



October 12, 1999

Secretary,
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attn: Rulemakings and Adjudications Staff

PROPOSED RULE NUMBER
1030, 31, 32, 170 + 171
(64FR40295)

Re: Proposed changes to 10 CFR Parts 30, 31, 32, 170, and 171

Dear Sir or Madam:

ABB Automation Inc. is a manufacturer, distributor, and service provider for industrial nuclear gauging devices. The proposed changes to Title 10 of the U.S. Code of Federal Regulations, outlined in the Federal Register on July 26, 1999, will have a direct and consequential impact on the way we currently do business. ABB has been involved in the development of these rule changes since the beginning of the process. It is ABB's intent to first assure the safe distribution, use, and disposal of nuclear material that is used in industrial gauging, measuring, and controlling devices. As one of a limited number of vendors for these devices, it is also our intent to minimize the non-value-added work for regulators, vendors, and end-customers with respect to oversight and tracking of the nuclear material and devices.

Because of the direct impact of these regulations on our business, ABB Automation is making these comments in writing to complement our comments made at the Public Meeting on the Proposed Rules held at NRC Headquarters on October 1, 1999. Many issues were raised at that public meeting and ABB had comments on many of those issues. However, these written comments will be limited to our most significant concerns, namely: compatibility classification; national tracking database; reporting requirements for "replacement" devices; requirement for responsible individual; requirement to provide information "prior to decision to purchase;" and permanent labeling.

Agreement State Compatibility

The proposed changes to 10 CFR 31.5 are currently identified as Category C for Agreement State Compatibility. ABB feels that the implicit trans-boundary effects of the current and proposed rules require Compatibility Category B for effective implementation nationwide. As ABB understands the categorization, Agreement State Compatibility Category C program elements must meet the objectives of the NRC element, but the means to meet the objectives need not be the same. This

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implies that there could and, as past history has shown, likely will be significant deviations from the NRC among Agreement States with respect to how these objectives are implemented. Category B program elements, on the other hand, are defined as having significant trans-boundary implications and the Agreement States' element should be essentially identical.

One important concept that seems to have been overlooked by the NRC in Agreement State compatibility classification is the fact that the devices of concern in the regulation are distributed from vendors located all over the country to General Licensees located all over the country. This type of distribution network makes any rules affecting the distributors and the recipients inherently trans-boundary, and thus appropriately subject to Category B Classification. Uniformity among NRC and Agreement State Regulations is particularly important to vendors in that we must be knowledgeable of the regulations and interpretation nuances of the regulations of all Agreement States to provide accurate and complete information to the General Licensees. Successful implementation of the objectives of the proposed changes require that the elements of Part 31.5, Part 32.51, and Part 32.52 be classified as Category B for Agreement State compatibility.

National Tracking Database

The proposed rule changes establish a tracking database for generally licensed devices. ABB believes in the objectives of this database, namely to be able to track source/device distribution, use, transfers, and disposals. However, for such a database to be truly effective in meeting these objectives, it must be a single database for the entire nation. The establishment of individual databases by each Agreement State would not only lead to higher costs for each registrant, but would result in 32 separate and incomplete databases. The proposed system, namely reports of individual transfers to individual organizations, is essentially the same type of system that is in effect now, and it has obviously been proven ineffective.

An effective system of tracking requires a single group collecting and soliciting information, maintaining the database, and disseminating information as necessary. Further, a single database is the only effective way to reconcile discrepancies among reports in or out of separate Agreement States. ABB recommends that the proposed rules require a single nationwide database for tracking all applicable sealed sources and devices.

Replacement Device Notification

ABB recommends that the NRC clarify the definition of "replacement device" in Part 32.52 and Part 31.5. Confusion is likely to arise under the current wording. ABB, for example, foresees several scenarios that may be considered "replacements." The situations include: replacements of sources alone, replacements of sources and devices, replacements of devices keeping the same sources, and upgrades of devices on the same measurement system or platform. Further confusion may arise from the time frame of the replacement. Frequently a "replacement source" may be at a customer's site for some time prior to removal and transfer of the old source. This procedure is necessary due to the nature of the measurement process and the associated industry. Thus, a replacement source may not be able to be directly associated with a particular returned source for several months. The final

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definition of "replacement devices" needs to address some of the uncertainties in these different procedures.

Responsible Individual

ABB agrees with the objectives behind requiring a Responsible Individual be assigned for each General Licensee. We believe that this requirement alone will lead to significant increases in control of devices at the General Licensee's locations. However, there needs to be some clarification with respect to the requirements for establishing this position. Particularly, make clear if the individual needs to be at the location of the devices under his/her responsibility and if the individual needs to be an employee of the General Licensee.

ABB believes that the Responsible Individual should be allowed to both be at a location separate from the devices (i.e. a corporate individual responsible for many company sites) and be from outside of the General Licensee's company (i.e. a consulting organization). For either situation to be permitted there must be the obvious requirements that the individual is physically able and has the appropriate authority from the General Licensee to perform all required duties. Not allowing either of these situations would put restrictions on General Licensees that are not applicable to Specific Licensees. A Specific Licensee's Radiation Safety Officer, a position of significantly greater responsibility, is permitted to be at a location separate from the materials on the license and is also permitted to be from outside of the organization. Further, these restrictions would not promote the objective of the proposed changes, control and accountability of Generally Licensed devices.

Requirement to Provide Information Prior to Transfer

The NRC proposes that certain information be provided to General Licensees "before the device may be transferred." The information to be provided includes the relevant regulations, a list of services that must be done under a Specific License, and disposal information. In the Discussion segment of the Federal Register Notice, the Commission states their intent is for the vendor to provide this requested information "before a final decision to purchase." ABB feels that it is unreasonable and ineffective to provide the requested information during the purchase decision. ABB also believes that it is unreasonable to require the vendors to provide information on "acceptable disposal" to the General Licensees.

ABB Automation does not only sell sources and devices, but entire measurement, control, and actuation systems. These systems frequently cost in the hundreds of thousands of dollars and are a major investment decision for large corporations. The negotiations for purchase of the systems may span several years and involve numerous individuals, most of whom would not be concerned with the information proposed to be provided. Further, the individuals within the General Licensee's company for which the information would be useful might not even be aware of the purchase decisions being considered. Along the same lines, ABB's Radiological Operations Center, the

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organization that would be responsible for providing the information to the General Licensee, is not currently aware of all sales efforts that are underway within ABB. It would be a substantial, and we believe inefficient, effort to train the full sales staff of ABB and provide them with appropriate information. ABB recommends that the information outlined above be provided to the General Licensees at the time of source transfer or at any time prior to transfer per the request of the prospective General Licensee.

Information on "acceptable disposal" can not be accurately provided by the vendors. The lifetime of many of the applicable sources/devices can be upwards to 30+ years. Right now, we can not assuredly state that there will be viable disposal options next year, let alone 30 years from now. It is important to remember that the willingness and ability of a vendor, or other Specific Licensee, to accept sources from a General License is dependent on the options for ultimate disposal of the sources. For example, there are not viable disposal options for Am-241 for most companies. The situation for radioactive waste disposal is currently so tumultuous that any information that a vendor would supply regarding source transfer/disposal availability or cost is subject to being very wrong and possibly misleading. Therefore, the vendors should not be required to provide this potentially wrong and misleading disposal information.

Permanent Labels

ABB requests that the Commission replace the term "permanent label" [32.51(a)(5)] with the term "durable label." This change would reflect the apparent intent of the proposed rules without conflicting with the requirements of Part 20.1904(b), which requires removal of labels. A "durable label" also implies that labels on a device could be changed to reflect new source serial numbers, as this information is required to be on the label. Many of ABB's devices allow for the interchanging of sources without replacement of the entire device. In this situation, the source serial number is likely to change many times in the lifetime of the device and hence the device labels will be changed many times as well.

ABB would like to thank the Commission for the opportunity to comment of the proposed changes to 10 CFR Parts 30, 31, 32, 170, and 171. We hope this information is useful and we trust that it will be considered in review of the proposed changes. If you have any questions or require any additional information, please feel free to contact us at 614/261-2337.

Sincerely,

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