

From: Lawyer, Dennis
Sent: Tuesday, December 28, 2010 11:22 AM
To: 'Walker, Mary D.'
Subject: RE: CDRH NRC License Amendment # 41

Ms. Walker,

I have reviewed the following licensing actions associated with the Department of Health & Human Services, Food and Drug Administration, Center for Devices and Radiological Health, NRC License No. 19-07538-01, Docket Number 030-04544:

In the licensee's letter dated, December 28, 2006, it was requested that you be added on as an authorized user for 3-83 and Am-241 sealed sources for purposes of Calibration, standardizing and testing of the licensee's instruments. Your qualifications to be an authorized user was submitted [ML070020154].

On January 17, 2007, Amendment #36 was issued which added you as the authorized user for the materials requested [ML070230202]

On June 7, 2010, I performed an inspection of this license. During inspection it was stated that you were using Am-241 and Cd-109 sources to perform checks on equipment (i.e. testing of licensee's instruments) [ML102740202].

In a letter dated September 23, 2010, a request was made to delete all authorized user and all material [ML102710316]. I explained to Mr. Shandruk that I not able to amend the license to that request, that a license must have material and an authorized user or needs to be terminated.

In a facsimile dated November 11, 2010, Mr. Shandruk requested that the September 23, 2010 amendment request be changed to include 3-83 sealed sources along with the authorized use of calibration, standardizing, and testing of instruments [ML103280490]

In a telephone conversation with Mr. Shandruk on November 24, 2010, I told Mr. Shandruk again that I would need an authorized user for the material and would put you on as the authorized user as you are on the license for this authorization and authorized use currently. He agreed to having you as the authorized user [ML103400306].

In summary, you may not have requested it, but authorized personnel at your facility have requested that you be the authorized user for regulated byproduct materials with atomic numbers 3 through 83 for calibration, standardizing, and testing of instruments. You met the qualifications associated with this task and you are and have been an authorized user for this material since January 17, 2007. You are currently the only authorized user on the license. In order to have a material license of this type, a material type and an authorized user is required. If you feel the license material and authorized use is not going to meet your and your management needs, you may request for a license amendment to a different material and use type, different authorized user, or request for license termination. Please discuss this with your management and submit changes as you determine necessary to meet the needs of the Department of Health & Human Services, Food and Drug Administration, Center for Devices and Radiological Health

Thank You,

Dennis Lawyer
NRC, Region 1, DNMS
610-337-5366

From: Walker, Mary D. [<mailto:Mary.Walker@fda.hhs.gov>]
Sent: Thursday, December 23, 2010 1:56 PM
To: Lawyer, Dennis
Subject: RE: CDRH NRC License Amendment # 41

Dear Mr. Lawyer,

I am only addressing information on the license as it refers to me as an authorized user. I never requested, and I am not an authorized user for regulated byproduct materials with atomic numbers 3 through 83 for calibration, standardizing, and testing of instruments as stated on the CDRH NRC License. I have questioned Mr. Shandruk several times in the past, and was never provided with an answer. If he reinserted item 6A on a later letter to you, he was wrong in doing so.

Mary Walker, Laboratory Leader

Ionizing Radiation Measurements Laboratory
Food and Drug Administration
10903 New Hampshire Avenue
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Office of Science and Engineering Laboratories
Division of Imaging and Applied Mathematics
mary.walker@fda.hhs.gov

From: Lawyer, Dennis [Dennis.Lawyer@nrc.gov]
Sent: Tuesday, December 21, 2010 3:52 PM
To: Walker, Mary D.
Subject: RE: CDRH NRC License Amendment # 41

Ms. Walker,

If you believe that I have made a mistake on the license amendment, please be more specific. The documents that you have sent me was the initial request and I have other documents associated with this license amendment telling me to do different things. On the request in September, I am not authorized to issue a license with no authorized user and no materials.

Please refer to additional information associated with the request: "ML103400306", "ML103410171", "ML103140798", "ML102850554" Place into: <http://wba.nrc.gov:8080/ves/>

Also, not sure why but the letter dated November 24, 2011 also has instructions for the amendment contrary to the first letter. You should obtain this letter from Mr. Shandruk.

Additionally, you may submit new amendment requests.

Dennis Lawyer

From: Walker, Mary D. [<mailto:Mary.Walker@fda.hhs.gov>]

Sent: Tuesday, December 21, 2010 3:13 PM

To: Lawyer, Dennis

Cc: Gill, Lillian J.

Subject: CDRH NRC License Amendment # 41

Good Afternoon Mr. Lawyer,

CDRH License Amendment 41 (see attached document **CDRH NRC Amendment 41.pdf**), which lists me as an authorized user of NRC regulated byproduct materials with atomic numbers 3 through 83 for calibration, standardizing, and testing of instruments, is incorrect.

Please correct the license as requested in CDRH Amendment 41 (see attached document - **NRC License Amendment Sept2010.doc**).

Attached are the referenced email documents.

Mary Walker, Laboratory Leader

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