Common Misconceptions Concerning U.S. NRC Exempt Quantity and Concentration Regulations

2009 Meeting of the Health Physics Society
July 14, 2009

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Exempt?

- When is “exempt” not exempt?
- 10 CFR 30.70 Schedule A Exempt Concentrations
- 10 CFR 30.71 Schedule B Exempt Quantities

History

- The Atomic Energy Commission Regulations related to exempt concentrations first came into effect in 1965, and the exempt quantity regulations in 1970

What is an exempt concentration?

- The NRC Defines Exempt Concentration Use under 10 CFR 30.14 as follows:

"The use of nuclear material to provide a desired effect, such as the coloration of gemstones or altering electrical properties in silicon chips or wafers, or for testing purposes, such as tracer gas flow studies in a refinery, may result in residual byproduct material in the final product. When the product is released to the public by an NRC licensee, it must not contain residual byproduct material above exempt concentration limits found in 10 CFR 30.70, Schedule A."

What is an exempt quantity?

- The NRC defines exempt quantity use under 10 CFR 30.18 as follows:
- “Exempt quantity use includes the use of small quantities of byproduct material such as found in check sources and calibration standards for commercial distribution. It also includes the use and transfer of small quantities of byproduct material such as may occur when two labs exchange tissue samples or counting standards for inter-comparison on a noncommercial basis.”

Exempt Quantities

- Note that there is no reference to the exempt quantity regulations as pertaining to RAM in devices {but it is referenced for this purpose under 30.15(9)(i), which is for sources used in ionizing radiation instruments for the purpose of internal calibration}

Misconceptions

- **Misconception#1-** Products containing low activity levels of RAM may be distributed without a distribution license or device registration
- **Misconception#2-** End users of products containing low activity levels of RAM are automatically exempt from licensing
- **Misconception#3-** Exempt devices are limited to activity limits in schedule B (or even 10 CFR 30.15)

Misconception #1

- Often individuals or corporations interpret these regulations to mean that if the quantity or concentration of radioactive material within a product is below the values listed in 10 CFR 30.70, Schedule A or 30.71 Schedule B there is no requirement for the manufacturer and/or initial distributor of the product to have a distribution license and/or a device registration. This is not the correct interpretation.

Regulation Text Is Not Clear

- These misunderstandings stem from the text in 10 CFR 30.14, Exempt Concentrations, which are written is a sort-of legal speak. It says that *"(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31-36 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in 30.70."*

Transfer?

- Note that “transfer” is not equivalent to “initially transfer”, which means to distribute
- Also note that unlike 30.14, 30.15 does specify “initially transfer”, though the context is unclear

Incorrect Interpretation

- Potential manufacturers and distributors of devices containing radioactive sources read 10 CFR 30.14 and think they can distribute products without any type of license or device registration. The NRC will then point out to them that this is not the case as specified in, for example 10 CFR 30 18(d).

10 CFR 30 18(d)

- *"No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under 32.18…"*

In Addition

- No where in the NRC definition of exempt quantities does it say that it pertains to devices containing RAM
- Quantity limits for exempt products are derived from 30 .15 Certain items containing byproduct material and NUREG 1556, Vol. 8
- Certain types of products require a device registration regardless of quantity

Misconception #2: End Users

- Manufacturers and distributors upon reviewing the exemption levels in 10 CFR 30.71, Schedule B conclude that their customers will not need a license, which unfortunately is not necessarily true. The limits for exempt distribution are primarily given in 10 CFR 30.15, Certain Items Containing Byproduct Material, as well as NUREG 1556 volume 8. Only products containing RAM approved for distribution to users exempt from licensing may be distributed to end users without a license.

Another Source of Confusion

- It is no wonder that device distributors in Europe, Japan, and Canada are confused about the US regulations, because in their countries exempt means exempt!!!
- For example in Canada if you have a product containing less than 2.7mCi (100MBq) Ni-63

it is completely exempt from regulation. <u>No device certification, no distribution license, no end user license</u>

Misconception #3

- Devices containing RAM above the limits in schedule B can not be distributed as exempt

Answer

- Again, activity limits for devices are not derived from Schedule B, but from 10 CFR 30.15 (with one exception)
- In addition, the NRC has shown flexibility in the past in increasing these limits on a case by case basis.

Exempt products containing RAM which require device registration

- Exempt products which require device registration are:
- Watches or Timepieces
- Compasses
- Gun Sights
- Smoke Detectors
- Chemical Agent Detectors
- Ionizing Radiation Detectors with internal calibration sources

Exempt products containing RAM which do not require device registration

- Electron tubes
- Certain illumination sources

- *Note we are talking about device components and not gemstones, etc.*

Schedule A vs. B

- Though it is not obvious from the regulations, Schedule A seems to be aligned with products which do not require registration (and only a distribution license), while to some extent Schedule B is aligned with products which do require device registration and a distribution license

No Exceptions

- We have a client who has less than 1 microcure of RAM in their product. Do they still need a distribution license???
- The NRC answer to us was YES; that they do not issue waivers from distribution license or device registration requirements based upon the quantity of RAM in the product, NO EXCEPTIONS

References

- US NRC 10 CFR 30
- NUREG 1556, Vol. 8, September 1998
- Federal Register 30 FR 8585, Part 30- Rules of General Applicability to Licensing of Byproduct Material, June 26, 1965.
- Federal Register 35 FR 6427, Part 30- Rules of General Applicability to Licensing of Byproduct Material, April 22, 1970.