

REPORT ON TRANSBOUNDARY IMPLICATIONS FOR IMPACTS ON COMPATIBILITY CHANGES FOR GENERAL LICENSE REGULATIONS

Background

On August 10, 2010, the staff of the U.S. Nuclear Regulatory Commission (NRC) submitted a paper to the Commission requesting approval to publish a final rule that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 31, "General domestic licenses for byproduct material." The proposed final rule would limit the byproduct material contained in a generally licensed device (GLD) to below one-tenth (1/10) of the International Atomic Energy Agency Category 3 thresholds. Individuals possessing devices with byproduct material at or above 1/10 of the Category 3 threshold values were to be required to apply for and obtain a specific license. The proposed final rule would also change the compatibility categories of 10 CFR 31.5 and 10 CFR 31.6 from Category B to Category C. On December 2, 2010, the Commission disapproved the publication of the proposed final rule, but approved revising the compatibility categories.¹

The Commission directed staff to report back with a description of which Agreement States, if any, will modify their program as a result of the change in compatibility for 10 CFR 31.5 and 31.6, how the programs were modified, and to provide an analysis of any transboundary impacts to the regulated community, particularly those operating on a multi-state basis, and recommend any corrective actions, if needed.

A description of the staff's process for gathering the requested information and timeline is provided in Appendix A. The questions posed to the Agreement States and to the regulated community during the public meetings to solicit information on the impacts of the compatibility change are provided in Appendix B.

Status of Agreement State Regulatory Modifications Due to Compatibility Change

On April 7, 2011, the NRC staff surveyed the Agreement States on their current regulatory programs, and whether they intend to modify their current regulations that are equivalent to 10 CFR 31.5 and 31.6 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110900263).

The Agreement States' responses to the survey indicate that there are no plans to modify the current general license (GL) regulatory programs as a result of the Commission's decision to revise the compatibility categories. A table showing the status of compatibility of general license regulations in the Agreement States is provided in Appendix C. Given the assumption that the current regulatory environment will continue, the staff concluded that there would be minimal impact to manufacturers, distributors, and end-users of GLDs. Feedback and the actions by the

¹ The NRC staff uses an established process to determine when a proposed or final regulation should be adopted as a legally binding requirement by an Agreement State and whether adoption is required for the purpose of compatibility or health and safety. Compatibility categories are established based on the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517; September 3, 1997). This Policy Statement sets forth the approach that the Commission uses to classify program elements that should be adopted by an Agreement State to maintain an adequate and compatible program. Management Directive 5.9, "Adequacy and Compatibility of Agreement State Program," describes the specific criteria and process that will be used to identify the compatibility categories of those NRC program elements that should be adopted by an Agreement State for purposes of compatibility, as well as for identifying those program elements that have a particular health and safety significance.

Agreement States with regard to their GL regulatory programs indicate that they support the actions by the Commission in changing the compatibility category from Category B to C.

Impacts on the Regulated Community based on Provided Comments

To gather information on the stakeholder licensee (manufacturers, distributors, and end-users of GLDs) impacts, the NRC staff queried the Agreement States to identify their licensees who would be most impacted. The NRC issued a *Federal Register* notice (76 FR 56124; September 12, 2011), requesting information from stakeholder licensees on the impacts of the revision of the compatibility categories for 10 CFR 31.5 and 31.6 to their businesses and providing notice of public meetings to be held on September 20 and 22, 2011. A summary of the information and comments obtained through the public meetings and the *Federal Register* notice is provided in Appendix D.

The feedback from the stakeholder licensees included concerns about the ability of the Agreement States to each have different GL regulations. The manufacturers and distributors would prefer to have the same GL regulations across all of the Agreement States and that the compatibility category of 10 CFR 31.5 and 31.6 remain Category B. However, if establishment of the same GL regulations in all of the Agreement States are not achievable, then some national consistency with respect to accountability of the end-users is desired. The manufacturers and distributors discussed, at length, the impacts of the compatibility change on their businesses including: different labeling requirements; different reporting requirements; different fees; and the burden of requiring members of industry to have a clear understanding of the differing regulations across the Agreement States. The manufacturers and distributors also claimed that the confusion created by the varied regulatory environments has led to health and safety issues although they did not provide specific information despite follow up from staff. The manufacturers and distributors also stated that this confusion has resulted in mistakes and violations, but did not provide specific examples despite follow-up from staff.

Summary of Feedback

Based on the feedback and comments submitted by some Agreement States and members of the regulated community, both groups have taken distinct positions regarding the Commission's decision to change the compatibility category to C. The Agreement States' feedback and actions on the change in compatibility for 10 CFR 31.5 and 31.6 can be summarized by the following: (1) Agreement State representatives provided comments in support of the Commission's actions in changing the compatibility category to C, and (2) to date, no changes have been made to Agreement State regulations equivalent to 10 CFR 31.5 and 31.6 by the States as a result of the compatibility change.

The regulated community indicated that their concerns are in the following areas: (1) economic impacts, (2) burdensome process, and (3) health and safety. Additionally, the regulated community has also indicated that national consistency with respect to GL regulations would address these concerns.

A complete analysis of the two perspectives is provided in Appendix E.

Conclusions

The NRC staff concludes that the change in compatibility category from B to C for the GL regulations addresses the need for flexibility in the Agreement States. The staff further concludes that there were no impacts to the Agreement States from the change in the compatibility category, since all of the States have adopted regulations that address their individual needs. A survey of the Agreement States showed that none of the States plan to amend their regulations in the near future. The Agreement States that have been identified as having less restrictive GL regulations than the NRC will need to revise their GL regulations to address the previously identified deficiencies.

Similarly, the staff concludes that the manufacturers and distributors and end-users of GLDs have been minimally impacted. The regulated community has been operating in the current GL regulatory environment where the Agreement States have been adopting more restrictive regulations than the NRC for over 10 years. Therefore, the staff does not recommend any corrective actions at this time.

It should also be noted that there has not been national consistency in the regulatory environment for GLDs since before the final GL rule was issued in 2000 (65 FR 79162; December 18, 2000). The staff recognizes that the manufacturers and distributors and end-users of GLDs expressed, during the public meeting, that having to operate in varying regulatory environments has resulted in some administrative and financial burden on these entities. However, the staff also notes that the manufacturers and distributors and end-users have demonstrated their ability to adjust their business practices and their ability to cope with the varied regulatory environments over the last decade. The staff also recognizes the regulated community's continued interest in the compatibility issue as indicated by the Petition for Rulemaking submitted May 7, 2012, on behalf of the Association of Device Distributors and Manufacturers to "Reinstate the Compatibility of 10 CFR 31.6, General License to install devices generally licensed in 31.5, from "C" to "B" and to create a new, similar regulation for exempt devices" (ADAMS No. ML12146A083).

List of Appendix

Appendix A: Information Gathering Timeline and Transboundary Impacts (ML121090103)

Appendix B: Questions to the Agreement States and the Regulated Community
(ML121090108)

Appendix C: Spreadsheet Summarizing the Current Status of the Equivalent Agreement
State General Licensing Regulations 10 CFR 31.5 and 31.6 (ML121090132)

Appendix D: Summary of Comments Obtained on Transboundary Impacts (ML121090148)

Appendix E: Summary of Feedback and Stakeholder Suggestions (ML12145A770)