From: Collins, Steve [Steve.Collins@illinois.gov]
Sent: Wednesday, October 22, 2008 4:59 PM
To: Catherine Mattsen
Cc: Vinson, Gibb
Subject: FW: IL Comments on RCPD-08-019

Gibb tried to forward to you again, but due to the appearance of the email address, I am trying this form of email address as well. Please let us know if you did not get either of Gibb's sent messages.

From: Vinson, Gibb
Sent: Wednesday, October 22, 2008 3:56 PM
To: 'Mattsen@nrc.gov'
Cc: Collins, Steve
Subject: FW: IL Comments on RCPD-08-019

Fyi

From: Vinson, Gibb
Sent: Monday, October 20, 2008 3:42 PM
To: 'Mattsen@nrc.gov'
Cc: Eastvold, Paul; Lynch, James
Subject: IL Comments on RCPD-08-019

Catherine R. Mattsen
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for comments on the draft proposed rule to amend 10 CFR Parts 30-, 31, 31, 40, and 70 – REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL (RCPD-08-019)

Dear Ms. Mattsen:

The Illinois Emergency Management Agency, Bureau of Radiation Safety (the Agency) hereby submits its comments on RCPD-08-019 regarding the changes to licensing requirements that affect manufacturers and distributors of sealed sources and devices containing byproduct material and future users of some products currently used under general or specific license. Several amendments are proposed to make requirements clearer, less prescriptive, more risk-informed, and to improve safety criteria for approving products through licensing actions, redefine categories of devices to be used under exemptions, and add explicit provisions for the use of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective and also to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and exemptions from license.

The Agency is supportive of actions to make licensing processes more efficient and effective. The Agency is also generally supportive of making its rules clearer, less prescriptive, more risk-informed, and improving safety criteria. The Agency cautions that the prescriptive nature of current requirements was partially the result of lessons learned from incidents caused by a few manufacturers who changed manufacturing processes without adequate evaluation causing great expense to state radiation regulatory programs. This has included generally licensed products such as static eliminators and even abuse of exempt products (stacking of exempt sources in gauges). The Agency will further evaluate these areas of concern and provide more comments later, if needed.

Implementation of the extensive changes will be a significant impact on Agreement States and three years is needed for the states to adopt the compatible revisions. Even more time will be needed to implement them. Changes to the various license documents from specific license to general license or vice versa will take significant time as well as the corresponding changes to SSD evaluations.

NRC proposes a class exemption in a new section 30.22 that together with section 32.30 would apparently exempt many devices that IEMA currently registers as generally licensed. This could ultimately exempt most registered Ni-63 electron capture detectors and XRF's containing only Co-57 or Cd-109. Many of us, for example, have long questioned the wisdom of licensing Ni-63 foils in consideration of the low toxicity of the nuclide. Furthermore, section 31.5 has grown over the years into a catch-all category comprising a disparate and unrelated group of devices. The exemption should eliminate some of this clutter.

For IEMA, the exemption would eliminate approximately 160 registered general licensees if all existing electron capture detectors and XRF's were eventually exempted. Concomitantly, IEMA should prepare for some reduction in the number of specific licensees – those authorizing only the above classes of devices. Also NRC proposes to force ahead with its "ten percent solution" as proposed for section 31.5(a) (RCPD-08-006). This is the proposal that would require a specific license for any device containing ten percent or more of a so-called security Category 3 nuclide, which is one percent or more of the corresponding Category 2 amount found in Appendix E to Part 20. In concert with that effort, this rulemaking proposes a new section 32.51(a)(2)(v), which would limit the amount of radioactivity permissible in manufacture of a generally licensed device. As previously discussed in RCPD-08-009, this would eliminate approximately 100 general licensees now registered with IEMA.

In aggregate, NRC's proposed limits and exemptions would probably reduce the scope of IEMA'S GL registration program by approximately two thirds; to around 120 registered general licensees. This would result from a loss of 100 general licensees exceeding the ten per cent limit and another 160 ultimately exempted.

However, the agency does recommend that the activities and types of devices be specifically identified in this rulemaking. This will save a lot of arguments with manufacturers and consultants. Also, environmental conditions should be considered for

each product. If any are to be used outside of a controlled environment (i.e. in the field), prototype testing should be considered regardless.

Further study of the dose limits versus the activity limits for certain exempt/generally licensed devices must also be made. It appears as if multiple units used or disposed of improperly could exceed the proposed limits specified. In cases where we are now seriously reviewing our history of disposal with H-3 exit signs and their impact on landfill operations, now may not be the time to contribute further to that problem.

Regarding the updates of SSD registries, currently many states review the SSD registries at the time of renewal and incorporate changes that have arisen as a result of failures, incidents or compliance concerns. Illinois recommends that this be made a standard practice, rather than adding an expiration date to each certificate. In addition, we currently do allow manufacturers to make product changes that do not affect health and safety without amending the SSD certificate. In practice, we suggest that the manufacturer submit the change to us informally so that possible health effects can be reviewed prior to marketing the product.

For inactivations, we recommend that a time limit be put in the regulation for inactivation of certificates. The Agency has historically had many problems enforcing such a requirement in a timely manner. Two years after the last distribution may be a good alternative. In addition, 32.210(a) should be amended to read "**shall** submit a request to NRC for evaluation." Similarly, inactivations in 32.211 should be required by "shall."

On page 19 of the "Predecisional Draft Information" 10 CFR 30.32(g)(4) appears to allow licensing of sealed sources that may be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1). An alternative included appears to allow distribution of some sealed sources and devices without an individual unique identification marking. This practice should never be allowed. The Agency understands that there are certain military and broadscope situations where submittal of all information in 30.32(g) is impractical. However, we much prefer applicants using the exemption process for these rare occasions rather than codifying it in a rulemaking. This concept in a rulemaking leads varying degrees of interpretation by licensees and regulators alike.

These revisions will obviously require a corresponding change to NUREG 1556, Vol. 3, Rev.1. This document is too prescriptive in certain areas such as quality assurance. However in other disciplines it contains very useful recommendations on prototype testing, labeling, servicing, etc. It has also allowed NRC/States to incorporate some degree of consistency in the information contained in SSD certificates. We should be careful that this is not lost again, and we are back to having 35 different versions of SSD documents.

The Agency recommends compatibility category C for these changes. The key elements should be compatible, but the manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met

The Agency appreciates the opportunity to comment on this important draft proposal. If you have any questions, please feel free to contact me at (217) 785-9928 or via email at Gibb.Vinson@Illinois.gov or contact Steve Collins, Acting Radioactive Materials Licensing Supervisor, at (217) 785-6982 or Steve.Collins@Illinois.gov.

Sincerely,

Charles G. Vinson,

Head

Radioactive Materials

Section

Illinois Emergency

Management Agency

cc: Jim Lynch
U.S NRC Region III