

CONVERSION OF GENERALLY LICENSED DEVICES TO EXEMPT DEVICES

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OVERVIEW

- Licenses and registration
- Decision for one company to pursue a conversion from GL to exempt status
- Results of that decision
- Outline of the process
- Conclusion

LICENSES AND REGISTRATION

- In order to sell a product containing radioactive material in the US, there are 2 licenses and 1 registration that are required:
 - 1 possession license to use and handle the radioactive material
 - 1 distribution license to distribute (sell, transfer) the products
 - 1 registration for most products

LICENSES AND REGISTRATION

- Possession licenses – if a manufacturer incorporates radioactive material (RAM) into its product, and the quantity of RAM exceeds the “exempt quantity” set by the NRC, then a possession license is required for this purpose. These licenses are obtained from the Agreement State or NRC, whichever has jurisdiction.

LICENSES AND REGISTRATION

- Distribution licenses – licenses for the distribution of generally licensed devices are obtained by the Agreement State or NRC, whichever has jurisdiction. Licenses for the distribution of exempt devices are only obtained from the NRC.

LICENSES AND REGISTRATION

- Registration – registration of generally licensed devices is obtained by the Agreement State or NRC, whichever has jurisdiction. Registration of exempt devices is only obtained from the NRC.

DECISION TO CONVERT GL DEVICES TO EXEMPT

- I was RSO for a manufacturer of a generally licensed explosives detector between 2000 and 2006.
- In 2001, this manufacturer was looking for a marketing advantage over its closest competitors.

DECISION TO CONVERT GL DEVICES TO EXEMPT

- Could the device be re-approved as an exempt device?
- This manufacturer used a single sealed source of 10 mCi (370 MBq) of Ni-63
- The NRC's exempt quantity of Ni-63 is 10 μ Ci (Reference 10 CFR 30.71 Schedule B Exempt Quantities)

DECISION TO CONVERT GL DEVICES TO EXEMPT

- Research of 10 CFR parts 30 through 32 wasn't clear as to whether such a device with greater than exempt quantity of Ni-63 could be approved as exempt
- Further investigation into NUREG 1556 Vol 3, (Draft version, pre-2003), suggested that detectors with less than 15 mCi could be granted exempt status

DECISION TO CONVERT GL DEVICES TO EXEMPT

- A meeting with the NRC was scheduled to discuss the proposed conversion from GL to “exempt”
- Once the NRC heard the proposal, it was deemed, “unprecedented” but “not impossible”.
- With “not impossible” in my pocket, I met with the leaders of the company

DECISION TO CONVERT GL DEVICES TO EXEMPT

- Some leaders were skeptical, while some were encouraged; finally all agreed to pursue “exemption” with the potential risk of lost man hours to research the regulatory requirements and compile the application of more than 80 hours

DECISION TO CONVERT GL DEVICES TO EXEMPT

- Skip ahead several months:
 - > To satisfy the NRC's many requests for information and mandates for changes to the device, a tremendous amount of planning, requesting engineering change orders, modifying labels, locating correct hardware, changing assembly procedures, modifying quality assurance documentation, etc. was required

RESULTS

- ◎ Several months after the submission:
 - > The NRC was convinced that the manufacturer was able to make the proper changes to its operating procedures, QA plan, and engineering documents, and issued a distribution license and registration for all of the manufacturer's products.
 - > The entire process took nearly 21 months.

RESULTS

- Good News: the process does not take nearly as long today.
- A few other companies have since followed suit, and their products have been “converted” from GL to exempt devices
- I learned from this experience how to efficiently bring GL devices to exempt status, and currently employ this knowledge as a consultant with IRSC

OUTLINE OF THE PROCESS

- ◉ How can a GL device be granted “exempt” status?
 - > Your device must meet certain criteria; (1 Ci of Co-60 will never be exempt)
 - > Your company must be able to process changes to products, procedures and documents efficiently
 - > Your company must effectively communicate to the NRC that your product will meet their safety requirements.

CONCLUSION

- Exempt status alleviates the requirements for end users of GL devices to leak test and register their devices.
- While this may not be burdensome to users of 1 or 2 devices, users such as the TSA or Navy who have literally thousands of such devices, will find it extremely beneficial

QUESTIONS

I'll take your questions now.