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February 4, 2012

US NRC RI
DNMS
475 Allendale Road
King of Prussia, PA 19406

RE: Addition of radiation sources to Decay in Storage base on Exemption 10 CFR 30.11(a), 10 CFR 20.2301, and 10 CFR 35.19

Dear Sir or Madam:

I hereby request an exemption to 10 CFR 35.92 (Decay-in-storage) that can be authorized by the NRC under 10 CFR 30.11(a), 10 CFR 20.2301, and 10 CFR 35.19 to increase the physical half-life to 275 days for decay-in-storage for NRC license #52-25430-03.

Exemptions
§ 30.11 Specific exemptions.

03636911

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

§ 20.2301 Applications for exemptions.

The Commission may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

§ 35.19 Specific exemptions

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Additional regulations:

576907
NMSS/RGN1 MATERIALS-002

§ 20.1905 Exemptions to labeling requirements.

A licensee is not required to label—

(a) Containers holding licensed material in quantities less than the quantities listed in appendix C to part 20.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(f) A licensee need not perform a leak test on the following sources:

(3) Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) or less of alpha-emitting material;

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

I therefore request that I may receive a license amendment as follows:

The licensee may hold byproduct material with a physical half-life of less than or equal to **275** days for decay-in-storage before disposal without regard to its radioactivity if it—

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

These are the specific isotopes that will fall under the 275 half-life (gamma emitters):

Gd-153
Co-57
Ge/Ga68
Ga68

Why the exemption is needed:

With the increase use of PET/CT and SPECT/CT equipment, the above-mentioned isotopes will be used through the US. The NRC regulations need to be flexible to adapt to changing usage and practices in the Nuclear Medicine field. Many facilities are not disposing sources due to the disposal cost. It is easier and cheaper for facilities to leave the old sources in storage and have it collect dust then to proceed with the cost for disposal. Once the sources decay below 100 uCi, these sources no longer need to be inventoried or tracked. Therefore leading to the possibility of the sources to be lost over time. Listed below are several reasons facilities do not return these sources:

1. Personnel are not trained in HAZMAT and therefore cannot prepare, ship, or transport radiation sources.
2. Low number of authorized HAZMAT transporters to the US.
3. Increasing cost for disposal (\$600/source) to dispose non-radioactive sources because they have already decayed to background levels.
4. Users remove non-radioactive sources from storage areas.
5. Users dispose of non-radioactive sources that are no longer being inventoried or track.
6. Based on the above regulations, once the sources have decayed to background levels and 100 uCi activity (gamma), the sources no longer have to be inventoried, labeled, and or leak tested. After a 3-year period, records no longer have to be kept. Therefore leaving the possibility open to disposal of these sources in the regular trash without any means to track these sources once the sources are dropped from the inventory list.

Why is it in the public interest?

1. When facilities close, the old sources are misplaced or not located, therefore ending up in the hands of the public because the personnel that knew when the sources were located are no long available to identify the location of the sources. A perfect example is a facility that closed down two years ago and when the NRC did an inspection, several sources were overlooked and therefore could have ended up in the hands of the public.
2. Old sources will have the proper paper trail of 10 CFR 35.92 to minimize the above scenario.
3. An individual, not knowing the regulation, may adversely dispose of the sources in the regular trash anyway. Therefore creating a lot of unnecessary paperwork for both the NRC and the facility.

4. Some small facility owners may dispose of the sources in the regular trash in hopes that all parties will forget the sources and records ever existed.

Why it is not a public threat:

1. Currently the NRC allows isotopes with a half-life of 120 days for decay-in-storage before disposal without regard to its radioactivity as long as it cannot be distinguished from the background radiation level. This has been the practice for over 30 years with the only problem of soiled absorbent pads that have been contaminated by patients while being hospitalized. Even then, the contamination posed little threat to the public.
2. Sealed sources have a higher level of security since these sources must be inventoried and accountable every six months. The sources that are listed above are used two to three years before replaced. The activity range are usually less than 100 uCi (3 half-lives) when they are removed from service, therefore not posing any greater health risk than the typical patient doses that are handled on a day-to-day basis. In fact the FDG-F18 dose poses a higher risk to radiation workers than the old sources.
3. The decayed sources have less activity than the excretion of a nuclear medicine patient or a I-125 seed expelled from a brachytherapy patient that can be measured by a survey meter.
4. This exemption will not endanger life or property or the common defense and security because the radiation measurements will not be distinguished from the background radiation level.

In summary, a facility is authorized to do the following (gamma emitters):

1. Obtain radiation sources as stated on their NRC license.
2. Once the source decays to below 100 uCi, sources no longer have to be inventoried (35.67(f)(3)). Maintenance of the records is only for 3 years after the source decays below 100 uCi.
3. Once the source decays below 10 uCi, a label is no longer required. (20.1905). Therefore all labels can be removed.
4. If the sources are no longer inventoried, labeled, monitored, and are indistinguishable from the background, where do all these sources finally end up? Most likely, some of these sources will end up in the regulatory trash. At least if it is authorized by the NRC, there will be a paper trail to the final disposition of these sources and these sources would not just disappear.

I hope that the NRC will consider and approve this request since the number of sources going into storage are only increasing every year.

Sincerely,



David Rhoe, MS, WSO-CHME, WSO-CSI
Health/Medical Physicist

This is to acknowledge the receipt of your letter/application dated

2/4/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (52-25430-03) There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576907.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.