

December 22, 2011

Mrs. Cheryl K. Rogers, Chair
Organization of Agreement States, Inc.
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Dear Mrs. Rogers:

I am responding to the petition for rulemaking (PRM) that Mr. Paul Schmidt submitted to the U.S. Nuclear Regulatory Commission (NRC or the Commission), dated June 27, 2005, on behalf of the Organization of Agreement States, Inc. (OAS). This petition was docketed as PRM-31-5 and requested that the NRC amend its regulations to strengthen the regulation of radioactive materials by requiring a specific license for higher-activity devices that are currently available under the general license in Title 10 of the *Code of Federal Regulations* (10 CFR) 31.5. Additionally, the petition requested that the NRC revise the compatibility designation of 10 CFR 31.6 from Category B to Category C.

The petition was considered together with a related request received from the Bureau of Radiation Control of the Florida Department of Health, and the notice of receipt of the petition for rulemaking was published in the *Federal Register* (FR) on December 20, 2005 (70 FR 75423). The comment period closed on March 6, 2006. Four comment letters were received. The NRC considered the petition and the supporting rationale, determined that issues and concerns raised in the petition merited further consideration, and initiated a rulemaking. On August 3, 2009, the NRC published a proposed rule, "Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (74 FR 38372). The proposed rule would have amended the NRC regulations to limit the quantity of certain byproduct material allowed in a generally licensed device to below 1/10 of the International Atomic Energy Agency's Category 3 thresholds; licensees with devices containing byproduct material at or above this limit would be required to obtain a specific license. The proposed rule also would have changed the compatibility designation of 10 CFR 31.5(a), 10 CFR 31.5(c)(13)(i) and 10 CFR 31.6 from Category B to C.

The comment period for the proposed rule ended on October 19, 2009, and 55 comment letters were received. The commenters on the proposed rule included Federal agencies, States, licensees, industry organizations, environmental advocacy groups, and individuals. Staff sent a final rule paper, SECY-10-0105, entitled "Limiting the Quantity of Byproduct Material in a Generally Licensed Device," to the Commission on August 10, 2010.

In the Staff Requirements Memorandum (SRM), dated December 2, 2010, the Commission disapproved the publication of the final rule, but approved revising the compatibility designation of 10 CFR 31.5 and 10 CFR 31.6 from Category B to C. For the reasons provided in the

enclosed *Federal Register* Notice (FRN) and consistent with the Commission's SRM, the petition for rulemaking is denied, but the compatibility designations for 10 CFR 31.5 and 10 CFR 31.6 are being changed from Category B to C.

The compatibility Category C designation will allow Agreement States the flexibility to enhance accountability; retain use of tools to track the location and movement of devices, manufacturers and service providers within the State limit; address issues specific to their jurisdictions; continue programs that have proven beneficial; and adopt requirements based on their specific circumstances and needs. The NRC plans to evaluate the degree to which the Agreement States modify their programs as a result of the change in compatibility category and analyze any transboundary impacts to regulated entities, particularly those operating on a multi-state basis. The Commission also plans to consider updates to the Policy Statement on Adequacy and Compatibility of Agreement State Programs and associated guidance documents to include both safety and source security considerations in the determination process.

In summary, the petition for rulemaking is being granted in part and denied in part. The Commission granted the petition to change the compatibility designation and denied the petition by determining that there is not a clear safety risk reduction or security enhancement that would justify the proposed threshold for requiring a specific license. The appropriate Congressional committees will be informed.

The FRN closing the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
Federal Register Notice

enclosed *Federal Register* Notice (FRN) and consistent with the Commission's SRM, the petition for rulemaking is denied, but the compatibility designations for 10 CFR 31.5 and 10 CFR 31.6 are being changed from Category B to C.

The compatibility Category C designation will allow Agreement States the flexibility to enhance accountability; retain use of tools to track the location and movement of devices, manufacturers and service providers within the State limit; address issues specific to their jurisdictions; continue programs that have proven beneficial; and adopt requirements based on their specific circumstances and needs. The NRC plans to evaluate the degree to which the Agreement States modify their programs as a result of the change in compatibility category and analyze any transboundary impacts to regulated entities, particularly those operating on a multi-state basis. The Commission also plans to consider updates to the Policy Statement on Adequacy and Compatibility of Agreement State Programs and associated guidance documents to include both safety and source security considerations in the determination process.

In summary, the petition for rulemaking is being granted in part and denied in part. The Commission granted the petition to change the compatibility designation and denied the petition by determining that there is not a clear safety risk reduction or security enhancement that would justify the proposed threshold for requiring a specific license. The appropriate Congressional committees will be informed.

The FRN closing the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
Federal Register Notice

Distribution:

DILR R/F
DMendiola, ADM

ML112140193/ML120050152/EDATS: FSME-2011-0101

OFC	PM: RBA/DILR	BC: RBA/IDILR	D:DILR	ADM
NAME	SSahle	JDanna	JPiccone(DJackson for)	CBladey
DATE	11/28/11	12/6/11	12/7/11	6/30/11
OFC	OGC	Tech Editor	D:FSME	EDO
NAME	BJones	PTressler	MSatorius (CCarpenter for)	RWBorchardt
DATE	11/7/11	12/8/11	12/16/11	12/22/11

OFFICIAL RECORD COPY