

October 17, 2014

MEMORANDUM TO: Tomas Herrera, Acting Chief
Materials Safety Licensing Branch
Division of Material, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

FROM: Justin Vazquez **/RA/**
Materials Safety Licensing Branch
Division of Material, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: MEETING BETWEEN THE NUCLEAR REGULATORY
COMMISSION AND THE ASSOCIATION OF DEVICE
DISTRIBUTORS AND MANUFACTURERS TO DISCUSS
RECIPROCITY ISSUES

On October 1, 2014, the Nuclear Regulatory Commission (NRC) staff met with the Association of Device Distributors and Manufacturers (ADDM) to discuss the NRC's reciprocity regulations.

A public meeting notice was issued on September 19, 2014, and was posted on the NRC's external (public) web page. The notice included a set of presentation slides (Agencywide Documents Access and Management System Accession No. ML14261A254) submitted to the NRC by Sean Chapel, President of ADDM, which his group presented and discussed during the meeting.

Justin Vazquez opened the meeting by welcoming attendees, taking roll of who was in attendance in person and by telephone, and then calling upon ADDM to present their slides.

ADDM Presentation and Discussion of Reciprocity Issues

The president of ADDM presented their slides, discussing the current situation regarding the regulatory atmosphere for distributors, manufacturers, and service providers for generally licensed (GL) devices. This presentation expressed concerns that the current situation results in a good deal of confusion for licensees. ADDM provided the following recommendations to the NRC to address these concerns:

1. Include an additional table in NRC NUREG 1556, Volume 19, similar in format to Table 2.1, indicating which tasks constitute reciprocity.

2. Codify, in the NRC regulations, which tasks constitute reciprocity, and require the Agreement States to adopt these changes.
3. Revert the compatibility of 10 CFR 31.6 back to Compatibility Category B.
4. Provide initial and refresher web-based training on reciprocity requirements for Agreement State regulators, NRC license reviewers, and inspectors.

Other recommendations ADDM introduced throughout the meeting included addressing the need for the NRC to provide clear guidelines on what situations constitute “emergencies” for reporting purposes, the NRC/Agreement States developing a program to inspect general licensees, and the NRC to giving industry representatives the opportunity to provide input on regulations that are in development before they are drafted and posted for public comment.

According to ADDM, one of the main issues that licensees encounter is difficulty in determining an Agreement State’s regulations before working in that State’s jurisdiction. They often find that the regulations posted on the internet are outdated, and there is often little guidance available to help them determine what situations require filing for reciprocity. Furthermore, when they contact the Agreement State’s regulatory staff, they can sometimes receive two different answers to the same question from two regulators in the same State.

Another assertion raised by members of ADDM is that Agreement State regulators will at times impose requirements not spelled out in their regulations. This issue entails a regulator’s “interpretation” or introduction of “unwritten regulations.” One member of ADDM stated that the reality of the situation is that licensees “don’t know, from State to State, whether [they] are compliant or not,” and that requirements need to be stated clearly in order for licensees to be able to abide by the regulations.

Another issue discussed by ADDM was the changing of the classification of a device (i.e. from generally licensed to specifically licensed) without notifying licensees. ADDM members expressed frustration in registering and distributing a product as a GL device, and then being told later by an Agreement State that it is not considered a GL device under their jurisdiction.

ADDM members emphasized the point that “the bottom line is safety.” When the regulations are confusing, companies feel that they are under pressure and can be tempted to do things without notifying regulators in order to avoid reciprocity issues. ADDM also suggested that service providers are “almost partners with the regulators” and that they will often find potential safety issues while performing their services and help the companies resolve such issues.

ADDM also noted that there are interstate commerce implications with the issue of reciprocity. They posed the question, “If [the regulation] good enough for NRC States, why is it not good enough for the Agreement States?” Licensees want uniformity in the regulations across the country, and ADDM believes that changing the categorization of 10 CFR 31.6 back to Compatibility Category B will resolve this issue.

NRC Feedback Regarding ADDM's Concerns

NRC staff provided feedback to ADDM regarding their concerns. NRC staff began by remarking that the discussion of reciprocity issues has been going on for some time, and the Commission has upheld a policy that recognizes the need for the Agreement States to have flexibility in their programs, based on their varying traditions and needs, in order to ensure safety.

Commission opinion can, however, change over time, and NRC staff suggested that if ADDM wishes to have their concerns fully considered, the process of doing so would be streamlined by submitting another petition for rulemaking (PRM) that includes any new information presented during the present meeting. NRC staff and ADDM also discussed the possibility of this PRM requesting a change in compatibility for 10 CFR 31.6, while leaving the parts of 10 CFR 31.5 addressed in the 2010 decision categorized as they are presently. NRC staff did, however, emphasize that if ADDM intends to submit a PRM, they need to review history of the matter carefully in order to fully understand the precedent, which the Commission will consider in making their decision.

Regarding ADDM's suggestion that the NRC/Agreement States begin inspecting GL programs, NRC staff explained that some Agreement States already inspect GL programs; however, the NRC does not. For the NRC, it is a matter of policy, based on the fact that there are limited resources available. Furthermore, GL devices are inherently designed to be safe for use by individuals with minimal radiation safety training, so inspection of these devices is a lower priority than it is for other devices. NRC staff went on to mention that the NRC does have certain inspection requirements outlined in NRC inspection manual chapters (IMCs). These IMCs periodically go out for public comment, and there is one for reciprocity inspections on which ADDM could provide input during a future revision.

Regarding ADDM'S interstate commerce concerns, NRC staff emphasized the fact that states cannot prohibit interstate commerce, and each Agreement State provides a way for individuals to do business in their State.

Regarding ADDM's issue with receiving different information from different regulators within the same Agreement State, NRC acknowledged that it is possible for an individual in a State to give a wrong answer. There are, however, means to check/confirm information, and licensees can contact the NRC, if needed. However, as long as they meet established NRC requirements, Agreement States maintain the authority to provide legal interpretation for their own regulations.

Feedback from the Organization of Agreement States and Other Members of the Public

At this point in the meeting, discussion was opened up to any members of the public participating over the telephone bridgeline. A number of members of the Organization of Agreement States (OAS) were in attendance and participated in the discussion.

OAS agreed that "safety is the bottom line," but stated that the Agreement States are given the capability to regulate more strictly than the NRC to ensure safety. OAS emphasized the importance of Agreement State regulators' experience and their understanding of their States' specific needs.

Regarding ADDM's interstate commerce concerns, OAS noted that while some Agreement State regulations might be more restrictive than others, they are not preventing commercial entities from working in their States. Furthermore, regarding the concern over getting different opinions on questions posed to an Agreement State, OAS stated that they would recommend reaching out to a State's Radiation Control Program Director if there is any confusion, rather than seeking an answer among different staff members. Regarding ADDM's issues with limited State-based regulatory guidance, OAS emphasized the fact that the guidance/policy of each Agreement State is their own prerogative, and that any issues should be discussed with the individual State.

Regarding ADDM's concerns with what activities constitute reciprocity, as well as any "unwritten" or "interpreted" requirements, OAS stated that any action that requires licensing/reciprocity will be listed explicitly in the Agreement State's regulations. It is the responsibility of licensee to contact the Agreement State representatives to determine what the requirements are if there is any confusion. However, OAS went on to encourage ADDM members to reach out to their organization if needed.

OAS expressed that it would be helpful for ADDM to put together a list of questions they would like to be distributed to Agreement States in the form of a survey. OAS believes that there are fewer differences among Agreement State regulations than ADDM perceives, and OAS can assist ADDM in understanding these differences.

OAS also made the point that general licensees often default to placing the burden of compliance responsibility on the distributor/manufacturer, rather than on themselves. The licensee will often assume that they are working under the distributor's general license, rather than their own. ADDM agreed with this statement and reiterated their point that distributors and service providers generally attempt to help licensees understand requirements when they are assisting these licensees.

A member of the public, a consultant and former radiation safety officer, made the point that there is confusion during NRC inspections as to whether a device is generally or specifically licensed. He also stated that there is general confusion with the tracking of GL devices, and end users are typically unaware of the GL status of a device in their possession.

The meeting was concluded at this point, with ADDM thanking the NRC for the opportunity to discuss their concerns, and with OAS calling on ADDM to reach out to OAS if they have any questions.

Conclusion

During this public meeting, ADDM presented concerns regarding Agreement State reciprocity regulations, NRC staff responded to these concerns, and OAS provided their own input and perspective on these issues.

Specifically, ADDM provided several examples of reciprocity issues with Agreement States, and encouraged the NRC to consider improving their guidance related to reciprocity. ADDM also reiterated their request that the NRC revert the categorization of 10 CFR 31.6 back to Compatibility Category B.

NRC staff encouraged ADDM to provide specific comments on recommended changes to the draft NUREG 1556, Volume 19, to the NRC by the end of the calendar year (2014). NRC staff will consider these recommendations before the revised Volume 19 is issued. Additionally, regarding the categorization of 10 CFR 31.6, NRC staff reiterated the reasoning for the 2010 decision, but encouraged ADDM to file another PRM with the NRC containing any additional information that has not been provided in the past. This will help streamline the process of reviewing any concerns documented in a PRM.

OAS emphasized the importance of allowing the Agreement States to determine their own reciprocity requirements in order to give them the flexibility they need to manage their programs and maintain safety within their jurisdictions. OAS, however, encouraged ADDM to reach out to the Agreement State if there is any confusion regarding requirements within that particular State, stating that OAS is available to provide assistance if needed. OAS also encouraged ADDM to provide them with a set of questions that they would like to have distributed to the Agreement States to support a survey of the various Agreement State members.

Enclosure: List of Attendees

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Enclosure: List of Attendees

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OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/ASPB	NMSS/MSTR/MSLB
NAME	JVazquez	AMcMurtray	DWhite	THerrera
DATE	10/16/2014	10/16/2014	10/16/2014	10/17/2014

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LIST OF ATTENDEES

MEETING WITH THE ASSOCIATION OF DEVICE DISTRIBUTORS
AND MANUFACTURERS TO DISCUSS RECIPROCITY ISSUES

WEDNESDAY, OCTOBER 1, 2014

<u>NAME</u>	<u>TITLE</u>	<u>ORGANIZATION</u>
Duncan White	Branch Chief	NRC/FSME/DMSSA
Jim Danna	Branch Chief	NRC/FSME/DILR
Anthony McMurtray	Acting Branch Chief	NRC/FSME/DMSSA
Kimyata Morgan-Butler	Policy Advisor for Materials	NRC/COMM/OCM
Jack Foster	Executive Technical Assistant	NRC/EDO/AO/TCCM
Sarenee Hawkins	Allegations Coordinator	NRC/FSME
Shirley Xu	Health Physicist	NRC/FSME/DMSSA
Catherine Mattsen	Senior Project Manager	NRC/FSME/DILR
Stephen Poy	Engineer	NRC/FSME/DMSSA
Solomon Sahle	Health Physicist	NRC/FSME/DILR
Maria Arribas-Colon	Project manager	NRC/FSME/DMSSA
Lymari Sepulveda	Engineer	NRC/FSME/DMSSA
Justin Vazquez	Engineer	NRC/FSME/DMSSA
Sean Chapel	President	ADDM
Jonathan Fortkamp	Corporate Radiation Safety Officer	ABB, Inc.
Gary Caines	Radiation Operations Program Manager	Honeywell International
Jack Ramsey	Senior Radiation Safety Officer	Metso Automation USA
Rod Harrell	Health Physicist	Honeywell International
Brian Barker	Health Physicist	Honeywell International
Mike Welling	President	OAS
Steve Matthews	Radiation Health Physicist	Washington
Spencer Wickham	Division of Radiation Control Staff	Utah
Cathy Biel	Acting Supervisor	New Jersey
Joseph Power	Industrial and Decommissioning Staff	New Jersey
Jennifer McAllister	Environmental Program Specialist	Oklahoma
Cheryl Rogers	Supervisor	Wisconsin
Paul Vause	Administrator	Florida
Michael Stevens	Administrator	Florida
Robert Dansereau	Assistant Director	New York
Dan Samson	Acting Chief	New York
Jack Pluister	Vice President	Heuft USA, Inc.
Darrel Liles	Senior health Physicist	SENES Consultants

FSME = Office of Federal and State Materials and Environmental Management Programs

DMSSA = Division of Materials Safety and State Agreements

DILR = Division of Intergovernmental Liaison and Rulemaking

COMM/OCM = Office of the Commission

EDO = Office of the Executive Director for Operations

AO = Assistant for Operations

TCCM = Technical Corporate and Correspondence Management