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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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SUBJECT: PRM–31–5: COMMENTS ON PETITION FOR RULEMAKING

To Whom It May Concern:

Please accept these comments on the Petition for Rulemaking filed by the Organization of Agreement States (OAS) published in the U.S. Federal Register December 20, 2005. This submission is offered by several manufacturers, distributors, and providers of services for radiological devices regulated under the affected rules.

These comments represent the consensus opinion of the signature companies based on many decades of experience with radiological devices from a safety, regulatory, and operational prospective. Each company has vast experience with the current and historic processes associated with the General License and the impact on the companies who manufacture and distribute the devices; the service providers; and the end users of the devices, the General Licensees – who are our customers.

Additionally, all of these companies and many of the individual signers were closely involved in the last significant rulemaking process conducted by the U.S. Nuclear Regulatory Commission (NRC) involving Generally Licensed devices, which resulted in the amended rules published in December 2000 (RIN 3150–AG03). During that rulemaking process, the issues raised in the Petition were discussed at length and it is understood that the rules published at that time were representative of the NRC's review of all parties' comments on the issues and the overriding concerns of safety and regulatory uniformity.

The comments below are grouped into three sections. The first addresses general comments on the petition as a whole, the second address specifically the proposed changes to 10 CFR 31.5, and the third addresses proposed changes to 10 CFR 31.6.

General Comments on Petition:

1. The safety and security of radioactive material use is of utmost importance to all entities involved in the distribution and use of radioactive material devices. The General License (GL) program was developed and has been successfully utilized as a tool for companies to safely and securely possess and use certain devices – that are certified as meeting strict safety and security standards – without the unduly burdensome requirements intended for more comprehensive and complex radiation safety programs. The GL provides for safety and security, management, and routine

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oversight of the devices by the licensee and the regulatory bodies. The NRC's revisions of the GL rules in 2000 reinforced this commitment to the GL program and provided improvements to safety and security in the Registration program.

In those rule changes the NRC further reinforced the fact that this rule should not and would not be open to broad diversion by individual Agreement States. This is due to the trans-boundary nature of the GL program. Specifically the fact that device distributors and service providers operate out of and have customers in multiple states. In the Statement of Considerations distributed with the 2000 rule, the NRC cites a clear limitation in the Agreement State Program.

> "In implementing the Agreement State Program through the regulations in 10 CFR part 150 in 1962, the Commission (then AEC) stated: 'The Commission's decision not to exercise its authority to license the transfer of products containing atomic energy materials (other than products designed for distribution to the general public) is based on the assumption that agreement States will maintain continuing compatibility between their programs and Commission programs; and that procedures will be devised assuring reasonable, reciprocal recognition of licenses and licensing requirements among such States and the Commission.' This will unfortunately require a number of Agreement States to revise existing registration programs; however, the Commission believes consistency of regulations in this area is very important to improve the effectiveness of the general license program."

As there are significant trans-boundary implications in the GL regulations (10 CFR 31.5, 31.6, 32.51, 32.51a, and 32.52), it is essential that the high level of compatibility – between the NRC and Agreement State regulations – be maintained and strictly enforced by the NRC. 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.

2. It has been the experience of the companies signing this letter that the NRC has not enforced compatibility with the current GL rules among the Agreement States despite the clear regulations and blatant disregard for such by certain states. The GL program, as is defined in the regulations, is more than adequate to provide safety and security for all persons. However, when these regulations are not dutifully enforced by the designated agencies, safety and security risks associated with the GL devices may increase.

   It is not appropriate to entertain proposals to change regulations and compatibility requirements that have not even been implemented by many Agreement States. The NRC should require individual states to comply with the current rule compatibility requirements and then, after a sufficient time for evaluation has passed, again review the rules with regard to the success the rules have in assuring safety and security of the GL devices.

Comments on Proposed Changes to 10 CFR 31.5:

1. There is no demonstrated safety or security justification for the changes requested by the Organization of Agreement States (OAS). The OAS suggests that certain GL devices "would be best regulated under a specific license in 10 CFR part 30." However, we do not believe that this change would increase security or safety of these devices and we are not aware of any safety or security concerns that could not be equally – and in some cases better – addressed by the current registration program.

   Possession and use of the GL devices is typically a very small aspect of the business for many General Licensees. Nearly all licensees are trying to do the right thing and maintain compliance. However, the licensees – as so many of us are – face varying priorities that must be addressed throughout the year.

   Under the current registration process General Licensees must submit annual reports to the NRC/Agreement State detailing what devices they possess and changes from previous reports. It also requires an individual within the company to confirm such by signature. Thus the GL reviews his inventory and compliance on an annual basis. This process also offers the NRC/Agreement State the opportunity to review the GLs on an annual basis. If there are unresolved discrepancies between annual reports then the NRC/Agreement State should require immediate clarification by the licensee.

   Under most fixed gauge specific licenses, there is a 5 year inspection cycle with no interaction between the NRC/Agreement State and the licensee in that period. Thus, there would be a net decrease in oversight by states if the General License is eliminated. We do not see this change as an increase in security or safety.

2. The proposed OAS wording of 31.5 (a) indicates that the devices must contain less than the indicated quantities of "isotopes of concern", but does not quite say that other isotopes would be permitted as well (e.g. Kr-85, Pm-147, etc.). We don't believe the exclusion of other isotopes from the GL is the OAS's intention, but the proposed wording doesn't allow for these other isotopes under the GL program.

3. For the reasons stated above, we disagree with petitioners' request that 31.5 (c)(13)(I) be dropped to "C" compatibility.

4. The OAS justifies their request for reduced compatibility by stating that a high percentage of Agreement States want this change. This is not adequate justification because individual states are concerned primarily with only their own jurisdiction. It is the responsibility of the NRC to consider trans-boundary issues related to their regulations and require high compatibility on issues that have significant trans-boundary implication, as with the GL rules.

5. The OAS states there is "low awareness of regulatory requirements by general licensees" after the 2000 rule revisions. However our experience shows there have been significant improvements in awareness. Compliance with the registration process has been very high and has subsequently increased regulatory awareness on devices that do not require registration. The information provided to General

Licensees has been improved and is often provided at different points to the licensees during the device procurement process.

6. The OAS states that there is no routine inspection of GL devices. However there is no restriction in the current rules for the NRC or Agreement States from conducting inspections. The NRC and all Agreement States have the ability to inspect any licensee within their jurisdiction, so we feel it is a policy decision that GLs are not inspected at this time. Though there are costs associated with inspections, the fees charged to many registrants (in some cases as high as Specific License fees) should be more than adequate to cover the costs associated with inspections and any increase in personnel requirements. The same cost and personnel availability issues will be present if a Specific License is required.
7. The OAS states there is no regulatory review prior to purchase of GL devices. This is blatantly incorrect. The review is two-fold. The NRC and/or Agreement States review the individual devices to assure the devices are designed so that the safety and security of the equipment is appropriate for such installations. The second review is conducted prior to distribution by the specific licensee that distributes the equipment. They must verify the General Licensee has a "Responsible Individual" in place and is aware of the pending distribution. Furthermore the specific licensee installing the device must assure the installation meets the GL requirements and the specific conditions of the device registration.

   This is the same process that would occur if the devices were specifically licensed. The NRC and Agreement States do not review the installations of specifically licensed devices other than at the time of inspection. Any licensing or "regulatory review" conducted prior to adding a device would be to assure the device is included in the NRC's registry and that a company's license allows the isotope and quantity requested.
8. The OAS states that there are continuing incidents involving loss of control of devices. We agree with the OAS that any loss of control is a serious issue, but we believe the number of incidents involving current General Licensees has decreased with the improved awareness of safety and security regarding radioactive materials.

   We believe the registration program has been very successful in maintaining awareness for Generally Licensed devices and we would not be opposed to seeing the registration and annual reporting requirements extended to all General Licensees, not limited to only certain isotopes and activities.

Comments on Proposed Changes to 10 CFR 31.6:

The only change proposed by the petitioners regarding 10 CFR 31.6 is a change in compatibility level from "B" to "C". This change in compatibility would be overly burdensome and financially detrimental to both manufacturers and licensees possessing Generally Licensed devices, as outlined below.

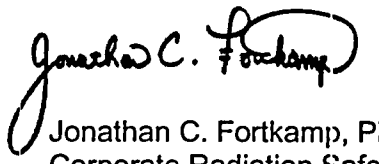
1. There are currently 33 Agreement States. Under the current 'B' level of compatibility, device manufacturers and service providers are working basically under one set of regulations nationwide. It is very easy to see that this situation is

far superior to the confusing alternative if the compatibility level of 10 CFR 31.6 is changed to 'C'. Working under one set of regulations is significantly easier to comply with than potentially working under 34+ sets of regulations, with a continuous flow of amendments and significant trans-boundary implications. It must be understood that the vast majority of manufacturers and service providers work nationwide and are not restricted to one regulatory jurisdiction.

2. The current wording of 10 CFR 31.6 issues a general license. Changing the compatibility level from 'B' to 'C' will allow Agreement States to potentially charge fees for reciprocal recognition of licenses from other Agreement States and the NRC. In many states, these fees can be significant. These fees are passed directly on to the General Licensee, who then passes the cost on to customers.
3. Under the existing regulations and the compatibility level of 'B', manufacturers and service providers can respond to requests for service of Generally Licensed devices immediately, without filing a request for Reciprocity and providing a three business-day advance notice prior to performing work. Requesting reciprocal recognition can often result in up to a five-day delay in providing service to Generally Licensed devices. This delay can result in the loss of millions of dollars in lost production while waiting for Reciprocity to be granted. Most states provide for immediate granting of Reciprocity for emergency reasons, but some states take the stance that 'emergency' means radiation safety concerns only and does not include any negative impact on business. This can result in a significant negative financial impact on U.S. industry and is especially detrimental to small business.
4. Everyone is aware that U.S. industry is facing stiffer and stiffer competition from other countries, many of which have minimal or no regulations regarding the use of nuclear gauging devices. One caveat we need to be aware of is that every time an unjustified regulatory and/or financial burden is placed on U.S. industry, foreign competitors are given a competitive boost.
5. The overall purpose of the Atomic Energy Act and regulations is to safeguard the public. Changing 10 CFR 31.6 from a compatibility of 'B' to 'C' will not enhance either radiological safety of the public 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. A change in the compatibility level to 'C' would result in a significantly more confusing situation and a decrease in the overall compliance level.
6. OAS requests a lower compatibility level 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." We are not aware of any such tool that is being utilized by the States. However a nationwide source tracking database for Generally Licensed devices was strongly recommended by manufacturers during the 2000 rule development process and we still believe that a single device tracking system would be very beneficial.

Thank you for your consideration of these comments. If you have any questions regarding this submission, please contact Jonathan Fortkamp, Corporate Radiation Safety Officer for ABB Inc. at 614-818-6407 or jonathan.fortkamp@us.abb.com.

Sincerely,



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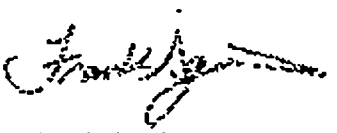

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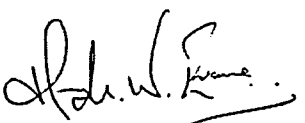

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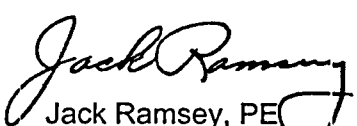

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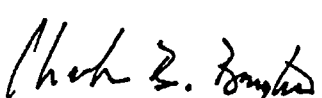

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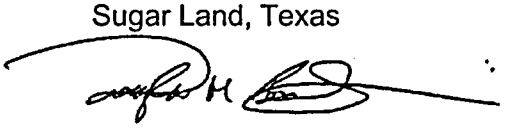

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Subject: PRM-31-5 Comments

Please accept the attached comments regarding PRM-31-5, Organization for Agreement States; Petition for Rulemaking. These comments are from a number of manufacturers and distributors of affected devices.

I look forward to additional discussions on this issue. Please let me know if you have any immediate questions regarding this submittal.

Thanks and best regards,
Jonathan Fortkamp

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(See attached file: 060306 OAS&FL Petition Response.pdf)

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