Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 31

[Docket No. PRM–31–5; NRC–2005–0018; NRC–2008–0272]

Withdrawal of Proposed Rule and Closure of Petition for Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of proposed rule and closure of petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is closing a petition for rulemaking (PRM–31–5) submitted by the Organization of Agreement States, Inc. (OAS). The petition 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 a general license, and change the compatibility designation of applicable regulations from category B to category C. The petition also addresses a request filed by the Florida Department of Health, Bureau of Radiation Control, to change the compatibility category of a certain part of the applicable regulation from category B to category C. In response to the petition, the NRC developed a proposed rule that would have changed the compatibility of the applicable regulations, and would have limited the quantity of byproduct material contained in a generally-licensed device to below one-tenth of the International Atomic Energy Agency (IAEA) Category 3 thresholds. After further review, the NRC has decided to withdraw the proposed rule and to change the compatibility designation of the applicable regulations from category B to category C.

DATES: The proposed rule to limit the quantity of byproduct material contained in a generally licensed device (74 FR 38372; August 3, 2009) is withdrawn on January 25, 2012. The docket for PRM–31–5 is closed on January 25, 2012.

ADDRESSES: You can access publicly available documents related to proposed rule or the petition using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O–1F21, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Document Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online at the NRC's Library at *http://www.nrc.gov/NRC/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–(800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.*
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this document can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2005–0018 or NRC–2008–0272. Address questions about NRC dockets to Carol Gallagher, telephone: (301) 492–3668; email: *Carol.Gallagher@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–3781, email: *Solomon.Sahle@nrc.gov.*

SUPPLEMENTARY INFORMATION:

The Petition

In its PRM, the OAS requested that the NRC amend its regulations to require specific licensing for devices exceeding the registration quantity limits in Title 10 of the Code of Federal Regulations (10 CFR) 31.5(c)(13)(i). Additionally, OAS requested that the NRC revise the compatibility category of 10 CFR 31.6 from category B to category C, which OAS believes would allow States to better track service providers and distributors of generally-licensed devices. In addition, the Florida Department of Health, Bureau of Radiation Control, submitted a separate request to change the compatibility category of 10 CFR 31.5(c)(13)(i) from category B to category C, which would allow the State to continue to require registration of other generally-licensed devices in addition to those currently registered by the NRC. Florida's request (ADAMS Accession No. ML052700236) was included with the OAS petition under PRM–31–5 (ADAMS Accession No. ML051940187).

Public Comments on the Petition

The NRC published a **Federal Register** notice requesting public comment on PRM–31–5 on December 20, 2005 (70 FR 75423). The comment period closed on March 6, 2006, and the NRC received four comment letters from States and industry. The commenters had differing views on using the registration levels to require general licensees to become specific licensees, and on changing the compatibility categories.

Comments on requiring some general licensees to become specific licensees.

Comment: One commenter supported adding a requirement to specifically license higher-activity-level devices that are currently available under a general license. The commenter argued that the requirement would enhance security and accountability of these devices, and would prevent aggregation of radioactive sources in the devices to quantities of concern. The commenter noted that the regulatory change to require higher-activity-level, generally-licensed devices to have a specific license was long overdue from a safety and security perspective, and that the rule would not impose a significant burden to implement.

Comment: Three commenters did not support requiring higher-activity-level, generally-licensed devices to obtain a specific license. The commenters include an Agreement State and two generally-licensed device manufacturers and distributors. These commenters believed that the general-license regulatory approach should remain as is. The Agreement State commenter stated that, in its jurisdiction, generally-licensed devices are registered and tracked to a very high standard. Another commenter stated that the proposed change would break with the established procedures for device

review conducted during the device-approval process.

This commenter also stated that the current criteria in 10 CFR 32.51 is used to determine if a particular device warrants being specifically or generally licensed. These criteria take into account additional factors other than the activity of the source and include requirements for prototype testing, potential dose considerations, etc. This commenter stated that the NRC and the Agreement States have been using these criteria for many years and that these proposed changes would be inconsistent with established policy. Another commenter, who represents several manufacturers, distributors, and providers of services for radiological devices, stated that there is no demonstrated safety or security justification for the changes requested in the PRM. This commenter also stated that the changes would not increase the security or the safety of generally-licensed devices, and he is not aware of any safety or security concerns that could not be equally, and in some cases better, addressed by the current registration program. Under the current registration process, general licensees must submit signed annual reports to the NRC or the Agreement State detailing what devices they possess and any changes from their previous reports. Thus, each licensee has a designated employee review their inventory and compliance on an annual basis. This process also allows the NRC or the Agreement State to annually review the general licensees. If there are unresolved discrepancies between annual reports, then the NRC or the Agreement State can require immediate clarification by the licensee. The commenter also stated that under most fixed-gauge specific licenses, there is a 5-year inspection cycle with no interaction between the NRC or the Agreement State and the licensee during that period. Thus, there would be a net decrease in oversight if this proposal is adopted.

These commenters stated that the registration program has been very successful in maintaining awareness of generally-licensed devices and they would not be opposed to seeing the registration and the annual reporting requirements extended to all general licensees, not limited to only certain isotopes and activities.

NRC Response:

In response to the PRM, the NRC developed a proposed rule that would have implemented many of the suggestions in the PRM (74 FR 38372; August 3, 2009). The NRC received public comments on the proposed rule, and considered those comments as part of the development of a draft final rule.

The Commission reviewed the draft final rule, and in the Staff Requirements Memorandum (SRM) for the draft final rule, dated December 2, 2010, the Commission disapproved publication of the final rule (ADAMS Accession No. ML103360262). In their voting records, several Commissioners, like some of the commenters, noted that they did not see a clear safety risk reduction or security enhancement that would justify the proposed threshold for requiring a specific license, or sufficient information on the aggregation of generally-licensed devices for malevolent purposes (ADAMS Accession No. ML103370094).

Comments on the compatibility change.

Comment: Two commenters supported changing the compatibility of 10 CFR 31.5(c)(13)(i) and 10 CFR 31.6 from category B to category C. According to these commenters, multiple Agreement States have long required more stringent regulation of generally-licensed devices than the NRC. As early as 1963, States began to establish additional regulatory requirements, ranging from specific licensing to registration of all generally-licensed devices, to address problems in their States. For the NRC and the Agreement States that did not have a generally-licensed device registration program, the general-license rule was a step forward. However, for those Agreement States that already had a registration program or required a specific license for generally-licensed devices, the general-license rule was a major step backward. The commenters believe that the Commission's decision to broadly apply compatibility B to 10 CFR 31.5 and 10 CFR 31.6 threatens to cancel long-standing State regulatory programs and activities that have helped to improve device accountability and reduce the number of lost sources. The commenters believe that the changes requested in the petition are necessary to enhance the security and accountability of generally-licensed devices. Further, the commenters believe that the change in compatibility category will provide those Agreement States with more stringent regulatory programs the flexibility to continue to impose more stringent requirements than the NRC.

NRC Response:

The NRC agrees with the commenters that the category C designation will allow Agreement States the flexibility to enhance accountability, address issues specific to their jurisdictions, continue programs that have proven beneficial, and adopt requirements based on their specific circumstances and needs.

Comment: Two commenters disagreed with the proposal to revise the compatibility of 10 CFR 31.6 from B to C.

One commenter stated that many States have adopted equivalent provisions to 10 CFR 31.6 in their regulations; however, as a matter of policy, these States still require reciprocity for the servicing of generally-licensed devices even if there are no specifically-licensed materials or activities involved. The purpose of this policy is to track generally-licensed device vendors in the same manner as specific licensees working under reciprocity. The commenter believes that this policy is inconsistent with the intent of the regulations, which are supposed to make it easier for vendors to service generally-licensed devices.

The second commenter stated that the change in compatibility would be overly burdensome and financially detrimental to both manufacturers and licensees that possess generally-licensed devices. According to this commenter, under the current designation of compatibility category B, device manufacturers and service providers are basically working under one set of nationwide regulations. The commenter believes that this situation is far superior to the confusing alternative that would be caused by changing the compatibility of 10 CFR 31.6 to category C. Working under one set of regulations is significantly easier to comply with than working under as many as thirty sets of constantly changing regulations. The commenter believes that this possibility indicates that there are transboundary implications associated with this change. Further, the commenter stated that current 10 CFR 31.6 grants a general license, and changing the compatibility designations from category B to C would allow Agreement States to charge fees for reciprocal recognition of licenses from other Agreement States and the NRC. The commenter believes that general licensees would then pass the cost of these fees on to customers. According to the commenter, the overall purpose of the Atomic Energy Act and the NRC's regulations is to safeguard the public. Changing 10 CFR 31.6 from compatibility category B to C will not enhance either the radiological safety or security of byproduct material. The current compliance level with 10 CFR 31.6 for manufacturers and service providers is very high because the regulations are concise and easy to understand. This commenter believes that a change in the compatibility could result in a significantly more confusing

situation and a decrease in the overall compliance with the regulations.

NRC Response:

The NRC disagrees with the commenters. Changing the compatibility designation of these regulations will not result in increased cost and burden to licensees operating in multiple jurisdictions. The NRC is confident that the Agreement States will exercise this new flexibility in a responsible manner that will continue to allow device manufacturers and service providers to work in multiple jurisdictions without undue burden or cost.

The commenter is correct that the purpose of the Atomic Energy Act is to ensure the protection of public health and safety. The Atomic Energy Act also establishes the Agreement State program, which allows States to assume regulatory authority over the licensing of certain radioactive materials that are used within their borders. As part of the implementation of this program, the NRC established ''compatibility categories'' for its regulations, which determine the degree of flexibility that States have in adopting their regulations. The compatibility category determination for each regulation involves careful review by the NRC to ensure that the national regulatory program is consistent. Where the NRC believes that there are transboundary implications associated with a regulation, the regulation is assigned to compatibility category B, which requires Agreement States to adopt essentially identical requirements. Where the NRC believes that there are not transboundary implications, but that the essential objectives of the regulation need to be adopted, the regulation is assigned to compatibility category C. When adopting compatibility-category-C regulations, the Agreement States can adopt regulations that are more stringent than the NRC's regulations. After extensive review, the NRC has determined that the compatibility changes requested in the PRM do not appear to raise significant transboundary issues. Based upon this determination, the NRC has decided to assign these regulations to compatibility category C.

In its SRM adopting these compatibility changes, the Commission acknowledged that these compatibility changes could result in transboundary problems, if there are unforeseen implementation problems. As directed by the Commission, the staff plans to: (1) Report back within 18 months on which Agreement States, if any, acted to modify their programs as a result of the change in compatibility category, (2) discuss how the programs were modified, (3) analyze the impacts to regulated entities, particularly those operating in more than one State; and (4) suggest corrective actions, if necessary (ADAMS Accession No. ML103360262).

The Proposed Rule

After considering the OAS petition and Florida Department of Health request, the NRC decided to grant the petition (i.e., the NRC agreed to start a rulemaking that would consider the issues raised in the petition; granting a petition does not mean that the NRC will adopt any or all of the requests in a petition) (ADAMS Accession No. ML072640423). On August 3, 2009, the NRC published a proposed rule, ''Limiting the Quantity of Byproduct Material in a Generally Licensed Device'' (74 FR 38372). This proposed rule would have improved the safety and security of devices currently authorized under a general license by requiring a subset of these devices to be specifically licensed. The rulemaking would have amended the NRC's regulations to limit the quantity of certain byproduct material allowed in a generally-licensed device to below one-tenth of the IAEA's Category 3 thresholds; licensees with devices containing byproduct material at or above this limit would be required to obtain a specific license. The NRC also proposed to change the compatibility category of 10 CFR 31.5(a), 10 CFR 31.5 (c)(13)(i), and 10 CFR 31.6 from category B to C.

Public Comments on the Proposed Rule

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.

The comments addressed the following areas: (1) The general provisions of the proposed rule; (2) alternatives to the proposed rule; (3) alternative threshold values; (4) proposed changes in compatibility categories from B to C, and discussion of any transboundary issues related to this approach; and (5) the additional revision to 10 CFR 31.5, which would have prohibited specific licensees from possessing a device under a general license. A discussion of each major comment area is summarized as follows:

Comments on the general provisions of the proposed rule.

Comments: Twenty commenters supported the provisions of the proposed rule that would have established a threshold value of one-tenth of Category 3 for material in generally-licensed devices. These 20 commenters included the OAS and 9 individual Agreement States. About the same number of commenters did not support any threshold value for generally-licensed devices; some of these commenters believe that the general license regulatory approach should remain as is, while others offered suggestions for modifying the general license program to achieve the objectives of the proposed rule.

The commenters who supported the proposed rule argued that the proposed rule would increase the safety and security of the sources, by protecting against aggregation of sources to quantities of concern.

These commenters noted that the regulatory change to limit the quantity of byproduct material in a generally-licensed device was long overdue from a safety and security perspective, and that the rule would not impose a significant burden to implement. Finally, the commenters stated that the one-tenth of Category 3 threshold was a reasonable compromise between the need for increased safety and security and the burden imposed by these requirements on affected licensees.

Some of the commenters who opposed the proposed rule questioned whether the NRC had a technical basis to support limiting the material in a generally-licensed device for safety and security reasons. In particular, they argued that there was no credible risk of aggregating generally-licensed devices that are used by industry for manufacturing process control applications. Also, they stated that it was unrealistic to believe that these devices and their sources would be removed from their assemblies. They noted, for example, that these sources are important and vital to the operation of a manufacturing facility. They also argued that the sources are: (1) Firmly mounted in process equipment; (2) surrounded by mechanical components moving at a high rate of speed with restricted access; and (3) within a security perimeter, which includes safeguards against entry by unauthorized people.

These commenters also believe that implementation of the proposed rule would cause a significant cost increase because of the additional requirements associated with a specific license, including training, administration, annual fees, and hiring of a radiation safety officer. Another comment from an industry trade group noted that small companies with few customers spread across a large number of States would

find it prohibitively expensive to conduct business in States that require specific licenses.

Many of the commenters stated that it was unnecessary to require generally-licensed devices to be specifically licensed if they were at or above the threshold level in the proposed rule. These commenters suggested alternatives to enhance the current general license program:

(1) A combination of features such as: (a) Maintaining the existing general license framework, while requiring additional hardening and design features in the devices to make it difficult to remove the sources from the devices; (b) imposing new security requirements in the regulations and in the device registries that would apply to users of the devices; (c) requiring regulators to periodically inspect the generally-licensed devices that meet or exceed the one-tenth of Category 3 threshold values; and (d) requiring device leak tests and shutter checks at 3- or 6-month intervals to improve source accountability;

(2) Strengthening the current general license regulations by: (a) Adding an annual physical inventory requirement for all licensees who possess a generally-licensed device under 10 CFR 31.5; (b) adding a requirement for generation and retention of written records of the physical inventories for review during regulator inspections; and (c) adding a requirement for general licensees to report their physical inventory results to the regulator;

(3) Amending 10 CFR 31.5(a) to exclude all portable devices, to require a specific license for portable devices regardless of their activity level; and

(4) Offering manufacturers and distributors a Master Materials License or a single licensing mechanism that would be valid for work in different regulatory jurisdictions.

Some commenters who supported the proposed rule suggested alternative threshold values for material in a generally-licensed device. These alternatives included: (1) Setting a threshold at IAEA Category 3; (2) considering the aggregate level of byproduct material at a site; (3) applying the threshold to the current activity level of the source instead of the licensed activity; and (4) setting a threshold below one-tenth of Category 3, such as the registration levels in 10 CFR 31.5(c)(13)(i).

NRC Response:

The NRC has decided not to adopt a final rule and is withdrawing the proposed rule. The Commission disapproved the staff's proposal to limit the quantity of byproduct material contained in generally-licensed devices under 10 CFR Part 31 to one-tenth of the IAEA Category 3 threshold. The Commission determined that there is not a clear safety risk reduction or security enhancement that would justify the proposed threshold for requiring a specific license and there is insufficient information to determine that the aggregation of generally-licensed devices for malevolent purposes is a likely scenario.

Comments on changing the compatibility of 10 CFR 31.5(c)(13)(i) and 10 CFR 31.6 from category B to category C.

The NRC received 20 comments on the proposal to change the compatibility of 10 CFR 31.5(c)(13)(i) and 31.6 from category B to category C. The OAS and 13 Agreement States supported the proposal; 5 commenters (2 Agreement States and 3 companies that manufacture, distribute, and service generally-licensed devices) opposed the proposal; and 1 Agreement State supported the compatibility change to 10 CFR 31.5(c)(13)(i) and opposed the compatibility change to 10 CFR 31.6. Commenters who supported the changes noted that the changes in the compatibility categories would allow States to continue to impose more rigorous requirements on their licensees. Many of these States commented that they would not support the proposed rule without an accompanying change in compatibility. The commenters who opposed the proposed compatibility changes noted that current regulations are very clear and that compatibility B ensures a single national standard for generally-licensed devices. These commenters noted that the change in compatibility could result in different sets of rules and guidelines in every State, and would allow Agreement States to arbitrarily set limits on the activity levels of generally-licensed devices that are not based on the risk to public health and safety. Some commenters stated that a change in compatibility would have a significant adverse impact on companies that service generally-licensed devices.

More detailed comment summaries, along with the NRC's responses, are included below.

Comment: The NRC should be adopting more stringent compatibility for its generally-licensed device regulations, which would allow installers and service providers to do their jobs without additional restrictions imposed by the States.

NRC Response:

The NRC appreciates the commenter's concern, but does not believe that compatibility B is necessary in this case. Under the Agreement State program, the NRC has relinquished its regulatory authority over certain radioactive materials in each Agreement State. As part of its oversight of the program, the NRC has established compatibility categories that allow it to ensure that there is a consistent national program in place, while also providing Agreement States with the flexibility to adopt different requirements when possible. In this case, the NRC has concluded that the additional requirements that would be imposed by Agreement State regulators are not a threat to a consistent national program. However, the NRC does recognize that there is the possibility for the Agreement States to adopt regulations in this area that would negatively affect a national program. The NRC is therefore planning to look at any modifications that the Agreement States make in response to this compatibility change, analyze the impacts to the regulated entities and suggest corrective actions, if necessary (ADAMS Accession No. ML103360262).

Comment: One commenter argued that the change in compatibility would result in no increase in security, safety, or accountability.

NRC Response:

The change in compatibility does not have to result in an increase to security, safety, or accountability. The purpose of the compatibility is to ensure that there is a consistent national regulatory program across the Agreement States and NRC states. In some cases, it's not necessary for the NRC and the Agreement States to have identical regulations. In this case, the NRC has determined that these regulations do not involve the transboundary issues that would trigger concern about a consistent national program. The NRC has therefore determined that compatibility category C is acceptable. This compatibility designation will allow Agreement States to adopt more stringent regulations.

Comment: A number of commenters argued that less restrictive compatibility will result in severe transboundary effects, which could drive some companies out of business. Less restrictive compatibility will make it more difficult for small companies that work in multiple States to stay in business. Also, the administrative burden of complying with different rules in each state and having to apply for reciprocal recognition before entering a State could become ''an administrative nightmare.''

An Agreement State and an industry commenter expressed opposition to the change in compatibility. One State

expressed concerns similar to some industry commenters that the compatibility change to 10 CFR 31.5(a) could result in 36 different sets of requirements, which would ''make compliance extremely difficult for any company that does not confine its activities to NRC jurisdiction or a particular Agreement State.'' Further, this commenter is concerned that the change in compatibility to 10 CFR 31.6 could result in improper disposal of generally-licensed devices because Agreement States might start to impose reciprocity or licensing fees for out-of-State general licensees that want to do business in the Agreement State.

In 2000, as part of the general-license-rule amendments, the NRC evaluated the compatibility of these regulations and concluded that this rule should not be open to the type of broad interpretation that would be allowed by a compatibility C designation (65 FR 79184–79185; December 18, 2000). The justification for this conclusion was the transboundary implications of allowing States to impose more strict criteria on generally-licensed devices under their jurisdiction.

NRC Response:

The 2000 general-license-rule amendments, which then designated the requirements in 10 CFR 31.5 and 10 CFR 31.6 as compatibility category B, were based on the concern that essentially identical regulations were needed to ensure reciprocal recognition of licenses and licensing requirements among Agreement States and the NRC. The commenter indicated that individual State variations in the regulations do not add any increase in safety or security at any level and only make more complicated and costly the compliance process for the general licensees, distributors, and service providers. After evaluating the post-2000 general-license-rule amendments, the NRC has reassessed its position. Since 2000, Agreement States have taken a variety of actions that are not consistent with the rule, despite its designation as compatibility category B. As a result, different practices already exist in different Agreement States; however, the NRC has not observed any transboundary problems from these different practices that would indicate compatibility category B is necessary. Further, complexity and cost are not aspects of determining significant transboundary health and safety impacts under the Commission's 1997 Policy Statement for Adequacy and Compatibility (62 FR 46517). The NRC disagrees with the commenter and believes it is appropriate to change the compatibility category to C for 10 CFR 31.5 and 10 CFR 31.6. This action acknowledges the current practice of many Agreement States to continue the practices they have already implemented and take additional steps they deem appropriate based on local circumstances.

The NRC does, however, recognize that if many more States change their regulations, there could potentially be transboundary impacts. As directed by the Commission, the NRC plans to determine the degree to which the Agreement States modify their programs as a result of the change in compatibility category and to analyze any transboundary impacts to regulated entities, particularly those operating on a multistate basis. The NRC may take corrective actions, if any are needed (ADAMS Accession No. ML103360262).

Comment: Another commenter is concerned that changing the existing regulations to compatibility C could ''be a step backward'' and could result in arbitrary limits on generally-licensed devices that are not based on public health and safety.

NRC Response:

The NRC has a program in place, Integrated Materials Performance Evaluation Program (IMPEP), which allows the NRC to evaluate the status of an Agreement State's program. If the NRC determines that a program is deficient, they will work with the Agreement State to correct the deficiencies.

Comment: One commenter is concerned that the change in compatibility could limit the ability of service providers to provide timely repairs, which could affect production at plants that rely on generally-licensed devices (delays range from three to five days, depending on the State).

NRC Response:

The NRC shares the commenter's concerns and will be evaluating any regulatory changes that the Agreement States make in response to this change in compatibility. The NRC will gather data and may take action, if necessary (ADAMS Accession No. ML103360262).

Comment: One commenter asked that, if the change in compatibility is adopted, the NRC offer manufacturers and distributors the option to obtain a Master Materials License that would be valid for work in any NRC State or Agreement State.

NRC Response:

The NRC cannot issue a Master Materials License to non-federal licensees; the NRC only issues these licenses to Federal organizations.

Comment: One commenter argued that some Agreement States want the revised compatibility designation because they believe that they will be able to generate more fees through reciprocal recognition and inspection, without any clear benefit to health and safety.

NRC Response:

The NRC disagrees with the comment. The commenter did not provide any support for its statement and the NRC is not aware of any statements by Agreement State employees or representatives that would support this claim.

Comment: A number of Agreement States supported some or all of the compatibility changes. One State supported only the change to 10 CFR 31.5(c)(13)(i), but noted that due to recent issues with tritium exit signs, the NRC might want to revise the list of isotopes that require registration.

Other States noted that their regulations were more rigorous than the NRC's general-license requirements, and that this difference has not resulted in any transboundary issues. Further, these commenters believe that the revised compatibility would allow for better tracking of generally-licensed devices, and that the more strict requirements result in increased health and safety. Finally, these states argue that the change in compatibility will allow States with more rigorous requirements to leave those requirements in place.

Other Agreement States simply noted their agreement with the NRC's proposed compatibility change. Another State noted that allowing states to adopt more strict licensing requirements might allow the NRC to make a better informed decision about using IAEA Category 4 as the threshold for general licensees. The OAS even indicated it would not support the proposed rule without the change in compatibility.

NRC Response:

The NRC agrees with the commenters. The change in compatibility will allow the Agreement States to adopt regulations that are stricter than the NRC's regulations, while the regulatory floor established by the NRC will continue to ensure that there is reasonable assurance of public health and safety.

Comment: Some commenter's suggested that the NRC amend 10 CFR 31.5 to require specific licenses for portable gauges and leave the compatibility category as B, which they believed would address the concerns of many States because a number of these States do not allow portable gauges to be held under a general license.

NRC Response:

The Commission has decided not to adopt the proposed rule. Further, the NRC appreciates the commenter's

concern about the compatibility change. The NRC staff will monitor the compatibility changes to ensure that there aren't unforeseen transboundary problems. If the NRC discovers that the compatibility change has caused transboundary problems, such as reciprocity problems for licensees that operate in multiple jurisdictions, the staff will provide that information to the Commission as part of its 18-month report (ADAMS Accession No. ML103360262).

Comment: With regard to transboundary issues, several Agreement States indicated that there would be no significant transboundary issues in changing the compatibility category from B to C. Some of these commenters said that for many years, under the current general license regulatory framework, there have been no transboundary issues resulting from their State having more rigorous requirements than neighboring States for generally-licensed devices. One Agreement State indicated that it has never authorized out-of-State generally-licensed devices under reciprocal recognition in accordance with its State regulations.

One commenter stated that transboundary issues would only occur if some States choose to specifically license portable devices. The commenter stated that there would be a significant effect on the movement of these devices because licensees would need to pay fees and could be subject to reciprocity inspections. Other commenters, primarily manufacturers and service providers, believed that there would be significant transboundary issues in changing compatibility from category B to category C and supported the retention of category B.

NRC Response:

The NRC is unaware of any significant transboundary issues with the current system. Although the change in compatibility may require a change in licensing process for some companies (including any reciprocity changes and fee payments), these actions are not considered a significant transboundary issue since a similar nationwide system is already used for specific licensees. However, the NRC plans to assess 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 multistate basis. The NRC may take corrective actions if needed (ADAMS Accession No. ML103360262).

Comments on the proposal to prohibit specific licensees from possessing generally licensed devices.

Comment: The NRC did not receive any comments that supported the proposal to prohibit specific licensees from possessing a generally-licensed device. One commenter opposed this proposal because current regulations already include incentives for licensees to transfer their generally-licensed devices to a specific license. The transfer process takes significant time and effort by both the licensee and the regulator and can make the specific license cumbersome to maintain and enforce due to the large number of low-activity sealed sources. Several commenters believe that the proposal would be unfair to specific licensees because it is likely that companies that possess generally-licensed devices and do not have a specific license would continue operations under the general license, while companies with both generally-licensed devices and a specific license would be required to move their generally-licensed devices to their specific license. This change would arbitrarily impose more stringent regulations on specific licensees.

Comments from universities and research and development specific licensees argued that the proposal would place a substantial burden on them, requiring the revision of device authorizations by the responsible Radiation Safety Committee for a very large number of generally-licensed devices subject to 10 CFR 31.5. The commenters noted that placing these generally-licensed devices under the authority of a specific license would require the users of those devices to have a minimum amount of documented training and experience, and could require personnel radiation monitoring because some specific licensees require dosimetry for all users. The commenters also argued that the users of these generally-licensed devices are students and researchers who continuously change; and these new requirements would require additional training and documentation that is not necessary under the current general-license program. The commenters believe that there would be no reduction in the hazard to workers or students due to the transfer of these devices to the broad-scope specific license. Several Agreement States, research organizations, and large corporations supported the existing regulations, which allow licensees the flexibility to decide whether they want to add generally-licensed devices to their specific licenses. A number of universities stated that they would prefer to keep the numerous generally-licensed devices used in health care and research environments under the requirements of a general license.

NRC Response:

The NRC agrees with the commenters that the proposal to amend 10 CFR 31.5(b)(3) could cause confusion. The NRC intended to preserve the flexibility that licensees currently have to decide whether to transfer generally-licensed devices under the authority of a specific license for a site, but to specify that if generally-licensed devices were transferred to a specific license then the terms and conditions of the specific license would apply to the generally-licensed devices. The NRC agrees with the commenters and has decided not to adopt this proposed change to amend 10 CFR 31.5(b)(3). This amendment would be too burdensome on numerous licensees with little or no improvement in the accountability of the sources in those generally-licensed devices.

Withdrawal of the Proposed Rule

On December 2, 2010, the Commission disapproved publication of the final rule, which would have limited the quantity of byproduct material in a generally-licensed device to below one-tenth of IAEA's Category 3 threshold (ADAMS Accession No. ML103360262). The Commission that there is not a clear safety risk reduction or security enhancement that would justify the proposed rule and that the current safety and security requirements for these generally-licensed devices are adequate (ADAMS Accession No. ML103370094). Consequently, the NRC is withdrawing the proposed rule.

Agreement State Compatibility

On December 2, 2010, the Commission approved revising the compatibility designation of all 10 CFR 31.5 and 10 CFR 31.6 from B to C (ADAMS Accession No. ML103360262). The Commission recognized the desire on the part of the States to exercise greater control over the actions of their licensees and to enhance regulation for higher activity generally-licensed devices (ADAMS Accession No. ML103370094). The current compatibility designation for these sections is category B. This designation was primarily based on transboundary implications. Despite this designation, many Agreement States have implemented more strict regulation of generally-licensed devices. These regulations include registration with annual reporting requirements and periodic inspection, expanded registration of more types of generally-licensed devices, specific licensing of

certain generally-licensed devices, and specific licensing of all generally-licensed devices currently registered by the NRC.

The NRC believes that the change to compatibility category C 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 to adopt requirements based on their specific circumstances and needs. As directed by the Commission, the NRC staff will assess 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 multistate basis. If transbounday problems are identified, the staff will suggest any corrective actions that might be necessary (ADAMS Accession No. ML103360262). The Commission also plans to consider proposed 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.

Closure of the Petition for Rulemaking

In its SRM, the Commission addressed all of the issues raised in the PRM: The Commission disapproved publication of the final rule and approved the change in compatibility for 10 CFR 31.5 and 10 CFR 31.6. The NRC is closing this PRM because all of the petitioners' requests have been resolved.

Dated at Rockville, Maryland, this 22nd day of December 2011.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. 2012–1523 Filed 1–24–12; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 100908440–1615–01]

RIN 0648–BA24

Proposed Expansion of Fagatele Bay National Marine Sanctuary, Regulatory Changes, and Sanctuary Name Change

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Re-opening of public comment period.

SUMMARY: On October 21, 2011, NOAA published a proposed rule in the **Federal Register** to revise the regulations for the Fagatele Bay National Marine Sanctuary (76 FR 65566). This notice re-opens the public comment period stated in that proposed rule until March 9, 2012.

DATES: NOAA will accept public comments on the proposed rule published at 76 FR 65566 (October 21, 2011) through March 9, 2012.

ADDRESSES: The instructions for submitting comments are detailed in the proposed rule published on October 21, 2011 (76 FR 65566).

FOR FURTHER INFORMATION CONTACT: Gene Brighouse at (684) 633–7792.

Dated: January 17, 2012.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries.

[FR Doc. 2012–1499 Filed 1–24–12; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

[CPSC Docket No. CPSC–2012–0005]

Products Containing Imidazolines Equivalent to 0.08 Milligrams or More

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (''CPSC,'' ''Commission,'' or ''we'') is proposing a rule to require child-resistant (''CR'') packaging for any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline, a class of drugs that includes tetrahydrozoline, naphazoline, oxymetazoline, and xylometazoline, in a single package. Imidazolines are a family of drugs that are vasoconstrictors indicated for nasal congestion and/or ophthalmic irritation. Products containing imidazolines can cause serious adverse reactions, such as central nervous system (''CNS'') depression, decreased heart rate, and depressed ventilation in children treated with these drugs or who accidentally ingest them. Based on the scientific data, the Commission preliminarily finds that availability of 0.08 milligrams or more of an imidazoline in a single package, by reason of its packaging, is such that special packaging is required to protect children under 5 years old from serious personal injury or illness due to handling, using, or ingesting such a substance. We are taking this action under the Poison Prevention Packaging Act of 1970 (''PPPA'').[1]

DATES: Written comments must be received by April 9, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0005, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through *http://www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 802, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice of proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade

[1] The Commission voted 4–0 to publish this notice in the **Federal Register**. Commissioner Robert S. Adler issued a statement, which can be found at *http://www.cpsc.gov/pr/statements.html.*