

June 17, 2010

Mr. Sean Chapel, President
Association of Device Distributors
and Manufacturers
P.O. Box 258
Winchester, MA 01890

Dear Mr. Chapel,

In your letter addressed to John Jankovich, dated December 23, 2009, and subsequent proposed meeting agenda sent via email on March 26, 2010, you expressed the concerns of the members of your organization, the Association of Device Distributors and Manufacturers (ADDM). In an email sent to you on April 4, 2010, James Danna, Chief Rulemaking Branch A, committed to responding to your organization's items of interest in your proposed meeting agenda. As stated in your letter and agenda, the issues of particular interest to your organization include: 1. Creating uniform reciprocity standards and procedures, 2. Repealing regulations that limit activity in generally licensed (GL) devices and modernize the quarterly reporting system, 3. ADDM's position that future regulations regarding security of devices must be written in relation to real radiation doses to workers and members of the public, and 4. ADDM's request that the U.S. Nuclear Regulatory Commission (NRC) consult with ADDM regarding new and pending regulatory initiatives affecting your industry.

In response to the first item, your letter and agenda reference ADDM's position that there should be uniform reciprocity standards and procedures on the national level. ADDM is particularly concerned with the NRC's proposal to change the compatibility of 10 CFR 31.5(a), 31.5(c)(13)(i), and 31.6 from compatibility "B" to "C" which you believe will further complicate reciprocity issues. As a compatibility "C" requirement the Agreement States would not be required to implement NRC regulations in the exact manner as the NRC. The NRC will address this compatibility issue in its final rulemaking package for 10 CFR 31.5. For more information regarding the compatibility of Agreement State programs, please see the NRC's Management Directive 5.9, "Adequacy and Compatibility of Agreement States," at:

http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU_ADAMS^PBNTAD01&ID=041880008

In regards to the second item, in the proposed agenda, you stated that ADDM intends to submit a petition for regulation to repeal activity limits in generally licensed (GL) devices. You also expressed interest in modernizing the quarterly reporting requirements in 10 CFR 32.52(a)(5) for GL devices. If you would like either of these issues to be addressed, you can pursue them through the rulemaking process.

To pursue either issue through the rulemaking process, you may submit a petition for rulemaking request to: Secretary, Attention: Rulemakings and Adjudications Staff, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Before filing a petition for rulemaking, you may consult with the NRC. The NRC is permitted to: 1. Describe the procedure and process for filing and responding to a petition for rulemaking; 2. Clarify an

existing NRC regulation and the basis for the regulation; and, 3. Assist you to clarify a potential petition for rulemaking so that the Commission is able to understand the nature of the issues of concern to you.

The detailed requirements for submitting a petition for rulemaking are included in the NRC's regulations at 10 CFR 2.802 and at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/petition-rule.html>. Once the NRC receives and processes a petition request, petitions for rulemaking that meet the minimum requirements are docketed and made available in the NRC's Agency wide Documents Access and Management System (ADAMS) and on the federal rulemaking portal <http://www.regulations.gov>.

Regarding the third point, your letter also states ADDM's position that future regulations regarding security of devices must be written to account for actual doses to workers and members of the public. Again, you can use the rulemaking petition process to make such a request or the NRC invites and encourages ADDM to comment on any future rulemaking involving the security of radioactive material.

Finally, you have requested that the NRC consult with ADDM on an ongoing basis concerning new and pending regulatory initiatives affecting your members. The NRC regularly invites stakeholder participants early in the formation of such initiatives, during the development of the regulatory basis. Many regulatory initiatives are eventually codified via rulemaking. The NRC invites you to actively participate in the rulemaking process during public comment periods. Rulemakings that are open for public comment may be found at the website below:

<http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/rulemaking-dockets/index.html>

I appreciate your organization's interest in the Rulemaking process. If you have any questions related to this matter, please contact Tomas Herrera at 301-415-7138 or by email: Tomas.Herrera@nrc.gov.

Sincerely,

/RA/

Jack W. Foster, Branch Chief
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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