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(75FR36211)

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Requirements for Distribution of Byproduct Material

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Requirements for Distribution of Byproduct Material

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Comment on FR Doc # 2010-15202

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Submitter Information

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General Comment

See attached file(s)

Attachments

NRC-2008-0338-DRAFT-0004.1: Comment on FR Doc # 2010-15202



On behalf of Metso Automation, I would like to submit the following comments on the NRC proposed rule 2010-15-202 issued June 24, 2010, "Requirements for Distribution of Byproduct Material".

1. Updating of registration certificates in the SS&D Registry (Discussed in Section III. A.2):
 - (a) Under what circumstances should proposed §32.210(h) be used to require a reevaluation? How should such a reevaluation be conducted with minimum impact to industry?

Comment:

A re-evaluation should be conducted upon request by the manufacturer or initial distributor due to changes or additions such as a new source used in a device or a new device added to a series. Changes in regulatory standards that would affect the conditions of a certificate can be used to initiate a re-evaluation by the Commission.

- (b) How might registration certificates best be updated so as not to discourage improvement in the design of sources or devices, more readily allow for the application of updated industry standards, and ensure that information in the certificates is fully consistent with current practices? (For example, in addition to the proposed provision in §32.210(h), other options could include reviewing certificates at the time of license renewal, in part or in whole; adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.)

Comment:

A certificate could be required to be updated every 10 years. The expiration date should be specific to each device, based on its certificate approval date. This would require the manufacturer or initial distributor to review the device and determine if there are any modifications that need to be made to the certificate to meet current industry standards. The renewal should be easily performed requiring only a request to renew and an explanation of any changes to be made in order to comply with current radiation safety standards.

- (c) How should certificates for previously approved devices be handled if the device does not meet current standards, such as in the case of the separately proposed (August 3, 2009: 74 FR 38372) quantity limit in the general license in §31.5 (and comparable Agreement State provisions)? How should registration certificates be handled in this situation? (For example, in some cases, the distributor may be able to limit the quantity of affected radionuclides, rather than change its certificate to one for specifically licensed devices.)



Comment:

Certificates that no longer meet current standards should be grandfathered for already distributed devices. New and re-distributions should require an updated certificate that complies with the current standards. In the case of limited quantities of radioactive material in a Generally Licensed Device, the certificate would be updated to reflect distribution as either a GL or SL device, depending upon the activity of the source(s) in the device.

- (d) In general, how might the NRC use the proposed provision for review in §32.210(h) in relation to changes in standards for products or limits in addressing continued distribution and the timing for changes to the authority to distribute tied to the registration certificate?

2. Comment on §32.211

Many industrial gauges are sold in small quantities over long periods of time, especially during the last years of their life cycle. In addition, they are often redistributed between licensees or between locations of the same licensee as operations and ownerships change. I would like to suggest that a certificate expire after 10 years (See Comment 1(b)) unless specifically renewed by the distributor. It should not be necessary to inactivate a certificate just because an initial distribution has not occurred within specific number of years.

The proposed regulation states: "A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to transfer such sources or devices for use." This should be changed to read: "... no longer authorizes the licensee to initially transfer such sources or devices for use." Redistributions should be authorized even if the certificate is inactive. If a device or source is at a facility and the licensee needs to move the device to a different location or transfer it to a different owner, this would be considered a redistribution and should be allowed, even though the certificate is inactive.

Respectfully Submitted,


Jack Ramsey
Sr. Radiation Officer

Rulemaking Comments

From: Gallagher, Carol
Sent: Wednesday, July 28, 2010 9:24 AM
To: Rulemaking Comments
Subject: Comment on Requirements for Distribution of Byproduct Material
Attachments: NRC-2008-0338-DRAFT-0004.pdf

Van,

Attached for docketing is a comment from Jack Ramsey, Metso Automation, USA, Inc., on the above noted proposed rule (75 FR 36211) 3150-AH91 that I received via the regulations.gov website on 7/27/10.

Thanks,
Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by TWMS01.nrc.gov
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Content-Type: application/ms-tnef; name="winmail.dat"
Content-Transfer-Encoding: binary
From: "Gallagher, Carol" <Carol.Gallagher@nrc.gov>
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>
Date: Wed, 28 Jul 2010 09:24:10 -0400
Subject: Comment on Requirements for Distribution of Byproduct Material
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