

General License Program Re-Evaluation

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Purpose and Scope of Working Group Activities

” Purpose

- . Evaluate the existing general license program to ensure that it continues to protect public health and safety

” Scope

- . Activity 1: Program Basis and Historical Review
- . Activity 2: Effectiveness of NRC Registration Program and Alternate Programs Implemented by States
- . Activity 3: Stakeholder Feedback

Tasks Completed

- “ Agreement States survey
- “ Data mining
 - . GLTS, NMED, and enforcement information in databases and ADAMS
- “ Data and trend analysis
 - . Initial transfers, lost/stolen, and recovered devices
- “ Historical studies
- “ Interviews of M&Ds
- “ Development of recommendations

Results of Agreement States Survey

- “ Responses from 30 Agreement States
- “ Areas covered by the survey
 - . Workforce
 - . Registration Program
 - . Inspection
 - . Communication
 - . Incident Reporting
 - . Database Information Tracking
 - . Processing and Data Management
 - . Fees
 - . Regulatory Considerations

Results of Agreement States Survey

” Workforce

- . Less than 1 FTE per year, 2/3 of States have <0.5 FTE

” Registration Program

- . Slightly more than half of States follow NRC program
- . Large variations in database capabilities and fees

” Inspection

- . Seven States have routine inspection program for GLs
- . Non-compliance found 25-50%
- . Loss of control

Results of Agreement States Survey

” Communication

- . Area for improvement
- . Outreach efforts often hampered by low staffing

” Incident Reporting

- . Follow guidelines for specifically licensed devices
- . Several States expressed concern that there is under reporting of lost devices
- . 60% of States report incidents involving exit signs
- . Several States questioned the health and safety basis if devices and quantities are low risk

Results of Agreement States Survey

- “ Processing and Data Management
 - . Need for additional information from vendors
 - . Several States indicated that it's difficult to validate vendor reporting
- “ Regulatory Considerations
 - . Consistency across all aspects of GL program is important
 - . Support for national GL database
 - . Wide range of suggested changes to improve GL program
 - . Registered versus non-registered GL devices
 - “ Inventory reconciliation

Results of M&Ds Survey

- “ Increase Communication
- “ Routine Inspection Program
- “ National Database
- “ Responsible Individual

Results of Data Mining

- “ Tritium exit signs are large volume of devices
 - . Large report of lost H-3 devices (Walmart)
- “ Observed decrease in initial distributions of GL devices

Working Group Conclusion

“ The General License Program continues to provide reasonable assurance that public health and safety are adequately protected.

Enhancements Under Consideration

The GLWG has separated its enhancements into two tiers. It is the working group's opinion that if approved, the enhancements in Tier 1 would inform the enhancements in Tier 2.

Tier 1

Tier 1 enhancements would inform the NRC on whether general licensees are meeting the regulatory requirements in 10 CFR 31.5 and whether there is a potential to remove some regulatory burden from some general licensees. Additionally, these enhancements would improve communications between general licensees and the NRC.

Tier 2

The information collected or identified in Tier 1 would have a direct impact on the enhancements in Tier 2, particularly on those associated with establishing minimum program requirements. Additionally, determining the quality of information received by the NRC with regards to transfers of generally licensed devices would help determine if the development of a national database to track transfer reports would be beneficial.

Enhancements Under Consideration

Tier 1

- ” Reconciliation of existing records
- ” Systematic approach to further risk inform the General License Program
- ” Communications

Tier 2

- ” Minimum GL program requirements
- ” National database for GLs

Reconciliation of Existing Records

- “ The data for registered devices appears to be reconciled due to routine correspondence with licensees.
- “ The remaining GLs have less communication . more uncertainty on whether distributed devices are reported when lost or otherwise disposed of.
- “ Important to assess status of current tracking system as a baseline to guide need and/or extent of additional enhancements.

Establishing a Systematic Approach to Further Risk Inform the GL Program

- “ Re-evaluate generally licensed devices using 10 CFR Part 32 methodology to determine if these devices should continue to be regulated as generally licensed or can be regulated as exempt products.

- “ Require that reporting requirements for GLs be risk informed and regulation requirements be aligned with these determined risks in the same manner used for specifically licensed devices.

- “ Evaluate device regulation needs based on risk (not a recommendation to eliminate all GLs)
 - . Some to be specifically licensed
 - . Some to be exempt products
 - . Likely be left with a group that are neither (still need GL program to manage this range)

Communications

- “ Leverage the lessons learned and information collected from the reconciliation effort and develop an annual communication device (e.g. newsletter or publication).
- “ Align communication enhancements with the establishment of minimum program requirements to support the GL program.

Minimum Regulatory Program Requirements

- “ Establish criteria to be implemented by all regulatory partners within the National Materials Program.
- “ As part of the criteria, consideration should be given to the following:
 - . a risk informed inspection program component;
 - . issuance of a physical general license (i.e. paper license); and
 - . development of guidance for M&Ds of generally licensed devices to consider transitioning their products to exempt status, based on their appropriate risk.

National Database for General Licenses

“ Create a centralized national database, managed by the NRC, where M&Ds would report all transfers of generally licensed devices across all jurisdictions.

Additional Items For Further Consideration

- “ Eliminate 10 CFR 31.5(c)(9)(ii) which authorizes an intermediate person to store a generally licensed device prior to the initial use.

- “ Establish a regulatory requirement to allow a regulatory authority to pursue enforcement action for an M&D not located in their jurisdiction but that distributes devices in their jurisdiction.

Next Steps

- ✓ Consolidate stakeholder comments and input
- ✓ Consolidate and summarize data analysis and trending
- ✓ Determine which enhancements will improve the program
- ✓ Overall program evaluation

- Provide GLWG recommendations to NRC management for consideration

Working Group Members

- ” Tomas Herrera, NMSS/Co-Chair
- ” Angela Leek, Iowa/OAS Co-Chair
- ” Adelaide Giantelli, NMSS
- ” Edward Harvey, Region III
- ” Todd Jackson, Region I
- ” Morgan Munera, Washington
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Questions?