

Discussion of State Comments

Seven Agreement States (Pennsylvania, Minnesota, Louisiana, Washington, Illinois, Texas, and California) provided comments on the draft *Federal Register* Notice (FRN). The State of Michigan also provided a minor correction and numerous suggested revisions to the regulatory text intended to apply plain language guidelines. Comments were generally supportive with a few questions and concerns. A number of the comments were outside of the scope of the proposed rule, such as a suggestion to eliminate general licenses. Other comments were a result of misreading some of the draft proposed provisions. In some cases, States were contacted to clarify their concerns. These concerns and comments were considered and reflected in the draft FRN.

One substantive revision of rule text was made as a result of State comment. A State commenter recommended that the Sealed Source and Device (SS & D) certificate inactivation provision should be mandatory and have a time limit, such as 2 years after the last transfer. While the NRC's fee structure creates incentive for licensees to seek inactivation of certificates, all States do not have fees for registration certificates. The text of proposed § 32.211 was revised to strengthen the requirement and add the suggested time limit. The staff recommends Compatibility Category B for those States that issue SS & D certificates, so that all such States will have a provision and process for inactivation and distributors would be required to notify the respective regulator and request inactivation of certificates for products no longer being distributed.

Some State commenters seemed more comfortable with product-specific exemptions than with class exemptions as they had concerns about what products and quantities would be covered by the new class exemption. There were recommendations as to what factors should be considered in evaluating products for use under an exemption from licensing, or which products should or should not be exempted. One State commenter specifically noted that the ingestion annual limit of intake in Part 20 for polonium-210 (Po-210) was low compared to the amount of Po-210 proposed for the exemption being added for static eliminators to § 30.15 and that Po-210 had been used as a poison. The staff notes that the proposed exemption in § 30.15, which would replace § 31.3, is for Po-210 in sealed sources contained in devices. The potential for ingestion is greatly reduced because of the form and the containment of the Po-210. This change would make an existing regulatory framework (which includes evaluation of chemical and physical form and containment) applicable for this product, improving assurance that the appropriate evaluations are made in licensing the distribution of such products in the future. As to the proposed class exemption, it would be restricted to devices manufactured, processed, produced, or initially transferred from a § 32.30 licensee. The provisions in proposed §§ 32.30, 32.31, and 32.32 would provide NRC staff with adequate tools to ensure that only those products that can be safely used under an exemption will be allowed to be distributed to persons exempt under proposed § 30.22. Also, information on the particular products approved for use under class exemptions is made available to the States through inclusion in the SS & D registry.

One State commenter suggested that the wording of the accident criteria for class exemptions may be more appropriate for use in the § 32.51 accident criteria. However, there are reasons for differences between the safety criteria for exempt products and those for generally licensed products related to the different status of users. The accident analysis for the general license was intended to be essentially a single "worst case" where a fire and explosion would result in release of the material. Because there are no controls once a product is transferred for use

under an exemption, the safety criteria for the class exemptions are intended to involve a more complete assessment of overall risk from various scenarios which might occur.

One State commenter noted that some States review SS & D registration certificates at the time of license renewal and recommended that this be standard practice. One State commenter recommended that all sealed sources and devices undergo a safety review before being distributed. One State indicated that it does not have the staff to keep registration certificates up to date. With regard to SS & D registration certificates, this rule would primarily codify current licensing practices. At this time, the staff desires to maintain flexibility as to approaches for updating certificates, being careful not to add to resource needs. As to any sealed sources and devices not required to be included in the SS & D registry, safety reviews are nonetheless conducted in the licensing process.

One State commenter questioned whether the provision in § 30.32(g)(5), which would allow some devices to not be specifically identified in the license, would affect tracking in the National Source Tracking System (NSTS). Another questioned whether this would allow devices to be distributed without identifying marks. Another disagreed with § 30.32(g)(5) without a stated reason. However, the staff notes that this provision would not affect the applicability of labeling requirements or that of NSTS requirements, under which the distributor would normally provide the initial transaction report. This provision would not be used in a renewal process for currently held sources subject to NSTS.

One State commenter suggested that § 32.56 be changed to quarterly reporting (rather than annual) and to include automatic null reports to all jurisdictions. As this would require 144 reports per year (and more as the number of Agreement States increase) for a relatively low risk device, the staff does not believe that this is warranted, and would not significantly improve tracking of § 31.7 generally licensed devices.