

From: Bell, Curtis [curtis.bell@HQ.DHS.GOV]
Sent: Tuesday, January 17, 2012 3:00 PM
To: Ullrich, Elizabeth
Subject: RE: Changes to NRC license 29-13141-06

We probably do need more time. We had some visitors from DC last week, our internal safety office. They want to pass our letters by the DHS lawyers (not my first choice). It appears it not a 'we need DHS legal review' and more of a 'I know this guy' type of review.

In terms of how we handle the modified device, my preference would be to put a label on the license indicating that the device has been modified and is now controlled by (our) license #####. If removing it is preferable, that's what we'll do.

From: Ullrich, Elizabeth [mailto:Elizabeth.Ullrich@nrc.gov]
Sent: Friday, January 13, 2012 10:24 AM
To: Bell, Curtis
Subject: RE: Changes to NRC license 29-13141-06

Curtis,

Before I respond to your question, please note that we have not yet received a response to our letter dated December 16, 2011 related to the inspection. It is almost at 30 days. If you will need additional time to respond to the letter, you should request that.

Here are some options that you can consider:

Under your specific license, you can modify the device; that is part of your research and development. That is different than Condition 14, which prohibits you from opening the source or detector cell – you are not removing the foil from the ECD etc, correct? So that condition remains.

This issue is with the devices that are distributed to persons exempt from licensing, and the devices distributed to persons who possess them under the general license. These are the devices that you want to modify, and need your specific license to do so.

For the items distributed to persons who are exempt from licensing pursuant to 10 CFR 30.20 "Gas and aerosol detectors": these devices are distributed by manufacturers who have a specific license pursuant to 10 CFR 32.26, 32.27, 32.28, and 32.29. they are required to do several things that affect you, among them to submit the design of the device for approval; to label the device to state "Contains Radioactive Material", the radionuclide and quantity, the manufacturer's name, the statement "this detector contains radioactive materials and has been manufactured in compliance with US NRC safety criteria in 10 CFR 32.27. the purchaser is exempt from any regulatory requirements."; they have to report the sale annually to the NRC. It is the approved device design that can be used, without modifications, by the end user. You could 1) request the same device from the manufacturer, to be transferred to you as a specifically licensed item, without the labeling designating it as an item for use by persons exempt. OR 2) you can submit procedures to the NRC that describe how you will deal with devices that are exempt when you decide you want to work with them under the specific license (describe how you will remove labels etc that state the device is exempt, how you will label the device so persons know that a radioactive source is present, track and control it) OR 3) both.

For the devices that are distributed to persons who possess them under the general license of 10 CFR 31.5, these devices are distributed by manufacturers who have a specific license pursuant to 10 CFR 32.51, 32.51a and 32.52. they also have to have the device design approved; it is this approved device that can be used by the general licensee; it has to have a label that states "The receipt, possession, use and transfer of this device Model _____. Serial No. _____, are subject to a general license...this label shall be maintained on the device in a legible condition. Removal of this label is prohibited. CAUTION – RADIOACTIVE MATERIAL" and the label must include the name of the manufacturer/initial transferor; additional labeling for the source housing; they must provide the end user with certain information; and they must report the transfers each quarter to the NRC or State and list the name of the individual that the device was transferred to; they also have to report when devices are returned to them. As a result, under the general license in 31.5, these devices cannot be transferred by the end user to another end user; they have to be transferred to the manufacturer. For these devices, you must follow the regulations in 31.5(c)(8)(iii) as follows

(8)(i) Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter. The report must contain—

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (c)(1) of this section) so that the device is labeled in compliance with § 20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained;

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

OR you could request to purchase the device as transfer from the manufacturer under the specific license, without all the labeling required by the general license, OR you can send the device back to the manufacturer to have them remove the labeling and return it to you under your specific license, and report the return of a GL device to the NRC, OR some combination of the above.

Betsy

From: Bell, Curtis [<mailto:curtis.bell@HQ.DHS.GOV>]
Sent: Wednesday, January 04, 2012 2:45 PM
To: Ullrich, Elizabeth
Subject: Changes to NRC license 29-13141-06

Betsy,

I have a list of the new authorized users and the changes to the list of buildings (Paragraphs 10 & 11). I have some questions as to what is needed for changing a sealed source device from a exempt/generally licensed device to one tracked under our specific license. My current draft will propose adding an item "C" to paragraph 9. Paragraph 14 also seems to address modification. What I've proposed adding is below:

Add Item 9 (C): Devices received as Exempt, under a General license, or under a specific license may be modified. The modifications will not involve removal of radioisotopes from encapsulation but may involve modifications to the device (housing/electronics) containing the encapsulated source. Devices so modified will be tracked under this specific NRC license and the NRC shall be notified via email or in writing within 30 days.

Could this also be addressed by deleting the current paragraph 14?