



October 12, 2009

Secretary, U.S. Nuclear Regulatory Commission
11555 Rockville Pike,
Rockville, Maryland 20852
secy@nrc.gov

DOCKETED
USNRC

October 16, 2009 (3:15pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

SUBJECT: DOCKET ID: NRC-2008-0272
COMMENTS ON PROPOSED RULE, 10 CFR 31

Dear Mr. Secretary:

Please accept these comments on the Proposed Rule published in the U.S. Federal Register August 3, 2009. This submission is offered by ABB Inc, a manufacturer, distributor, and provider of services for radiological devices regulated under the affected rules.

ABB Inc. has many decades of experience with radiological devices from a safety, regulatory, and operational prospective. Additionally, we have 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, ABB was closely involved in the last significant rulemaking process conducted by the U.S. Nuclear Regulatory Commission (NRC) involving Generally Licensed devices. This process resulted in the amended rules published in December 2000 (RIN 3150-AG03). During that rulemaking process, many of the issues raised in the Proposed Rule 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.

Please also refer to comments submitted by ABB Inc. and other device manufactures in response to the initial Petitions for Rulemaking from the Organization of Agreement States and the State of Florida.

The comments below are grouped into four sections based on the "Specific Questions for Comment" in the Proposed Rule notification.

1) Comments on GL material quantity limits:

ABB does not have an issue with the specific radioactive material quantities the NRC is proposing to remove from the General License. It is preferable that the NRC maintain regulatory consistency with regard to referencing the IAEA quantities referenced in Appendix E of 10 CFR 20.

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2) Comments on Aggregation - None

3) Comments on Lower Threshold

In Section A.2, Agreement State concerns regarding the security and accountability are mentioned. ABB does not believe that limiting the quantity of radioactive materials in GL devices would increase security, accountability, or safety of these devices and we are not aware of any safety or accountability 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 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 for these devices. Thus, we do not see this change as an increase in security, accountability, or safety.

4) Comments on Compatibility

(General Comments) Statements of Consideration in the Proposed Rule state that Agreement States want lower compatibility for 10 CFR 31.5 and 31.6 in order to require additional GL device registration and to allow states to “better track service providers and distributors...”, respectively. 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.

During the 2000 GL Rule modification, the NRC considered this specific issue. 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. ABB has customers in all 50 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.

In the 2000 Statements of Consideration, the NRC explicitly stated that 10 CFR 31.5 and 31.6 must have high levels of compatibility.

"These [31.5 and 31.6] requirements are a matter of strict compatibility for Agreement State regulations, that is, the State regulations were required to be essentially identical to NRC regulations. The amendments are also a matter of strict compatibility so that revisions to Agreement State regulations will be necessary and distributors in Agreement States will be affected. The basis for this compatibility requirement is significant direct transboundary implications because devices are distributed under various Agreement State and NRC authorities into other jurisdictions where different regulatory agencies regulate the possession and use of the devices."

ABB fully agrees with the NRC's compatibility interpretation in 2000 and we see no justification to alter the compatibility requirements.

(4)(A) No comment

(4)(B) It is recommended that a period of no less than one year be provided for General Licensees to submit an application to the NRC for the transfer of GL devices onto an SL. No specific limit should be provided for completion of the process as delays outside of the control of the licensees may cause them to go out of compliance (e.g. slow turnaround license applications).

(4)(C) The notification requirement should be maintained. This allows for flexibility for different transfer situations that may arise with certain General Licensees.

(4)(D) ABB strongly disagrees with the proposed change in compatibility for 10 CFR 31.6. This change in compatibility would be overly burdensome and financially detrimental to both manufacturers and licensees possessing Generally Licensed devices, as outlined below. However, most importantly, there would be no increase in security, safety, or accountability by reducing the compatibility.

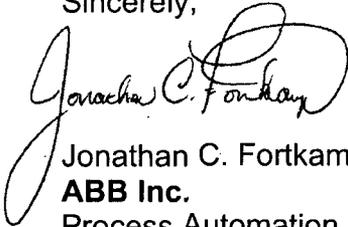
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- i. The overall purpose of the Atomic Energy Act and regulations is to safeguard the public. Changing 10 CFR 31.6 from a compatibility of 'B' to 'C' will not enhance either radiological safety of the public or security of byproduct material. The current 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.
- ii. 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 39+ 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.
- iii. The current wording of 10 CFR 31.6 issues a general license. Changing the compatibility level from 'B' to 'C' will permit Agreement States to require Specific Licenses for on-site services, to charge additional fees for reciprocal recognition of licenses from other Agreement States and the NRC, and to modify other requirements for providing services on devices approved for distribution under a General License. In many states, the fees can be significant and the cost in labor hours to track regulatory changes, maintain authorization, and document the varied regulatory requirements will be very large. These fees and costs must necessarily be passed directly on to the General Licensee, who then passes the cost on to customers.
- iv. 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.
- v. If compatibility is reduced, the NRC should offer manufacturers and distributors an alternative in the form of a Master Materials License or a single licensing mechanism that would be valid for work in NRC and Agreement State regulated jurisdictions.

ABB Inc.

Thank you for your consideration of these comments. If you have any questions regarding this submission, please feel free to contact me at 614-818-6407 or jonathan.fortkamp@us.abb.com.

Sincerely,



Jonathan C. Fortkamp, Ph.D.

ABB Inc.

Process Automation

Director Health, Safety & Environmental –

Corporate Radiation Safety Officer

Westerville, Ohio

Rulemaking Comments

From: Jonathan Fortkamp [jonathan.fortkamp@us.abb.com]
Sent: Friday, October 16, 2009 12:21 PM
To: Rulemaking Comments
Subject: NRC-2008-0272
Attachments: 091012 Proposed Rule Response_ABB.pdf

Dear Mr. Secretary,

Please find attached comments from ABB Inc. on the NRC's proposed rules affecting 10 CFR 31.5 and 31.6.

You may feel free to contact me if you have any questions regarding the attached.

Thanks and best regards,
Jonathan Fortkamp

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