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Rulemaking Comments

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Subject: GL Rule (10 CFR 31.5) Comments NRC-2008-0272
Attachments: 10-09 GL Rule comments.doc

Attached are Virginia's comments to the proposed rule in Docket ID NRC-2008-0272. Thank you.
<<10-09 GL Rule comments.doc>>

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10 CFR PART 31 PROPOSED RULE COMMENTS BY VIRGINIA

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.

No, the current limits of 1/100 of category 2 limits appear adequate. The review and approval of a generally licensed device through the sealed source and device registration process is a determination that the device has no health or safety impacts when used by personnel with minimal training.

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.

No as this would create a resource conundrum on regulators and manufacturers/distributors of generally licensed devices. This would require that the regulators and M&D have an up to date inventory of all licensed material the licensee possesses. In some instances the aggregation of activities does not make sense as the devices are located in the same area but are separated from each other which does not allow for the simultaneous contact of the devices.

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.

No. The NRC stated in A.4.3.2.2 B that "The NRC successfully implemented the GL registration program with 80 to 98 percent of general licensees responding annually with completed registration forms. This rate of registration can be attributed in part to general licensee's enhanced awareness of regulatory reporting, transfer, disposal, and recordkeeping requirements." 10 CFR 32.51 and 32.52 contain specific requirements of the M&D licensees in terms of providing information to the general licensee and distribution reports. The NRC and agreement states in which the M&D reside must enforce these two regulations. Based on the NRC assessment and the guidelines of the IAEA, the proposed levels (1/10 Category 3) are adequate, especially if adequate efforts are made to follow up on the current registration system for lesser activity sources.

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?

It is recommended that the requirements for specific licensing continue to be a matter of compatibility as they are now. To allow a variety of more rigorous requirements among the states can only be justified if the NRC proposal is, in itself, insufficiently rigorous. When licensed activities cross jurisdictional borders, such as in transfers between distributors and recipients, too many differences create confusion within both the regulated and regulating communities. If the described sources actually represent a threat from terrorists, the excuse that regulations are inconvenient or require work by the regulatory agencies is specious. If the NRC believes that regulations which determine the requirements for specific licenses should be more rigorous in some cases than the suggested rule change, the NRC should make them as rigorous as is necessary to protect the public health and safety.

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?

From the regulating authority it would not be difficult, if a specific license has been issued then all radioactive material received by the licensee must be incorporated into their license. The regulatory authority would need to ensure that all licensees are made aware and understand the new regulation. If the devices are to be used at multiple locations each one must be listed on the license while if temporary jobsites are used then temporary jobsite approval must be in the location license condition.

From the M&D side it would be difficult. The M&D would need to contact the regulatory authority associated with their client to see if they had a specific license before shipping the device. With the current regulations they must supply their clients with regulatory information and inform the NRC and agreement states of any device shipments.

(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?

While we do not agree with this proposed regulation amendment, the licensees should be given no less than six months to comply with this regulation change. If the device is held under a GL only, the company should apply for a specific license within a six month time period.

(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?

Yes as 10 CFR 30.41 (c) requires that specific licensees verify that the recipient is allowed to receive the device/source in question before it is shipped.

(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?

Not in Virginia as all portable gauges utilized in Virginia are specifically licensed under our regulations.

(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?

Yes, since these devices have been deemed to be safe for use by personnel with limited training and experience and have little health and safety issues, it would be advantageous to apply the security requirements and 6-month inventory requirement to GLs to satisfy the accountability issue being raised.

(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?

At this time Virginia does not have specifically licensed GL M&D. As stated above we envision this to be a very time consuming effort as there is currently 37 agreement states as well as the NRC for regulatory authority. During these economic times, states are requiring staff to take furlough days and not allowing new hires for radiation programs, so M&D licensees would have a difficult time reaching staff to ensure that the devices are being transferred to a company who possesses a valid specific license.

(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?

This is the crux of the problem to date, multiple SSDs are listed as B for both, which allows the regulatory authority a choice on how to license the device. The SSD should only be allowed to state whether it is a GL or SL, not both and the regulatory authorities should abide by the SSD.