



Illinois Emergency Management Agency

Division of Nuclear Safety

PR 31
(74FR38372)

Pat Quinn, Governor
Andrew Velasquez III, Director
Joseph G. Klinger, Assistant Director

April 1, 2010

Mark R. Shaffer, Director
Division of Intergovernmental Liaison and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

DOCKETED
USNRC

April 8, 2010 (4:45pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Subject: Draft Final Rule for Limiting the Quantity of Radioactive Material in a Generally Licensed Device (RCPD-10-001)

Dear Mr. Schaffer:

The Illinois Emergency Management Agency, Division of Nuclear Safety's Bureau of Radiation Safety (the Agency), hereby submits its comments on the Draft Final Rule for Limiting the Quantity of Radioactive Material in a Generally Licensed Device (RCPD-10-001). The Agency submitted comments on this proposed rule on October 5, 2009. We are disappointed in the draft final rule. It appears that many of our original comments, as well as those of other states, were not adopted in this document. Consequently, the majority of these comments (attached) still apply to this draft.

We noticed that the compatibility level did get dropped to a 'C' and appreciate that change. We also noted that the concept of making all specific licensees that also had generally licensed devices convert to a specific license was dropped as well. This change was essential to make the proposal manageable under any terms.

Our recommendation to amend the affected SSD registrations was adopted as well. That step should eliminate a lot of confusion but will take some time to complete. The level of radiation safety measures to be included in the amended registries will need serious consideration and will have to be compatible with other specifically licensed devices.

The Agency still maintains that NRC has greatly underestimated the impact on resources to the licensees and regulatory agencies involved. These licensees will certainly be impacted by fees. NRC should well be aware of this with their recent fee increase. In addition, NRC implies that a full time radiation safety officer will not have to exist as part of this transition for general licensees. These licensees will be subject to the same requirements as any specific licensee under this rulemaking. Consequently, a RSO/radiation safety program will be required on-site for training, maintenance, incident response, facilitating unannounced inspections, etc. NRC needs to seriously reconsider the impact of the economic burden on the private sector.



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The impact on regulatory staff should be obvious. With the recent salvo of security changes in licensing and compliance such as NSTS, ICs, ASMs, Pre-licensing screening/inspections (for which many States are still trying to allocate resources) regulatory agencies nationwide are operating at full capacity with even less resources than were available before 9/11. The impact of these programs has been confirmed time and again during various Integrated Materials Performance Evaluation Process (IMPEP) audits. This deficit has to be addressed on a national scale by NRC.

The Agency asks that the reservations expressed in our October 5, 2009 letter be reconsidered in the constructive spirit of the NRC agreement state partnership. NRC appears to be proceeding over the objections of the Agreement States without adequately understanding the impact on general licensees or the regulatory environment. This proposal represents a burdensome regulation that is detrimental to the private sector but without commensurate security benefit. We appreciate the opportunity to comment on this important rulemaking. If you have any questions, please feel free to contact Gibb Vinson of my staff at (217) 785-9928 or via e-mail at Gibb.Vinson@Illinois.gov.

Sincerely,



Joseph G. Klinger
Assistant Director

JGK:CGV

Attachment

cc: Jim Lynch
U.S. NRC Region III



Illinois Emergency Management Agency

Division of Nuclear Safety

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Pat Quinn, Governor
Andrew Velasquez III, Director
Joseph G. Klinger, Assistant Director

October 5, 2009

Mark R. Shaffer, Director
Division of Intergovernmental Liaison and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

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Subject: Proposed Rule on Limiting the Quantity of Radioactive Material in a Generally Licensed Device (FSME-09-066, Docket ID NRC-2008-0272)

Dear Mr. Schaffer:

The Illinois Emergency Management Agency, Division of Nuclear Safety's Bureau of Radiation Safety (the Agency), hereby submits its comments on Docket ID NRC-2008-0272 regarding the expansion of the specific licensing programs to include generally licensed sources (GL) equal to or greater than 1/10 the IAEA Category 3.0 source thresholds. The Agency does not support the inclusion of these sources under specific licensure (SL). There are much less obtrusive means to accomplish additional oversight of these devices under the GL provisions including manufacturing/security changes and additional inspections. Specific licensing is attractive initially to NRC because it gives the appearance of radical change that is attuned to the current GAO mindset. It also appears to be an easy fix initially (although long term it involves many programmatic revisions including SSD registration changes). Finally, it avoids questions about decades of ineffectual GL management by many programs. We hope the following comments are useful:

1. NRC's arguments in favor of this decision regarding congressional pressures, inability to manage GL licensees, rulemaking issues and potential for aggregation of sources are not universally true. States with vigorous GL programs do not encounter many of these problems and should not be penalized for organizations that are deficient in the oversight of these sources. In addition, NRC needs to identify a threat basis upon which to make these kinds of policy decisions (see Item 4 below).
2. Any change to this process must involve the manufacturers and the potential to implement additional security measures in the manufacturing/distribution process (see Item 3 below). This would greatly reduce the number of licensees involved if the manufacturers can be targeted for change as opposed to their customers. In addition, much of the financial incentive for GL devices is the marketability of less bureaucracy. If this sales incentive is removed by requiring specific licensure, some may no longer be able or willing to compete. Additional financial and bureaucratic restrictions are exactly what our adversaries are hoping to achieve. We should do our best not to accommodate them in this area while protecting the public health and safety.

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3. The sealed source and device registry process will have to be revisited as well. Illinois is in favor of keeping these GL devices while putting additional hardening/design features in the product, security requirements in the registry/rule for users and including inspections for the 1/10 IAEA Category 3.0 devices. Options involving permanently mounting devices in place with specialized tools or welding equipment such that only manufacturers can remove them should be explored. In addition, manufacturers are allowed to do leak testing and shutter checks on certain devices every 3 years. The shutter checks should be reduced back to 6 month (or even 3 month) intervals so that devices are accounted for more frequently. This change would also support the information in your latest Information Notice 2009-18. Regardless, all of the product registrations falling into 1/10 IAEA Category 3.0 and above will have to be amended to change the general license designation and to include security provisions before the licensing process begins. In Illinois, the product registries are legally binding documents as they are conditionally included in license documents.
4. The level of aggregation necessary in this category is important to note as well. It would take 10-20 high end 1/10 Category 3.0 devices to equal a Category 2 device. The loss/theft of this number of devices at one facility or in any given area would certainly result in numerous investigations under current regulatory oversight. The Agency does not believe the IAEA study supported the aggregation scenario as feasible at this level and would like to see additional IAEA documentation regarding aggregate RDD devices.
5. If the intense security oversight of all uses of radioactive materials continues, NRC will need to get directly involved in staffing issues at the Agreement State level. Another alternative is to deem other licensing/compliance activities as unnecessary to make way for these additional measures. The impact of these additional measures goes far beyond the simple issuance of a license. There is additional administrative and IT support that is required. NRC has previously indicated that they have hired several hundred new employees to address security issues with more on the way. With nationwide budgetary shortfalls, staffing is not going to improve at the Agreement State level. IMPEP reviews are already noting programmatic shortfalls as a result of these additional mandates.

Illinois would have approximately 45 new specific licensees (a six percent increase) and 23 amendments as a result of this rulemaking. To moderate the impact on regulators and the regulated community, the following measures should be taken:

1. Limit specific licensing requirements to security matters. Avoid case-by-case evaluations of health and safety considerations and user training and experience. Limit the scope of the new class of specific licenses to security matters only.
2. Publish or otherwise provide secure handling guidance for fixed gauges. Do this by regulation wherever possible.
3. Keep inspection frequencies realistic and the requirements for site inspections simple and commensurate with risk.

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4. Augment the existing health and safety considerations for manufacturing that exist in 10 CFR 32.51 and 51a to include security and design changes. These safety features should be perpetuated into the new class of specific licenses.

Specific Questions for Comment

In Section D of the FRN for the Proposed Rule the NRC invited comments on eleven questions. The text of these questions has been extracted and Illinois comments have been inserted:

- (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.
Answer: Illinois is in favor of adding restrictions to current rules for manufacturing, security and inspection of GL devices as an alternative to this very disturbing proposal. We prefer not to go beyond Category 3 for this proposal. As a worst case scenario, NRC should certainly not go beyond 1/10 of IAEA Category 3.
- (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.
Answer: Additional protection against aggregation of sources appears to be unnecessary due to the low probability of occurrence and the number of sources that would have to be aggregated to get a Category 2-3 quantity.
- (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.
Answer: A lower threshold limit for requiring licensees to obtain a SL is not needed. Our experience is that registration/periodic audits of the devices or equivalent methodology has been sufficient to protect public health and safety and to minimize loss, abandonment and diversion.

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- (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.

Answers: The only transboundary issues would be if certain states chose to make certain devices SLs outside of the terms the final rule. Within the current GL rule, Illinois is one of the states that has had more rigorous requirements for GLs for many years. The Illinois approach has worked satisfactorily without any transboundary issues. The approach proposed by NRC will allow states with existing more rigorous requirements to continue if they choose to do so. The proposed NRC approach will have significant effect on transportation or movement of the devices in and out of States for those devices going from GL to SL. These will have to pay substantial fees and be subject to reciprocity inspections.

For the proposal in Section C, Illinois would like to keep the current freedom for licensees to choose or not to choose to add the GLs to their SL. The NRC prohibition to possess a GL at a SL facility would add a significant burden to licensees, NRC and Agreement State staff with no apparent commensurate benefits. Specific questions for comment are:

- (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?

Answer: Applicability of 31.5 should not be determined by the location of use but by the status of the licensed entity. If the licensed entity has any SL devices, all GL devices regardless of location become SLs under this proposal. However, Illinois again recommends that only the 1/10 of IAEA Category 3 devices be considered in these cases rather than every GL under the entity's control.

- (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?

Answer: Illinois prefers to issue/amend these licenses within a specified transition period (i.e., 365 days).



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- (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?

Answer: Since NRC is pressing for accurate possession limits on licenses, the process would have to be mandatory.

- (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?

Answer: The impact of reciprocity requirements could be significant. GLs converted to SLs would require notice of reciprocity and payment of fees unless NRC regulations that are required for compatibility limit such action. Reciprocity inspections would also be required. If the priority for these inspections is set at too high a level, the impact could be substantial.

- (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?

Answer: First, only 1/10 of IAEA Category 3 devices should be changed to SL devices. Yes, it would be preferable to apply only certain SL requirements to these.

- (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?

Answer: Significant impact because the 32.51 or equivalent licensees would have to confirm with the regulatory authority in each case to get a reliable answer. If this would be applied to H-3 exit signs, Ni-63 ECDs or Po-210 static eliminators, then the burden would be tremendous for distributors and regulators.

- (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?

Answer: Yes, both should be addressed in the registry and rulemaking.

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The Agency appreciates the opportunity to comment on this important proposed rule. If you have any questions, please feel free to contact me at (217) 785-9928 or via e-mail at Gibb.Vinson@Illinois.gov.

Sincerely,

Charles G. Vinson, Head
Radioactive Materials Section
Illinois Emergency Management Agency

CGV:SCC

cc: Jim Lynch
U.S. NRC Region III

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