

Nuclear Regulatory Commission

PRM-31-5

10 CFR Part 31

Organization of Agreement States; Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Request for comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received a petition for rulemaking filed by the Organization of Agreement States (OAS). The petitioner is requesting that the NRC amend its regulations to require specific licensing for devices that are currently regulated by a combination of general licensing and registration, and to revise the compatibility category for 10 CFR 31.6 from “B” to “C”. The petitioner believes that these actions are needed to establish a higher national standard of regulation for higher risk generally licensed (GL) devices, and to allow retention of a tool used by Agreement States to track the location and movement of device manufacturers and service providers in their State.

This action also addresses a request filed by the Bureau of Radiation Control (BRC) of the Florida Department of Health for the NRC to change the compatibility category of 10 CFR 31.5(c)(13)(I) from category “B” to category “C”. Florida BRC believes that NRC regulations are less stringent and that assigning a compatibility category “B” will require the State to reduce its current health, safety, and security regulatory control of GL devices.

DATES: Submit comments by (insert 75 days from date of publication). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include PRM -31-5 in the subject line of your comments. Comments submitted in writing or in electronic form will be made available to the public for inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission. Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: [SECY@nrc.gov](mailto:SECY@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email [cag@nrc.gov](mailto:cag@nrc.gov). Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this petition may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text

and image files of 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 Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to [pdr@nrc.gov](mailto:pdr@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301 415-7163 or Toll Free: 1-800-368-5642 or E-mail: [mtl@nrc.gov](mailto:mtl@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

On December 18, 2000, (65 FR 79162), the NRC issued a final rule that amended the requirements applicable to certain generally licensed industrial devices containing byproduct material. The final rule, among other actions, included more explicit provisions for a registration and accounting program. The final rule also modified the quarterly transfer reporting requirements for manufacturers and initial distributors of these industrial devices.

Section 274b of the Atomic Energy Act (Act) provides for agreements under which the NRC relinquishes and a State assumes regulatory responsibility for the use of byproduct, source and small quantities of special nuclear material within a State. The December 18, 2000, final rule was a matter of compatibility under the Policy Statement on Adequacy and Compatibility of Agreement Statements issued September 3, 1997 (62 FR 46517). The provisions of 10 CFR 31.5 and 31.6 were designated as Category B because the provisions affected a program element with significant transboundary implications.

### Petitioner's Issue

The petitioner believes that certain devices containing higher level of activity, which are currently regulated under a general license in 10 CFR 31.5, would be best regulated under a specific license in 10 CFR part 30. The petitioner states that multiple Agreement States have already established more stringent requirements for GL devices to address accountability problems, source melt incidents and other issues related to such devices in their States, and that the decision by the NRC to revise the compatibility category of 10 CFR 31.5 from "D" to "B" will require these Agreement States to reduce their current regulatory control of GL devices in order to be compatible with less stringent NRC regulations. The petitioner states also that the NRC decision to revise the compatibility category of 10 CFR 31.6 from "C" to "B" removes the ability of Agreement States to directly track the movement of many individuals and companies servicing GL devices and thus indirectly verify the location of these devices. The petitioner asserts that regulation of GL devices containing higher levels of activity should be under more rather than less regulatory oversight to further enhance the accountability and security of these devices.

### Petitioner's Interest

The petitioner is a non-profit, voluntary, scientific and professional society incorporated in the District of Columbia. The membership of the OAS consists of State radiation control program directors and staff from the 33 Agreement States who are responsible for implementation of their respective radioactive material programs. The purpose of the OAS is to provide a mechanism for the Agreement States to work with each other and with the NRC on regulatory issues associated with their respective agreements.

The petitioner offers that Agreement States are those States that have entered into an Agreement with the NRC under section 274b. of the Act. The Agreement States regulate most

types of radioactive material, including reactor fission byproducts, source material (uranium and thorium) and special nuclear materials in quantities not sufficient to form a critical mass, in accordance with the compatibility requirements of the Act. The petitioner notes that NRC periodically reviews the performance of each Agreement State to assure adequate protection of public health and safety and compatibility with its regulatory requirements.

The petitioner further states that Agreement States issue radioactive material licenses, promulgate regulations and enforce these regulations under the authority of each individual state's laws. The Agreement States exercise their licensing and enforcement programs under direction of their governors in a manner that is compatible with the licensing programs of the NRC. The 33 existing Agreement States currently license and regulate approximately 16,800 radioactive material licenses, whereas the NRC regulates approximately 4,400 licenses.

#### History of Issue

In July 1996, the joint NRC-Agreement State Working Group, approved by the Commission to evaluate problems with licensees maintaining control over and accountability for devices containing radioactive material provided their recommendations to the NRC. One of the recommendations was that the NRC establish a registration program for GL devices containing specific isotopes above certain quantity limits that posed a comparatively higher risk of exposure to the public or property damage.

The petitioner states that on December 18, 2000, the NRC issued a final rule, effective on February 16, 2001, that revised portions of 10 CFR Parts 30, 31, and 32 to add new requirements for manufacturers, distributors and users of GL devices. The combined changes were called the "Generally Licensed Device Rule," which included a revision that established a new registration program for certain GL devices in 10 CFR 31.5(c)(13) that was based on the earlier recommendations of the working group. In addition, the petitioner states the NRC

changed the compatibility category for 10 CFR 31.5 from “D” to “B” and for 10 CFR 31.6 from “C” to “B”. Agreement States were given until February 16, 2004 to adopt the new regulations.

The petitioner states that in a letter dated July 28, 2004, the NRC presented the results of a survey of Agreement State compliance with adopting the new Generally Licensed Device Rule which showed that 12 of the 33 Agreement States had not adopted the new GL device requirements.

The petitioner states further that during the May 2004 National Conference on Radiation Control and the September 2004 Organization of Agreement States annual meeting, the Agreement States discussed problem areas associated with the current system of regulating certain devices under a general license. These problem areas include:

- The compatibility change from “D” to “B” in 10 CFR 31.5 limits States that choose to be more restrictive in regulating GL devices.
- The compatibility change from “C” to “B” in 10 CFR 31.6 allows device manufacturers/service providers to service devices in Agreement States for less than 180 days without obtaining reciprocity or notifying State radiation control programs at a time when State programs believe enhanced tracking is required.
- New materials security requirements have not been factored into general license device regulations.
- Low awareness of regulatory requirements by some general licensees due to high turnover in the industrial sector and minimal interaction with regulator.

#### Petitioner’s Proposal

The OAS proposes the following amendments to 10 CFR part 31, and changes in compatibility category.

1. Section 31.5 (a) would be revised to read as follows:

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere, provided each device contains less than 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60 or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label.

2. In §31.5 paragraph (c)(13) would be deleted in its entirety.
3. Revise the compatibility category of §31.6 from “B” to “C”.

#### Petitioner's Justification

OAS stated that the newly formed OAS Rulemaking and Compatibility Committee surveyed the 33 Agreement State radiation control programs to determine the reaction to the change in compatibility of 10 CFR 31.5 and 31.6 and the potential to specifically license devices currently regulated under a general license. Thirty-one States responded to the survey, as follows:

- Eighty-seven percent of the responding States disagree with the CY 2000 Commission decision to revise the compatibility category of 10 CFR 31.5 and 31.6 (27 of 31 States).
- Ninety percent of the responding States currently allow a specific license for devices that may be generally licensed (28 of 31 states).

- Ninety-seven percent of the responding States support the OAS taking action in this area (30 of 31 states).

The OAS believes that requiring specific licensing of the higher risk gauging devices identified by the 1995 NRC-Agreement State joint working group can further enhance control and accountability of GL devices. OAS states that while the GL device rule was an improvement over past regulation of these devices, there are still on-going problems with the regulation of GL gauging devices, including:

- Low awareness of regulatory requirements by general licensees.
- No routine inspection of GL devices for compliance with requirements.
- No regulatory review prior to purchase.
- Continued incidents involving loss of control of real or suspected GL devices.

OAS believes that specific licensing of higher activity GL gauging devices would provide the following advantages:

1. Allow regulatory review (through the license application process) of higher-activity device purchases prior to receipt.
2. Increase security of the higher risk gauging devices to minimize the possibility of these devices being used in malicious acts.
3. Increase licensee awareness of regulatory requirements by virtue of the specific license application process and periodic inspections.
4. Improve licensee control of devices, which may reduce the number of potential orphan sources.

### Petitioner's Conclusion

The OAS understands and agrees with the desire of the Commission and device manufacturers for more uniform regulation of devices within the NRC and Agreement States. At the same time, the Agreement States' desire to assure better accountability for sources and devices that are within the states' jurisdiction. The Agreement States believe that the manufacture and distribution of the devices is best addressed uniformly by the methods described in this petition. Therefore, the OAS is proposing that 10 CFR 31.5 be amended to require specific licensing for devices that are currently regulated by a combination of general licensing and registration. This action would establish a higher national standard of regulation for identified higher risk devices. In addition, the OAS is proposing that the compatibility category for 10 CFR 31.6 be revised from "B" to "C" to allow retention of a tool used by States to track the location and movement of device manufacturers and service providers in their State. This would allow Agreement States the opportunity to assess and monitor the radiation safety programs of device manufacturer representatives working within the State. The OAS believes the NRC and Agreement States can implement the proposed changes with limited impact on regulatory agencies and licensees, resulting in improved regulation and control of radioactive materials.

### Florida's Request

In addition to requesting comment on the petition by the OAS, NRC is seeking comment on a request by the Florida BRC. The issues raised in Florida's request are closely related to those in the OAS petition, so NRC is seeking comment on both the OAS petition and the Florida request at the same time.

Florida, an Agreement State, requested that the NRC change the compatibility category of 10 CFR 31.5(c)(13)(I) from category "B" to "C". Florida believes that the decision of whether

and how to register additional types and quantities of generally (GL) devices beyond what the NRC requires should be a decision left to the State with the authority for regulating the devices. Florida states that it has had well-established requirements for the registration and regulation of GL devices for many years before the NRC adopted regulations to register certain GL devices. Florida states that NRC's decision to assign a compatibility category "B" for 10 CFR 31.5(c)(13)(I), will require it to reduce its current health, safety, and security regulatory control of GL devices in order to be compatible with the less stringent NRC regulations.

Florida states that they issue and currently regulate over 1500 radioactive material licenses, promulgate regulations and enforce these regulations under the authority of Chapter 404, Florida Statutes, and Chapter 64 E-5, Florida Administrative Code. Florida notes that the NRC periodically reviews the performance of its programs thereby assuring compatibility with the NRC's regulatory requirements.

Florida requires registration of all GL devices with the exception of some tritium exit signs. Their program includes source registration, fees, annual inventories and inspections.

Florida is concerned that the December 18, 2000, final rule, effective on February 16, 2001, revised portions of 10 CFR Parts 30, 31, and 32 to add new requirements for manufacturers, distributors and users of GL devices, and that part of the revision established a new registration program for certain GL devices in 10 CFR 31.5 ©)(13) and assigned a compatibility category of "B". According to Florida, it has instituted a number of changes required by the rule as legally binding license conditions and also is working on promulgating rules to address these issues, with the exception of the new registration requirements that would force it to adopt less stringent registration and accountability standards for certain GL devices containing radioactive material.

Florida notes that NRC's procedures in Management Directive 5.9, for categorizing program elements or regulations, states that to be included in Category "B", an NRC program

element is to be one that applies to activities that have **direct and significant effects** in multiple jurisdictions (emphasis added). Examples include; transportation requirements, approval of products that are distributed nationwide, and definitions of products. Florida believes the registration of additional GL devices would not have a direct and significant effect in multiple jurisdictions.

Florida asserts that States and the NRC have had different GL requirements for years with little discussion of any transboundary problems, and that any actions concerning the registration of additional GL devices in Florida would be between the State and individuals in Florida. According to Florida, this registration process does not have any direct and significant effect on device manufacturers or distributors, the transportation of the devices, the requirements for approval, or the movement of devices into or out of Florida.

In the request, Florida cites its ability to register, inventory, and inspect all GL devices, as providing many benefits for the safety and security of its citizens and visitors and therefore to move to NRC's registration scheme would require it to cease to be able to register and account for over 1,000 radioactive sources in GL devices currently being regulated. Florida believes that its ability to continue to register all GL devices clearly meets the essential objective of NRC's Generally Licensed Device Rule.

Florida notes also that NRC's categorization criteria further states that for a program element to be included in Category "C", it should be one that the essential objective should be adopted by an Agreement State to avoid conflicts, duplications, or gaps in the regulation of agreement material on a nationwide basis and that, if not adopted, would result in an undesirable consequence.

