

PR 30,31,32, 40 and 70  
(75FR36211)

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**Docket:** NRC-2008-0338  
Requirements for Distribution of Byproduct Material

**Comment On:** NRC-2008-0338-0001  
Requirements for Distribution of Byproduct Material

**Document:** NRC-2008-0338-DRAFT-0005  
Comment on FR Doc # 2010-15202

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July 28, 2010 (10:30a.m.)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

## Submitter Information

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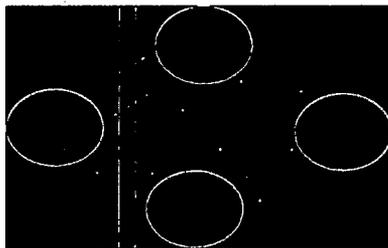
**Organization:** Association of Device Distributors and Manufacturers (ADDM)

## General Comment

See attached file(s)

## Attachments

**NRC-2008-0338-DRAFT-0005.1:** Comment on FR Doc # 2010-15202



Association of Device Distributors and Manufacturers (ADDM)  
P.O. Box 258, Winchester, MA 01890  
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*ABB Inc.*

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*Honeywell  
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*Industrial Nuclear  
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*Metso Automation  
USA, Inc.*

*RMD, Inc.,*

*Source Production  
and  
Equipment  
Company, Inc.*

*Thermo EGS  
Gauging, Inc.*

July 26, 2010

Below are the ADDM's comments on NRC proposed rule 2010-15-202 issued June 24, 2010. For your reference we have listed the NRC's questions regarding this rulemaking and our response.

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?

Licensees and holders of device registration certificates are required to maintain the conditions of their device registrations. This includes the models they are distributing, any design modifications potentially affecting radiation safety, company name and ownership, etc. Certificates need only be reevaluated if the NRC or Agreement States suspect that the registrations have not been maintained by the owner and are no longer accurate.

Note that ADDM has encountered instances in which licenses were amended by licensees and regulators but not the accompanying certificates. We are also aware of instances when amended Agreement State Certificates were not updated in the NRC National Registry of Sealed Sources and Devices. It is not rare to find certificates still listed for active vendors when the company's distribution license had been previously terminated. We suggest that the NRC perform a comprehensive audit of all certificates in the registry and reconcile them with NRC and Agreement States Distribution License issued.

- (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.)

The NRC has previously stated that any change to a registered device, no matter how small, or whether or not it is directly related to radiation safety, may require an amendment to the device registration certificate. This is an awkward situation since only the NRC can make the determination as to when an amendment is required. A better policy would be to explicitly list which criteria constitute an amendment such as change in product name, company name, or any component directly related to radiation safety.

We do not think that requiring a request to inactivate a device should be required after 2 years. This would severely restrict business and put an undue burden on both the State & NRC programs, and companies that only distribute small numbers of their devices over extended periods of time. We would prefer the NRC require a renewal of a certificate after no less than 10 years, at which time the certificate can be updated to meet current industry 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.)

ADDM disagrees with the content of 74 FR 38372 as stated in previously issued comments. Until this rule is repealed it may be necessary to amend some certificates to "B" to allow distribution to both specific and general licensees.

- (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?

The NRC should monitor changes to relevant ANSI and ISO standards for reference during the review process.

2. New class exemption for industrial products in § 30.20 (Discussed in Section III. B.):

- (a) Is the 20 mrem/year routine dose criterion appropriate, given that users are workers, but there is no control of conditions of use once a product is distributed for use under an exemption from license?

What health physics criteria did the NRC use to arrive at the dose rate of 20 mrem/year for members of the public? The dose rate of 20 mrem/year is conservative, and there is no reason not to maintain the current member of the public dose of 100 mrem/year. What mechanism does the NRC propose to monitor compliance with this new rate, considering that members of the public are not typically issued dosimetry (unless they are visitors to a restricted area)?

- (b) Would it be appropriate to apply certain aspects of the proposed standards for this class exemption to the safety criteria (§§ 32.23 and 32.27) for the existing class exemptions (§§ 30.19 and 30.20), namely, the use of more up-to-date methodology for dose assessment as reflected in the proposed definition of the term "committed dose," the inclusion of a misuse scenario and/or a specific quantity limit to control quantities that may meet the safety criteria when a source is well contained and shielded, and the consideration of the number of products likely to accumulate in one place in the dose assessments for all scenarios?

Manufacturers in any industry can not typically be held responsible for the intentional misuse of any product. However, there are certain safety features which can be incorporated into products. For example, some XRF devices have an infra-red positioning sensor which can tell if the unit is level with the target, and prevent incorrect operation. Some devices also are constructed with a computer password or a physical on/off key to restrict access.

3. Expanding the class exemption for gas and aerosol detectors in § 30.20 by revising the requirement of "designed to protect life or property from fires and airborne hazards" to instead be "designed to protect health, safety, or property" (Discussed in Section III. C.):

- (a) Are there additional products that may be exempted under this expanded definition of the class not specifically considered by the NRC?

No comment

- (b) (b) Are these words adequate to ensure that products present a clear societal benefit?

Yes.

- (c) Are there any potential problems with approving additional products for use under this exemption and later reevaluating the safety criteria associated with this exemption for potential alignment with newer recommendations of the ICRP?

IRSC is in agreement in expanding the scope of exempt device approvals. We endorse the position taken by the Canadian Nuclear Safety Commission, various European countries, and Japanese regulators to allow the complete exemption without device registration or distribution license of products with activities below IAEA exemption "clearance" levels (for example products containing 100MBq or less of Ni-63).

4. Changes to certain quality control requirements in §§ 32.15, 32.55, and 32.62 to (i) raise the statistical acceptance criteria; i.e., increasing the required confidence that the Lot Tolerance Percent Defective will not be exceeded from the current 90 percent (consumer risk of 0.10) to 95 percent; and (ii) require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license and that testing after repairs must be performed by an independent reviewer (Discussed in Section III. E.). These proposed revisions are in § 32.15(a) and (b) for certain exempt items, § 32.55(b) and (d) for luminous safety devices used in aircraft, and § 32.62(c) and (e) for ice detection devices.:

- (a) Would any actual changes in practice need to be made by affected licensees? The NRC would welcome information that would aid in evaluating any impact.

No Comment

- (b) Would there be any impact on manufacturers or distributors of products for which oversight of quality control practices are proposed to be removed, if the new provisions were applied to these products instead, i.e., if all of the exceptions in § 32.14(b)(5) were not made effective as proposed? (As discussed under Section III. F. "Make the Requirements for Distributors of Exempt Products More Risk-Informed," products for which quality control oversight may be removed are: ionization chamber smoke detectors, electron tubes, and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, covered by exemptions in § 30.15, and for products to be used under the proposed new exemption in § 30.15(a)(2), static eliminators and ion generating tubes formerly covered by the general license in § 31.3.)

Many manufacturers are ISO 9001 certified and their current procedures are adequate to address any quality control issues.

5. Proposal in § 30.32(g)(5) to allow some licenses to specify only constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used (Discussed in Section III. A.3):

- (a) In view of the expectation that this authorization would only be granted in limited situations and due to special circumstances, how can NRC make it clear that approval of this approach would be at the NRC's discretion, rather than this being an open-ended option for anyone, or should the regulation specify when this approach is acceptable?

ADDM encourages the NRC to be as clear and detailed as possible when imposing new regulatory requirements in order to avoid any potential for confusion. Please add an example of the type of use exemptions envisioned in regulatory reference documents (i.e. NUREG-1556, Vol 3.).

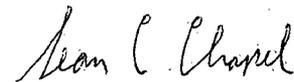
- (b) Are there other situations besides those discussed, when identifying all of the sealed sources and devices to be licensed are particularly impractical?

The issuance of generally licensed or exempt devices should not be tied to any quantity distributed. This is only relevant for specifically licensed devices.

6. With regard to § 32.211, 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.

If you have any questions please call me at 781.767.2176 or email me at [schapel@irsc-inc.com](mailto:schapel@irsc-inc.com).

Sincerely,



Sean C. Chapel,  
President

## **Rulemaking Comments**

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**From:** Gallagher, Carol  
**Sent:** Wednesday, July 28, 2010 10:07 AM  
**To:** Rulemaking Comments  
**Subject:** Comment on Requirements for Distribution of Byproduct Material  
**Attachments:** NRC-2008-0338-DRAFT-0005.pdf

Van,

Attached for docketing is a comment from Sean Chapel, ADDM, 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