Overall Summary - Agreement States GL Survey

SECTION OVERVIEW

Workforce

Out of the 30 agreement state responses, the overall workforce dedicated to processing and registering generally license (GL) devices and sources is limited to one or two people who work less than 1 FTE on their GL program.

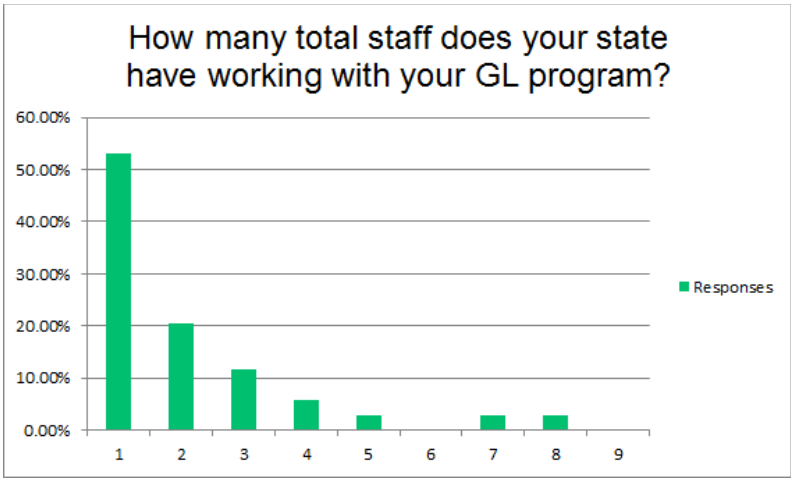

Figure 1. The percentage of responses that correspond to the number of total staff working on their GL program.

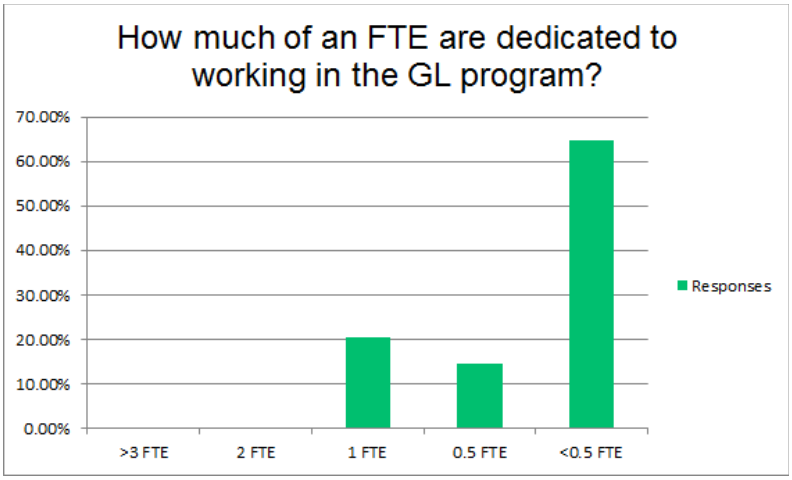

Figure 2. The percentage of responses that correspond to which fraction of GL work a Full Time Employee (FTE) is assigned.

In terms of workforce personal, most agrement states have not dedicated a large percentage on their GL program. These results were expected due to flexibility in GL management and the varying degrees of oversight across all the agreement states. The overall lack of workforce may make increased requirements a challenge to implement for small programs.

GL Registration Program

Out of the agreement states that answered the survey, slightly more than half follow the same GL registration quantities as the NRC. The other half of agreement states register any GL device or material that is above exempt quantities or they follow a different quantity threshold somewhere in between the NRC and exempt.

The answers regarding how they register new GL devices were opened ended, but the responses were similar. Most registration processes begin with vendor reports notifying them that material has been shipped into their state. The information is inserted into a database and they send out an application and fee to the registrant. Most states follow this flow process for new GL registrants.

Although the process flow is the same, there are large variances in database capabilities, and fees which may create differences in registration process. Most new registration processes are highly dependent of the quarterly vendor reports from manufacturers and distributors. One concern might be if a vendor forgets to send a notice, and there is no way of knowing that material has entered your state and can create an incomplete database. Most contact is initiated from the regulatory side and they notify the registrant of their registration requirement.

Most states have a different process for registering GL compared to specific licensing. Most recognize there is less oversight, and therefore a simpler licensing process. Most states do not require procedure reviews, a facility diagram, or other pre-licensing activities. The registration renewal frequency is higher or equal compared to their specific licenses.

The level of involvement in registering a GL device varies greatly. Some registrations are one page, while other registrations can be pages of conditions.

Inspection

Out of the 30 responses, almost less than half of the agreement states performed inspections.

Only TX, PA, NJ, AL, OR, NC, and WI perform regular inspections on their GL Licensees. All the states that perform regular inspections, except for OR and NC, follow the NRC on what is registrable and non-registrable GL devices, which can affect the inspection workload if they inspect only registerable GLs. OR and NC inspect all their GLs. NC made a note that they inspect everything but tritium exit sign users.

Other states like MA, TN, VA, OH, and MS only inspect GL facilities on a reactive basis after an incident or on a periodic basis up to the discretion of the reviewing official. VA only inspects GLs that also have a specific license. AR only inspects high activity sources and fixed gauges.

TX, PA, and TN have 9 or more inspectors for GL registrants. MA, VA, and MS have 4-8 inspectors and WI, OR, NC, NJ, AL, and AR have less than 3 inspectors. AL, NC and PA have

expressed concerns about GL inspection workload. NC transitioned from performing in-person inspections to sending out an annual Survey with inspection type questions to combat the required travel requirements of inspecting.

The items looked at during a regular inspection were the about same. For example some states looked at leak tests, shutter test, label integrity, and inventories. NJ just started their GL inspection program in 2014. They inspected all of the GL registrants between the years 2014 and 2015, and will be implementing a regular inspection frequency. Most GL inspection frequencies are around 5 years.

Noncompliance items are found on average 25-50% of the time. Common noncompliance items that were found are listed below:

- Lost/Abandoned device.
- Devices found that are not registered, or improper inventory.
- Devices that are transferred/disposed of improperly.
- Retention of stored devices over 2 years that are not being used or leak tested.
- Not performing leak test and/or shutter checks at the appropriate frequency.
- Failure to notify agency of changes to their General License Acknowledgement.
- Lost paperwork or records.
- Improper labeling.

7/14 states performing GL inspection recognized that loss of control was the main noncompliance item found that was directly related to health and safety concerns. 2/14 states believe there are no items that cause a concern for health and safety. The other states left no comments.

Table 1. The positive and negative outcomes from inspecting general licensees. Generated from opened ended responses from Agreement states.

Pros of performing GL inspections	Cons of performing GL inspections
● Educating the licensee of their responsibilities. ● Opportunity to provide training and assistance in complying with the regulations. ● Develop proper safety cultures within their program. ● Overall compliance can increase. ● Hightenawanress can lead to less devices ending up in scrap yards. ● Better communication. ● The Licensee is more likely to report changes or incidents to the regulatory office.	● Licensees that do not want to take responsibility of transferring and/or disposing of devices properly. ● Difficulty in reaching the "responsible person" to schedule the inspection due to change in personnel or facility has relocated or shut down. ● Difficulty in explaining regulatory requirements. ● Turnover and accountability are not communicated properly. ● Finding who can account for the GL device. ● Not being able to perform enough inspections on an annual basis.

All states agreed that performing inspections increases compliance, but 2 states said they would discontinue doing the inspections if they could.

Communication

Overall communication between GL registrants is regular and annual for most agreement states. Agreement states contact their GL registrants for billing annually, and they contact them for regular registration licensing items. It seems the communication effort will need to rely heavily on the regulator. Most programs require the regulator to initiate contact which might eventually lead to good communication effort from both ends. Majority of the agreement states agree that communication could be better or communication is limited. States with low communication satisfaction levels are AR, MD, RI, MS, WA, and WI. RI and NC reported that low staffing has limited their ability to communicate regularly.This is an indication that although communication exists, low staffing is limiting their ability to effectively communicate with their GL registrants. Overall communication is critical in managing a successful GL program, but some agreement states lack the resources to handle the correspondence volume.

Agreement states provided their successful communication practices that have helped their program:

- Annual billing is helpful for states that charge fees per source. The regulators can find out a change in inventory based on the fees they are receiving.
- Email and phone availability is always nice to have a direct form of contact with the licensee.
- Completion of a self-evaluation form that can be submitted or reviewed on site.
- Annual reports of licensee's inventory.
- Performing inspections, and communicating weeks before renewals are due.
- Emailing to all GL registrants on a list serve about fees or reminders.
- Sending out surveys that can act as an inspection or self-audit.

Communication with manufactures rarely occurs, most communication is one sided from the quarterly reports. When regulators do reach out to vendors, it is to confirm information about device or sources sent out. Some states might need to reach out to the vendor if they are having a difficult time getting that information from the licensee.

Incident Reporting

In terms of procedures, incident reporting follows the same guidelines as SL incidents. Some agreement states report directly to the NRC, some to NMED, and some report the incident only on their local database. Some states only report required devices, and they do not report tritium exit signs. One issue WI pointed out, lost or orphaned sources being reported as "lost" maybe inaccurate due to the lack of retention of old records and database errors.

When asked about how confident they were that all lost device were reported, some states like AR, RI, NJ, WI, and ME, had some concerns. Most states said that it is rare that a device would be reported lost.

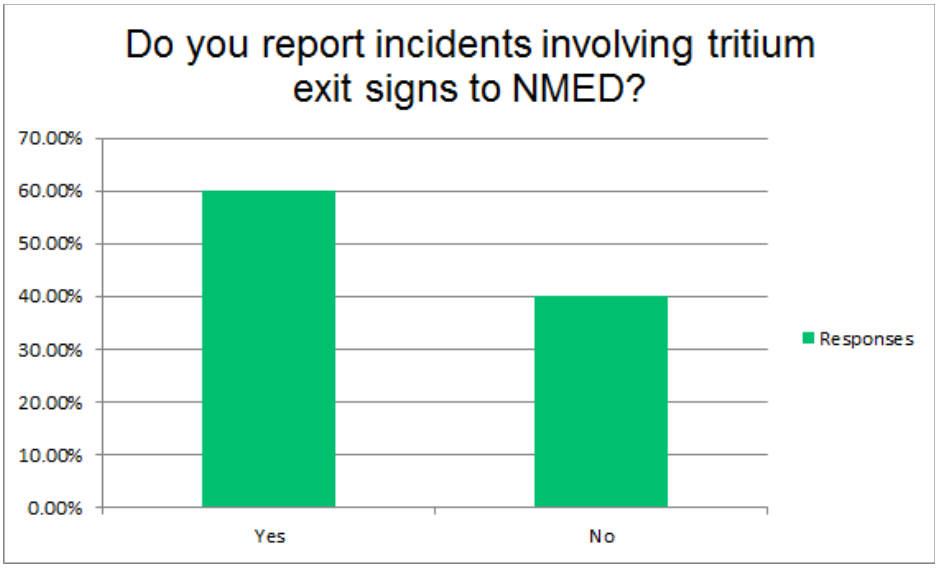

Figure 3. Graph displaying the responses for reporting tritium exit signs.

Some states do not track tritium exit signs, therefore reporting incidents on these events can be considered difficult.

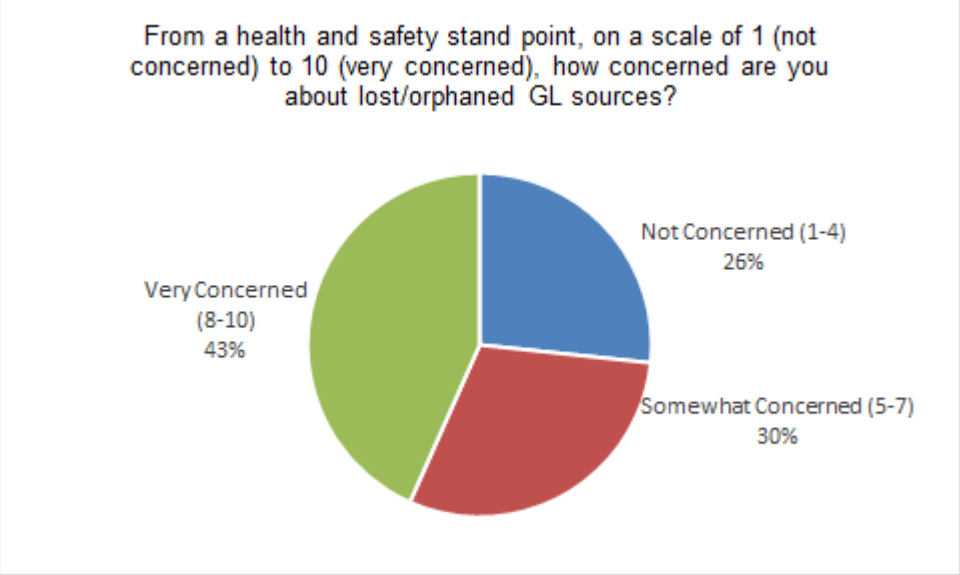

Figure 4. The health and safety concerns for lost/orphaned sources and devices.

The states are split across the board regarding efforts for recovering or reporting these devices for the sake of health and safety. This was an interesting outcome that shows that although loss of control is a large concern in general, in terms of health and safety there is some uncertainty.

Agreement states were asked about recommendations on incident reporting. The comments that were provided are below in Table 2.

Table 2.The recommendations from agreement states regarding incident reporting.

LA	“Get rid of GLs”
TN	“I think what is done now is streamlined.”
TX	“The NMED reporting software needs to be upgraded to 64 bit.”
KS	“Periodic communication with the registrant regarding regulatory requirements.”
PA	“Develop clearer regulations regarding necessary reporting requirements.”
MD	“More staff available to spot field checks”
RI	“Establish a tiered reporting system. Not everything has to be treated like a missing radiography camera with 100+ Ci of Ir-192”
NJ	“An online portal for reporting, rather than having to email. Access could be restricted by VIP credentials.”
AL	“Get rid of GL's and you get rid of the GL incidents”
IL	“Be able to upload events that are critical directly to HOO rather than scan email. -Reduce the number of inputs into NMED. Many serve no function.”
OH	“I believe that the current process is easy.”
WA	“GL incident reporting is difficult on the licensee end, and the overall lack of information and business turnover is hindering the process.”
NC	“NMED works”
WI	“The State is rarely notified when a device is disposed of. Our registered GLs have routine communication with us, and know that they are supposed to send us a disposal update, but the unregistered GLs have no idea. Some, but not all, of the manufacturers send disposal records in their quarterly updates and only a couple service providers notify us when they have contracted to dispose of GL material. Specifically licensed GL distributors/service providers have more knowledge and association with State radiation programs and are more likely to appropriately send disposal records if they were required to do so.”

Database Information Tracking

The majority of states (29) report that they use a database internal to their state, with the remaining reporting that they use Excel or paper tracking processes. There is some overlap in the numbers, so it appears that most states are using a hybrid approach to tracking.

Most states report that they spend 10 days or less per quarter processing vendor reports. Six states report that their processing takes 10 or more days, and only to report more that 60 days spend on this activity.

Most feel that their databases and the data within are reliable. Less than 5 report a reliability value of 5 or less for these two questions. Eight states report that they do not have a process to audit/verify the integrity of the data within the database. The remaining states report various processes to review this data, to include:

- Annual inventory information verified with registration
- Reviewed on inspection and/or after violation
- As staff is available to look through data
- Rely on self-audit by registrant

Five states register all devices under one registration, regardless of locations of use. All of other states require a registration for each location separately.

Most states provide a registration document/license that lists the device specific information covered in the registration. There were five states reporting that their document does not include this information.

Registration cycles varied as follows:

- Annual - 20
- No expiration - 8
- 5 years - 4

25 states require annual inventory submission, with only 7 stating that this was not required.

Processing and Data Management

States reporting number of staff to process vendor requests were reported as:

- 1 staff - 27
- 2 staff - 2
- 3 staff - 1

Most states indicated that they didn't have a way to verify if vendors had submitted reports or not, and most cite staffing limitations as the reason they are unable to undertake a systematic cross check. One state indicates that they actively track vendor reports with a list of know mfg vendors.

States have various methods of recording vendor notices, from filing to cross checking in their database systems to ensure that the recipient is registered. Specific to tritium transfer/disposal notices, the states varied from tracking like all other notices, just filing the

notice, to not handling at all due to lack of staffing. The majority of the states indicated that they rely on the vendor reports for their GL program activities.

States indicated that additional information on vendor reports would be helpful, as follows:

- More complete contact information to include the name, phone and email for the person actually responsible for the use of the device.
- The name of the person who physically received the device.
- One state noted that they have launched an investigation regarding distributors who are not reporting any information on source exchanges, specifically on XRF devices.
- Specifics on disposal records.

Fees

Mosts states have an annual fees assessed to GL registrants, although a few have biannual or one time fees. The amounts of these fees vary widely from $50 per device to over $1000.

Some states charge per device some charge a one time annual fee not dependent on the number of devices. MM

Most states are satisfied with their fees and think they cover the cost of the work being performed. There were only 6 states that reported a satisfaction of fee amount less than a rank of 5.

Regulatory

Outside of changes to maintain compatibility, several states have enacted additional changes to their GL programs over time, as follows:

- If SS&D has “B”, SL is required.
- Lowered the activity level for requiring devices with certain isotopes to be specifically licensed. The state reports that this change has allowed for better control, accountability, and compliance.
- Added a few sources not listed in 31.5.
- All GL’s requiring registration by NRC are required by state to hold SL.
- Requires SL for devices not at a fixed location. One additional state is considering this due to problems with reporting related to XRF devices.
- Smaller sources are required to register as GL device for health and safety concerns. This was enacted as a result of trends and inability to reconcile records.
- Leak tests required for all sources, even those in storage.
- Implemented an inspection program.

States felt that the following changes to the GL program would be most effective:

- Seven states noted that there should be no GL’s - make devices exempt or require SL.

- Two states noted that no changes need to be made.
- Qualification criteria for those who will use/handle GL devices.
- Change compatibility to D to allow states to better control.
- Register all sources above exempt.
- Registration electronically to dedicated database.
- Inspection program in each state.
- More consistency.
- Require annual inventory reports.
- Vendors cannot sell equipment until regulatory agency is notified.
- Limit the amount of material available in any one location so aggregate quantities are controlled.
- Better tracking of distribution and disposal.

When asked their opinion on the value of evaluating GL registrants prior to receiving the device, the states primarily (11) disagreed with requiring a pre-evaluation and cited staffing resource concerns as the main reason that they didn't support this direction. The other responses were split as follows:

- 5 - All GL's
- 5 - only above a certain activity, and further cited Cs-137 above 10mCi, above exempt quantities, and no specific limit but when there is aggregate potential.
- 6 - only Cat 3, stating that any movable sources should also be included in this.

Most states indicated that compatibility across all aspects of the GL program is important.

Many states indicated that they would not be able to comment on changes without specifics, but several cited the following concerns about making changes to the GL program:

- Increased staffing needs and fees to registrants.
- Pushback from registrants on increased fees/regulation.
- Stretch already limited resources and take focus from Cat 1 and 2 oversight.

22 states noted that a nationwide database may be beneficial, with 10 indicating opposition. Specific notes regarding this:

- Depends on the functionality of the database.
- Concerns that the database would be a more time consuming process to populate.
- Noted that a central database could be helpful if implemented correctly (several cited "like NSTS")
- Have vendors input to a central database and NRC track if vendors are reporting or not.
- One state indicated that they prefer that the reports continue to come directly to the states.

Closing Remarks (AL)

There were a few overarching comments left at the end of the survey:

- Two stated that the GL program should be stopped - sources should be exempt or SL.
- Consistent quarterly report format would be helpful.
- GL device tracking is important, but need to be careful in considering resource needs.
- States and NRC just need to do what is appropriate - a new layer of bureaucracy is not always the best solution.
- Manufacturers have a role in making things better, to include training (online).
- May need to look at rule on timing of reporting to authorities.

OVERALL TRENDS/FINDINGS

What kind of inspections are OR and NC doing where they inspect every GL except Tritium exit signs and only have 3-1 inspectors?	There appears to be a sentiment that states want the GL program "gone", but I think more accurately they are looking for a threshold where a line can be drawn to either specifically license or exempt materials.
Staffing resources are a consistent concern and limitation for any increase activities within most state's GL programs.	Most states supportive of development of national level database, but some have concerns that this would be more burdensome. Of note, a statement was made that it would be helpful to have NRC validate vendors reporting at required frequencies. Most states noted it is difficult to validate if reporting was completed for each vendor as required..
States that follow the NRC registration quantities, do not follow-up, or make contact with non-registerable GL users. Non-registerable users are changing their inventories and most of the time the information with in the database is incorrect or non-existent. I believe we need to find a solution with non-registerable GL material	

<u>Non-registerable verse registrable GL material</u>

Most States that follow the NRC registration quantities, do not follow-up or make contact with non-registerable GL users on a regular basis. This leads to non-registerable users not communicating with regulators any changes in their inventory. For example WI states *"With non-registered GLs, every time we have been asked a question we answer it and request a*

*copy of their inventory to check our database. Every time for the past 2.5 years, the two inventories have not matched."*The underlying problem is lack of staff resources to manage the volume of non-registerable material.The solution is to determine the health and safety risks of non-registrable material, and translate that into how much effort should be spent on tracking and verifying information for these GL users. The agreement states would overall like to have some clarity as to what they should and should not be doing with their non-registerable GL inventories. For example one argument made was that tritium exit signs have little to no regulatory follow up after they are lost, so why where they being tracked in the first place?