

## **Agreement State Comments on Draft Rulemaking Plan**

### **Summary:**

The States of Colorado, Ohio, Kansas, Washington, New York (Department of Labor), and Illinois commented on the draft Rulemaking Plan. Washington and Illinois specifically provided support for the recommended Option 2 and expressed particular support for addressing some of the specific issues. The comments were generally supportive with concerns about a few specific issues: (1) not fully applying recent ICRP methodology in regulations, (2) the use of the Sealed Source and Device Registry, (3) the possible exemption of general licensees from immediately reporting thefts or losses under § 20.2201(a)(i), (4) the possible NRC licensing of manufacturers for possession and use in Agreement States, and (5) not specifically requiring demonstration of ALARA in designs of products. Colorado, Ohio, and Illinois questioned NRC's continuing to retain authority to license exempt distribution under § 150.15(a)(6). Colorado suggested the use of a standing compatibility committee for this rulemaking. Kansas suggested that addressing all the issues as in Option 3 would provide the most comprehensive protection of the public from unnecessary exposure to radiation, but expressed concern about reducing distributor and general licensee requirements. New York's Department of Labor (NYDOL) maintains that making the requirement for registration in the Sealed Source and Device Registry explicit in the regulations should involve justification as a new requirement and that doing so should be addressed in a separate rulemaking. NYDOL also suggests that there are questions of legislative authority for the registration requirement that need to be answered.

### **Discussion:**

Regarding the comments on exempt distribution under § 150.15(a)(6), in a clarifying revision to that paragraph published April 16, 1969 (34 FR 6517), the reasons for NRC's retaining this authority were summarized as follows: "[T]he Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment." This general intent, as well as the more specific related goals of the Consumer Product Policy, could not be well attained with multiple entities regulating such distribution.

In response to Colorado's comment on a standing compatibility committee, if such a committee is established, as recommended by the National Materials Program, the compatibility categorization of the proposed rule would be reviewed by that committee.

Concerning NYDOL's comments on the issue of making the regulations explicit on the use of the Sealed Source and Device Registry, the staff agrees that the rulemaking process should include an explanation of the rationale for using a registration process as a licensing mechanism and basis for determinations on which products should be included in the Registry. The staff does not agree that there is a problem with legislative authority in using this tool in the licensing process or that this issue warrants a separate rulemaking.

With respect to the possible inconsistency in the risk basis of generally licensed devices meeting the criteria for immediate notification when lost or stolen (i. e., allowing a device to be generally licensed when its loss or theft may justify immediate notification), comments

suggested that the NRC needed to revisit either the appropriateness of some of the devices' generally licensed status or the appropriateness of the risk levels associated with the criteria for immediately reporting thefts or losses under § 20.2201(a)(i). The staff has not identified a problem with the safety criteria associated with generally licensed devices. Although the criteria in § 20.2201 may require immediate notification for quantities of some radionuclides that present too low a level of risk, the staff believes that a reevaluation of these criteria should not fall within the scope of the subject rulemaking. Also, the situation for general licensees and specific licensees is sufficiently different, particularly in the area of training, that it would be reasonable for specific licensees to be required to call the Operations Center immediately concerning thefts or losses, and general licensees within 30 days, for the same quantities of radionuclides. As generally licensed devices meeting the requirement for registration are considered a potential problem for contamination if smelted, this aspect will also be evaluated. In addition, generally licensed devices are not expected to contain the types and quantities of radioactive material that would be of concern for possible terrorist use in a radiological dispersion device. However, the staff will consider any conclusions developed with respect to that issue and the need for improved control of sources, when developing the subject proposed rule.

Clarifications have been made to the draft rulemaking plan in response to Agreement State comments. In addition, Attachment 6, which was not reviewed by the Agreement States, provides supplemental discussion of some of the issues. Such clarifications may reduce State concerns (e. g., allowing an option for NRC licensing of possession and use by manufacturers in Agreement States may have implied that the NRC might reduce States' authority to do so; however, the staff only suggests that a possible option might be made available for this to happen if the individual State agrees). The Agreement State comments will also be considered during the development of the proposed rule.