May 13, 2004

Mr. Paul S. Schmidt, Manager
Radiation Protection Section
Division of Public Health
Department of Health and Family Services
P. O. Box 2659
Madison, WI 53701-2659

Dear Mr. Schmidt:

Thank you for the opportunity to review and comment on Wisconsin's study of general license (GL) registrations. Specific comments are found in the enclosure. The following general comments are provided for your consideration.

Prior to the December 2000 NRC rulemaking, the intent of the GL database was not to track generally licensed devices, but to be able to identify general licensees and the types of the devices they possess, so that they could be contacted or inspected. If, for some reason, a particular type of device became a concern, the newly imposed requirement would make it easier to locate the device. Historically, the general licensee was limited to possessing fixed devices installed by specific licensees; thus some of the rulemaking changes were also an attempt to "close the loop" and improve the tracking of these devices.

General licensing is much more complicated than the determination of the amount of material within the device. The regulatory structure approves the distribution of generally licensed devices based on safety criteria which permits a wide range of new devices to be used without the need for individual rulemaking. The applicant must only demonstrate that the proposed product meets the current safety criteria.

Presently, the Nuclear Regulatory Commission (NRC) follows up with general licensees who do not respond appropriately to requests for registration. General licensees who do not respond to a registration, or request for information, will result in an inquiry to the general licensee. NRC Regional offices inspect general licensees under certain circumstances such as bankruptcy, lost or stolen devices, and violations of the regulations.

The study very succinctly identified problems with a system in which data was historically collected but not updated or checked for accuracy. NRC's Regional experience also shows that the NRC GL database contains errors such as redundant information, incorrect addresses, incorrect company names, incorrect points of contact, incomplete device lists, wrong activity information, erroneous number of devices, etc. NRC's new GL registration program should rectify most of the issues identified above.

The disposition of devices in the Wisconsin database is comparable to what was found by NRC during its first GL registration effort. Although the details differ, Wisconsin was able to make contact with 80% of the selected general licensees, thereby improving their knowledge about generally licensed devices in their State. We commend the State for its actions.

We are looking forward to seeing your presentation at the Conference of Radiation Control Program Directors (CRCPD) Annual Meeting in May 2004.

If you have further questions, please contact me at (301) 415-3340 or Jim Myers at (301) 415-2328.

Sincerely,

/RA/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

We are looking forward to seeing your presentation at the Conference of Radiation Control Program Directors (CRCPD) Annual Meeting in May 2004.

If you have further questions, please contact me at (301) 415-3340 or Jim Myers at (301) 415-2328.

Sincerely,

/RA/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

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DOCUMENT NAME: G:\JHM\Paul Schmidt Response Letter. wpd;
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GL PAPER COMMENTS

The comments below follow the format of your paper.

BACKGROUND:

It is stated that, "The 30,000 devices consisted of approximately 29,250 non-registered generally licensed devices...and 750 registered devices at 130 facilities." It is not clear if the reference is to registrable devices or to devices previously registered by NRC in the first round of registrations.

The number of redundancies in the Wisconsin information appears high. The NRC has not experienced such a large reduction in the number of devices as a result of consolidating data in the General License Tracking System (GLTS). Also, it is not clear what criteria was used for removing redundant information in the database, which resulted in a reduction of the number of devices from 45,000 to 30,000 devices, without loss of data.

Item 2 may not be fully understood as there are portable generally licensed devices that contain millicurie quantities of radioactive material. (See as examples TX-634-D-175-B and RI-164-D-101-B). Was the intent that the more hazardous isotopes require a specific license?

Item 4 requires some clarification. 10 CFR 31.5(c)(15) indicates that storage beyond 2 years is only allowed if quarterly inventories are conducted. This requirement is intended to limit any burden of a "timeliness requirement" to those who need to keep additional devices on hand for immediate replacement, while reducing the likelihood of registrants losing track of stored devices.

The study states that, "Due to workload considerations, the evaluation was limited to generally licensed devices subject to a state registration requirement and associated annual fee." Will Wisconsin continue to track non-registrable generally licensed devices?

GOALS:

The paper discusses those devices which will be registered in Wisconsin. The criteria for registration, as discussed in Wisconsin's paper, are not compatible with the regulation in 10 CFR 31.5(c)(13)(i). Wisconsin's rules were reviewed for compatibility prior to its Agreement and found to be compatible. However, Wisconsin includes a broader range of devices that are included in its registration process. Several Agreement States have adopted similar requirements and NRC is working to resolve this issue.

STRUCTURE:

Note 1 discusses the establishment of the general license program. The general license program has undergone several significant revisions since its establishment in 1959. Accident criteria were added in 1974. Major revisions to §§ 31.5, 32.51, 32.51a, and 32.52 were completed in 2000. These regulations have a compatibility category B designation. Clarification is needed to refer specifically to the regulation change.

Are the devices mentioned in Items 3 and 4 registered devices? Clarification is needed to clearly identify the types of devices covered in the study.

Note 4 appears to be incorrect. 10 CFR 31.5(c)(15) allows storage beyond 2 years only if the registrant conducts quarterly inventories. This was intended to limit any burden of a "timeliness requirement" to those who need to keep spares for immediate replacement, while reducing the likelihood of people losing track of and forgetting about stored devices.

CONCLUSION:

Number 1 states that "The NRC database did not accurately reflect the number or location of many general license devices in Wisconsin or identify devices subject to a registration requirement." NRC agrees that there may be outdated information in GLTS as a result of many years without assessing the data, however the information in GLTS is continually being updated. Also, the GLTS does have the capability to sort devices subject to a registration requirement. Please consider revising the recommendation to reflect this information.