

From: [Jankovich, John](#)
To: [Bensen, Debbie](#)
Cc: [Herrera, Tomas](#); [Kotzalas, Margie](#)
Subject: RE: Changes to the Flexitron unit
Date: Wednesday, October 30, 2013 4:06:00 PM
Attachments: [image001.png](#)

Ms. Bensen,

This is a response to your request below for approval of label changes for your registration certificate GA-0497-D-115-S.

We reviewed the three proposed new labels and found them equivalent to the current ones. However, we cannot approve their use at the present time because none of the labels shows the distributor's name and address in the U.S. Such information is needed for U.S. users of the device to be able to reach a licensed distributor within our country.

Please note that you may use an additional 4th label for the units which are distributed in the U.S., or modify one or more of the proposed labels to show, in addition to the manufacturing address in The Netherlands, Elekta's name and address as the distributor in the U.S.

We will need this label from you before we can approve their use. Please send me a copy of the label/s, so that we could respond to your request.

Please also note that I will be out of the office until noon, Nov. 1. Please contact Mr. Tomas Herrera during my absence either by e-mail or on the phone at 301 415-7138.

John P. Jankovich, Ph.D.
Team Leader
Sealed Source and Device Registrations
Office of Federal and State Materials and
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U.S. Nuclear Regulatory Commission
Washington, DC 20555

From: Bensen, Debbie [mailto:debbie.bensen@elekta.com]
Sent: Wednesday, October 30, 2013 10:30 AM
To: Jankovich, John
Subject: FW: Changes to the Flexitron unit
Importance: High

Dear John,

Some time ago I sent an email to you requesting guidance. Nucletron B.V. in Veenendaal has changed the labels for the Flexitron, see attached. They currently have devices ready to be shipped but I have not heard back from you whether they can be shipped while we are waiting for the SS&D. Can you please look at the attached and get back to me? I am under a tremendous amount of pressure from Company management.

Thank you,
Debbie

Debra Bensen | Radiation Safety Officer
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From: Bensen, Debbie
Sent: Thursday, October 03, 2013 3:22 PM
To: 'john.jonkovich@nrc.gov'
Subject: Changes to the Flexitron unit

Dear John,

I hate to be a pain, but working with my mother company in the Netherlands is sometimes a little trying. It seems they have changed the configuration of the Flexitron in that it can now be purchased with a 10 or 20 channel configuration in addition to the original 40 channel configuration that is registered. They have also updated the software and user's manual as well as changed the labels. (New labels attached) I do need to submit an amendment for these changes (correct me if I am wrong) but are these changes enough to stop delivery and installation while the SS&D is being amended? Please advice.

Thank you,
Debbie

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