

October 19, 2009 (3:25pm)

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Subject: Docket ID NRC-2008-0272

The following are comments submitted on behalf of Thermo Niton Analyzers LLC regarding the proposed rule (RIN 3150-AI33, Docket ID NRC-2008-0272) for limiting the quantity of byproduct material in a generally licensed device. Thermo Niton Analyzers LLC manufactures and distributes specifically and generally licensed handheld XRF analyzers under License Numbers MA 53-0388 and MA 55-0238.

An element of the proposed rule is described in Section C as follows...

"The proposal would prohibit specific licensees from possessing generally licensed devices under 10 CFR 31.5 at the same site. Any specific licensee possessing a device generally licensed under 10 CFR 31.5 at a site for which an SL is in place would be required to transfer the device to the authority of their SL. As noted, the possession and use of the device would then be subject to the terms and conditions of the user's SL. Any such device obtained by specific licensees in the future would be required to be obtained as a specifically licensed device. Under these requirements, all licensed material at a site where specifically licensed material is used would be governed by the same set of regulations."

Further, in Section D under specific questions for comment, the agency poses the following question...

"(F) How much impact would there be to 10 CFR 32.51 licensees and Agreement State equivalent licensees to ensure that they are transferring these devices to entities without an SL?"

Comments:

The proposed rule will put excessive burden on 32.51 licensees because there is no mechanism by which they can verify that an entity does not have a specific license.

Licensing authorities will need to establish and maintain a mechanism by which 32.51 and other licensees can independently verify the licensing status of a device or entity.

Discussion

It is anticipated that there will be many issues with this proposal, with particular dependency on the final wording. One significant issue is regarding general license distributors. If the agency adopts wording making it clear that 10 CFR 32.51 licensees (general license distributors) are responsible to NOT ship a device under the provisions of general licensing to a specific licensee, how is the 32.51 licensee supposed to verify that an entity does not have a specific license? How does a GL distributor convince themselves that they have sent their GL device to someone without a specific license?

Even more difficult, how does a 32.51 licensee demonstrate to their licensing authority that they are in compliance with this responsibility? What record(s) does the agency propose we maintain to demonstrate that we are fulfilling this obligation?

Further, if it is not the responsibility of the GL distributor, but rather the general licensee to obtain specific license amendment and make the transfer after the distribution has already taken place, what is to become of the general license label? Will the licensee be expected to remove or replace it? Are they allowed to do this on their own? Will they need to have the distributor change the labeling at this later date? How will an agreement state know if the device is generally or specifically licensed when it arrives in their state at a temporary jobsite? The general license label may no longer be valid if the device has since been transferred to a specific license.

Thermo Niton Analyzers LLC manufactures and distributes portable devices approved for either general or specific licensing. If Thermo Niton Analyzers LLC initially distributes a device under general license, and at a later date has it in for service, we will need to investigate the current license status of the device because of the significantly increased likelihood that it has since been transferred to a specific license. This will be necessary each time we service device so that we can identify the correct requirements for labeling, reporting, and license verification. We will no longer be able to rely on the labeling of the device or our prior records of how it was initially distributed.

Because of these issues, Thermo Niton Analyzers LLC anticipates a heavy reliance on communication between us as a 32.51 licensee and the NRC and agreement state licensing authorities who are the only entities that can verify the actual licensing status of our customers. This will require that agreement states and the NRC have additional tools or resources to be able to communicate the licensing status of entities in question.

Sincerely,



Jim Blute, CHP
Health and Safety Manager, RSO
Thermo Niton Analyzers LLC

Rulemaking Comments

From: Blute, James J. [jim.blute@thermofisher.com]
Sent: Monday, October 19, 2009 2:51 PM
To: Rulemaking Comments
Subject: Docket ID NRC-2008-0272 Comments for Submission
Attachments: Proposed Rule Comments 2009.pdf

The following are comments submitted on behalf of Thermo Niton Analyzers LLC regarding the proposed rule (RIN 3150-A133, Docket ID NRC-2008-0272) for limiting the quantity of byproduct material in a generally licensed device. Thermo Niton Analyzers LLC manufactures and distributes specifically and generally licensed handheld XRF analyzers under License Numbers MA 53-0388 and MA 55-0238. Attached is a signed pdf version of these comments on letterhead.

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Licensing authorities will need to establish and maintain a mechanism by which 32.51 and other licensees can independently verify the licensing status of a device or entity.

Discussion

It is anticipated that there will be many issues with this proposal, with particular dependency on the final wording. One significant issue is regarding general license distributors. If the agency adopts wording making it clear that 10 CFR 32.51 licensees (general license distributors) are responsible to NOT ship a device under the provisions of general licensing to a specific licensee, how is the 32.51 licensee supposed to verify that an entity does not have a specific license? How does a GL distributor convince themselves that they have sent their GL device to someone without a specific license? Even more difficult, how does a 32.51 licensee demonstrate to their licensing authority that they are in compliance with this responsibility? What record(s) does the agency propose we maintain to demonstrate that we are fulfilling this obligation?

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[Thermo Scientific NITON Analyzer Licensing](#)

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To: <rulemaking.comments@nrc.gov>

Return-Path: jim.blute@thermo.com

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From: "Blute, James J." <jim.blute@thermofisher.com>