

Discussion of State Comments on Draft Final Rule

The Organization of Agreement States (OAS), Virginia, and Washington submitted comments. OAS' and Virginia's comments were the same and involved mostly suggested editorial revisions for rule text with the intent of achieving consistency with other regulations. For various reasons, most of these changes were not made. For example, the suggestion of using English units first (with International System of Units (SI)) following in parentheses) in new dose standards would be contrary to the Commission's policy on use of the SI units. Also, these comments suggested being more uniform in using the terminology, "equivalent regulations of an Agreement State." However, this terminology is generally used when there is a requirement for or an expectation of equivalency based on compatibility requirements. The rule retains the use of "comparable" in place of "equivalent" when referring to Agreement State regulations, in some instances where there are limited or no compatibility requirements for the subject regulations and equivalency is not important to the applicability of the particular regulation.

One comment from OAS and Virginia dealt with the annual transfer reporting requirements for luminous aircraft safety devices (§ 32.56), which is being revised to require transfer reports to Agreement States and clarify that a report must be provided even when there are no transfers into NRC jurisdiction, i.e., a "null report." The draft rule would also require a null report to an Agreement State if they request it. The comment was that the States should not have to make such a request. However, the null report serves the purpose of verifying to the agency issuing the license that the licensee has not failed to comply with reporting requirements, eliminating any need to follow-up with the licensee concerning the possible noncompliance. It is not necessary for all jurisdictions to receive such a report, just the agency that issued the license, nor is it justified for the licensee to have to generate numerous such reports every year, particularly for this device for which tracking beyond the initial report is not required. Consequently, no change was made by the staff.

Washington's comments were very supportive of the rule with support specifically stated for 1) issuing guidance concurrent with the final rule, 2) prompt reporting and making inactive SS & D certificates for products no longer being initially distributed, 3) the concept of grandfathering, 4) not issuing SS & D certificates with expiration dates, and 5) exemptions for sources without a significant health and safety, environmental, or security hazard. With regard to item 4, Washington believes that licensees should be required to confirm that SS & D certificates are accurate and current at the time of license renewal. No change was made to the draft rule in this regard; however, under the existing requirement in § 32.210(f), the certificate holder has an ongoing responsibility to manufacture and distribute in accordance with the certificate and statements made in obtaining the certificate. Each State has flexibility as to the degree to which it will verify that this is being complied with on an ongoing basis and at the time of license renewal.

With regard to item 5, Washington was concerned about the NRC ensuring that landfill disposal impacts are limited and suggested that EPA's Toxicity Characteristic Leaching Procedure (TCLP) be part of the exemption process. TCLP is a test for certain toxic chemicals in waste and the extent to which they might leach out in a landfill. Requiring such a test on a product would be beyond NRC's jurisdiction. To the extent that there is a concern about byproduct material leaching out in landfills, there are existing provisions in NRC regulations and in these draft regulations that address containment under conditions of use and in the case of class exemptions, criteria for exposures from uncontrolled disposal. Because of the uncertainties involved, assessments for potential exposures from disposal of products authorized for use under exemption are conservative and do not assume that the byproduct material is retained in

the products after disposal. The staff believes that the potential impacts of uncontrolled disposal of products used under exemptions have been and are being adequately addressed in our regulatory program, including the provisions in this rule.

With regard to licensing flexibility for unspecified models of sources and devices, Washington supports this concept *only* for manufacturers and distributors and service provider licensees, and provided that licensee staff are trained and experienced with the product type, and are trained how to recognize and get help for emergency or unfamiliar situations. In response to this comment, the staff notes that the regulation does not provide such a specific limitation, but limits it to when it is not feasible to identify each source and device individually. The statement of considerations and NRC's draft interim guidance include limited additional circumstances acceptable to the NRC staff; however, the Agreement States will be free to determine what is reasonable and acceptable to them in licensing within their jurisdiction.

A significant comment made by Washington that is outside of rulemaking was a suggestion for the NRC to establish a database of information on "problem products." Specifically, Washington stated that "licensees, jurisdictions, emergency responders, and Homeland Security agencies, may need prompt access to a single 'problem products' reference list of radioactive material products that have suffered failures or leaks." This would include details of the radiation hazard (such as failures or leaks) and brief emergency response and radiation hazard abatement directions for use during an incident. While SS & D certificates may be updated to include such warnings, Washington believes it is impractical for the SS & D Registry to serve as a database of information for that purpose and the staff agrees. The Nuclear Material Events Database (NMED) does have information about reportable issues with sources and devices and the various required reports would also form the primary basis of any such new database. However, NMED and the SS & D Registry are not available to some of the entities referred to by Washington, including licensees. Recommendations about the appropriate response and hazards abatement for a particular source or device are best provided by manufacturers and such information is at least in part included in operating manuals and similar documents that are required to be provided to licensees by manufacturers and distributors.