

Rulemaking Comments

From: Sean Chapel [schapel@irsc-inc.com]
Sent: Tuesday, August 25, 2009 1:37 PM
To: Rulemaking Comments
Cc: Tim Brandon; manish@jaschgauging.com; David Gillmore; Fenshya Chang; Garth Brown; Irene Dunn; Jack Ramsey; Jerry Tucker; Kevin Schehr; Lila E. Murphy; Mick Schwartz; Sia Afshari
Subject: NRC-2008-0272 Comments on Proposed Rule
Attachments: Final Draft Reply to NRC Rule Limiting GL Quantities.pdf

Dear Secretary,

Please accept the attached comments on the NRC Proposed Rule Limiting Quantities of Radioactive Material in Generally Licensed Devices, Docket NRC-2008-0272.

We are also mailing a hard copy.

If you have any questions please let me know.

Sincerely,

Sean Chapel, President
ADDM

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USNRC

August 31, 2009 (10:22am)

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Return-Receipt-To: "Sean Chapel" <schapel@irsc-inc.com>

From: Sean Chapel <schapel@irsc-inc.com>

To: <Rulemaking.Comments@nrc.gov>

CC: "Tim Brandon" <tbrandon@irsc-inc.com>, <manish@jaschgauging.com>, "David Gillmore" <dgillmore@climatronics.com>, "Fenshya Chang" <fenshya@aol.com>, "Garth Brown" <garth.brown@verizon.net>, "Irene Dunn" <irened@ir100.com>, "Jack Ramsey" <jack.ramsey@metso.com>, "Jerry Tucker" <jerrytucker1@aol.com>, "Kevin Schehr" <kevin@spec150.com>, "Lila E. Murphy" <lmurphy@irsc-inc.com>, "Mick Schwartz" <mick.schwartz@bertholdtech.com>, "Sia Afshari" <safshari@rmdinc.com>

Subject: =?us-ascii?Q?NRC-2008-0272_Comments_on__Proposed_Rule?=
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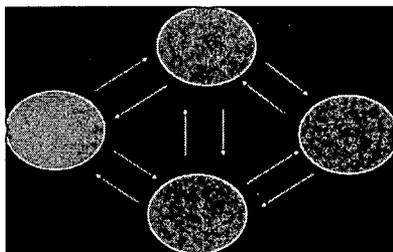
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Return-Path: schapel@irsc-inc.com



Association of Device Distributors and Manufacturers (ADDM)
P.O. Box 258, Winchester, MA 01890
www.addm.us

Berthold Technologies USA LLC,

Industrial Nuclear Company, Inc.

IRSC, Inc.,

Jasch Industries Ltd.

Met One Instruments, Inc.

Metso Automation USA, Inc.

RMD, Inc.,

*Source Production and
Equipment Company, Inc.*

Thermo EGS Gauging, Inc.

August 24, 2009

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Dear Secretary,

Enclosed please find the ADDM's comments on the NRC Proposed Rule Limiting the Quantity of Byproduct Material in Generally Licensed Devices.

If you have any questions about our comments please call me at 781.767.2176 or e-mail me at schapel@irsc-inc.com

The organization is willing to meet with the NRC at your convenience to discuss the impact of these regulations on our members and our customers who are gauge users.

Sincerely,

A handwritten signature in cursive script that reads "Sean C. Chapel".

Sean C. Chapel,
President

A.4.3.2.2 (D) D. *Specific Questions for Comment*

The NRC invites comment on its proposal to place a limit on the quantity of byproduct material allowed in generally licensed devices, specifically:

(1) Whether the 1/10 of IAEA Category 3 limit is the appropriate threshold level of byproduct material below which general licenses would still apply;

What is the technical basis the NRC has used for the establishment of the 1/10 activity level of category 3 sources?

The ADDM disagrees with the principal of setting activity limits for generally licensed devices. This proposed regulation seems to be based on vague security concerns related to the potential for an individual or group to aggregate devices for ill purposes.

The arbitrary limiting of activity levels has no basis related to safe operation of devices. In the US devices are evaluated for dose potential based upon several factors besides radionuclide and activity, including the intended use of the device, prototype testing, review of product construction, annual occupational and accidental doses, etc. at great cost to the manufacturer. This is a comprehensive regulatory system in use for many years which has proven to be effective in regulating the approval of safe devices.

Most generally licensed devices affected by this regulation are critical to the operation of a manufacturing facility and are firmly mounted in process equipment, and are surrounded by conveyor belts or other mechanical components moving at high speed with restricted access. These are often large, heavy devices which could not be carted off. In addition, these devices have built in tamper resistant features (evaluated by the NRC) which restrict access to the source.

Please note that many other types of GL devices are under secure control, as they are security devices (however most of these would not be affected by this regulation). In addition GL devices are often expensive and owners have an inherent need to guard their property.

In section A.4.3.1 of the Federal Register the NRC said that an evaluation of the current General License (GL) regulatory system "... found that the relatively few administrative or operational regulatory constraints (mainly as a result of safety features incorporated into the design) imposed on GL devices raise a number of concerns about security vulnerabilities." This statement contradicts itself. How many GL devices were reported lost or stolen to the NRC last year? Has there ever been a specific documented incident in the US where someone has stolen aggregated devices and used them in a malevolent way to cause doses to the general public in excessive quantities?

The Federal Register also states that Specific Licenses (SLs) would also ""provide an opportunity for reviewing radiation safety programs, opportunity for written and oral dialog, more rigorous screening of applicants and prelicensing inspections and routine

inspections, etc.” Where is the evidence that these type of devices related to this proposed regulation are being stolen from facilities? The types of devices which are lost or stolen each year are lower activity devices such as Troxler gauges, usually taken or fallen off the back of a truck in which it was not secured. These instances are few and far between compared with the thousands of gauges which are in use.

In a meeting between the Organization of Agreement States (OAS) and the NRC on August 14, 2008, Barbara Hammick, Past-Chair of the OAS and Director of the California Department of Public Health, Division of Radiological Health Services stated that:

“ If the Category 2 source is a risk, then why not the very high end of the Category 3 because they're almost Category 2. And if they are, why not the 3.5 category since they're very close to Category 3 and on and on until eventually individual atoms of radioactive material are effectively equivalent to a Category 2 source...”

Note that the commission recently voted to decline the tracking of category 3 devices. Devices with activities 1/10 of category 3 have been referred to by the NRC as category 4 devices. Further regulation of category 4 devices is inconsistent with this vote.

Ms. Hammick then went on to state:

“As we envision it, this practical risk threshold would essentially address the potential increased risk of cancer that might result from an RDD event because that appears to underlie the continued concerns with area denial or psycho-social effects resulting from an RDD.”

So what is the legal or practical, radiation dose risk threshold the NRC is addressing by limiting the activity level of GL devices? There is no statement in the federal register on what the dose risks would be to the public associated with devices which could be aggregated and used as a dirty bomb.

(2) Whether there should be additional protection against aggregation of sources by either requiring that if the aggregated amount of byproduct material that a general licensee possesses in devices exceeds 1/10 of IAEA Category 3, then the general licensee must obtain an SL, or more simply, by using the IAEA Category 4 threshold level as the limit for the GL;

The ADDM believes there is no need to take additional steps to limit the number of generally licensed devices end users may possess. This action will unnecessarily interfere with our members' ability to engage in commerce.

There is no practical way an individual or group could aggregate typical process instruments such as web/thickness gauges due to their cost and size. They also could not be collected as waste for illicit purposes as they must be hauled away by a licensed radioactive waste broker.

(3) Whether an even lower threshold limit for requiring licensees to obtain a SL should be used, such as the registration levels in 10 CFR 31.5(c)(13)(i). In providing support for this approach, the NRC is interested in whether there is specific information (i.e., lack of accountability due to generally licensed devices being lost and/or abandoned) that would indicate that the GL registration program as instituted in the 1999 and 2000 rulemakings (see Section II.A.4.2 of this document) is no longer working satisfactorily from the standpoint of protecting the public health and safety from routine use of these devices by general licensees:

In the Federal Register Notice the NRC states that “the GL registration program instituted in 1999 and 2000 did not foresee the need for the current proposed regulatory amendments...” This confirms that these proposed regulation changes are only security related and are not related to safety and dose potential related to operation and use of devices.

What facts does the NRC provide that there is a security issues associated with these devices? There are no details in the NRC’s proposal on dose limits from aggregated devices used in a “dirty bomb.” Within the Federal Register it does state that it takes 10-12 category 4 devices (similar to 1/10 category 3 devices) to equal a category 2 device. Note that there is great variability in the radionuclides and activities of GL devices.

What evidence is there that any group or individual in the US has ever attempted to aggregate devices in attempt to use them for ill purposes? To the best of our knowledge a dirty bomb has never been set off in the U.S. (This means that either there is no threat or the current regulations and activities of law enforcement are effective at suppressing this sort of attack). There is no empirical data available for the effects of such an attack.

(4) Whether the approach regarding Compatibility Categories laid out in Section II.B of this document, i.e., in which states have flexibility to adopt more rigorous requirements for general licensees, based on their circumstances and needs, can work satisfactorily. In particular, will there be any significant transboundary issues related to this approach or, will such an approach not have direct and significant effect on the transportation of the devices or on their movement in and out of States? Concerning the proposal discussed in Section C of this document which would prohibit specific licensees from using GL devices under 10 CFR 31.5 and would require these devices to be possessed and used under an SL, the Commission requests comments to assist in its evaluation of the impacts of such a change on specific licensees and on how best to implement the change. Specific questions for comment:

(A) How should this change be applied in the case of devices used by a specific licensee at different locations? Would there be difficulties in determining which devices used by a given entity must be under the specific license, if the applicability of 10 CFR 31.5 were to be determined by the location of use, as suggested?

This rule unnecessarily complicates the regulation of devices. The ADDM understands that the current quarterly reporting system is outdated. We are willing to begin a dialog with the NRC and Agreement States in order to come up with a modernized reporting system for the location of devices.

(B) How much time should be allowed for the specific licensees to transfer their currently held generally licensed GL devices to their SLs? Should devices currently held under the GL only be added to the SL only at the time of license renewal or amendment?

The ADDM disagrees with the need to transfer GL devices to specifically licensed.

(C) Should the details of the voluntary transfer process in 10 CFR 31.5(c)(8)(iii) become mandatory and be maintained in the regulation to assist the process?

ADDM believes that transfer of devices among end users could be handled by requiring registration of devices in each state by end users.

(D) Would there be a significant impact from the applicability of reciprocity requirements in 10 CFR 150.20 for portable gauges currently licensed under 10 CFR 31.5 and equivalent Agreement State regulations that are used in more than one jurisdiction? How would this proposal affect servicers of devices currently operating under the reciprocity provision of 10 CFR 31.6 and equivalent provisions of Agreement States?

This proposed regulation will have a severe impact on manufacturers and distributors of generally licensed devices containing radioactive sources. For years the industry has been hoping that Agreement States would implement the intent of 10 CFR 31.6, which was to allow installers and service providers to do their job without additional restrictions. We feel that in 2009 the NRC should be moving toward greater compatibility between regulations between states and the federal government, and not towards reduced compatibility. We suggest that this compatibility for 10 CFR 31.6 be revised from B to A.

Small companies with a few customers spread across a large number of States will find it prohibitively expensive to conduct business within these States. Just dropping by to perform a leak test twice a year represents a major administrative burden securing licenses, paying exorbitant fees, and giving adequate notification so as to allow a State inspector to show up for an onsite inspection. The burden of reciprocal recognition on visitors to the States could become prohibitive without some assurance from the NRC that the overall regulatory burden for service of GL devices will be minimal.

If the States want more control over GL service work within their boundaries, we suggest allowing manufacturers to register with the State on an annual basis. This way they will know who is working within their borders. This would allow us the flexibility to service our equipment without the current burden we face of providing an exorbitant fee, a 3 day notification and specifying and updating work times that continually change, as some States currently require. There is no potential that we can see for an increase in public safety or a reduction in the threat of a terrorist attack, which would result from placing this level of burden on a GL distributor or service provider.

Many Gauge distributors and service organizations are small companies without a lot of resources, and cannot afford to pay thousands of dollars in each state for Specific Licenses, in addition to the time and cost of applying for and renewing these licenses.

The cost of the license fees and the administrative burden of submitting reciprocal notifications for every visit can be prohibitively expensive.

With increasing regulation, the manufacturers of GL's will become less likely to win sales of their devices. Customers are less apt to purchase devices that require full-fledged radiation safety programs, radiation safety officers, radioactive materials licenses, higher license fees etc. than those that don't have such requirements.

(E) Would it be preferable to maintain the applicability of 10 CFR 31.5, but to apply some or all of the terms and conditions of the SLs, e.g., by removing the exemptions in 10 CFR 31.5(c)(10) for those holding an SL?

ADDMM believes that it is unnecessary to regulate current generally licensed devices as SLs. We believe that as an alternative to specifically licensed devices it may be beneficial for all GL devices to be registered by the end user.

(F) How much impact would there be to 10 CFR 32.51 licensees and Agreement State equivalent licensees to ensure that they are transferring these devices to entities without an SL?

Currently a specific license is not required so if the regulation does not change there would be no impact.

(G) Should the sealed source and device registration certificates authorizing devices for use under 10 CFR 31.5 and equivalent Agreement State regulations be required to address transfers to both general and specific licensees?

We are unclear what the NRC is asking under this question. Are you referring to the designation of "B" at the end of the registration certificate, which allows the option for devices to be distributed as either generally licensed or exempt? If so, many of these certificates are unclear as to what the terms of transfer by license type are.