servicing arrangements for the sources previously distributed. All records will continue to be maintained as established before the name change to Elekta Inc. d/b/a Nucletron Corporation. Source exchanges 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 black ink, appearing to read "Debra Bensen".

Debra Bensen
RSO

Enclosure: As stated