PUBLIC SUBMISSION

As of: 12/7/17 12:30 PM
Received: December 02, 2017
Status: Pending_Post
Tracking No. 1k1-904h-hb1p
Comments Due: December 06, 2017
Submission Type: Web

Docket: NRC-2017-0159
Naturally-Occurring and Accelerator-Produced Radioactive Materials

Comment On: NRC-2017-0159-0006
Naturally-Occurring and Accelerator-Produced Radioactive Materials; Extension of Comment Period

Document: NRC-2017-0159-DRAFT-0020
Comment on FR Doc # 2017-24122

Submitter Information

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General Comment

See attached file(s)

Attachments

Pharmalogic response

PharmaLogic
Take The Lead

To: Secretary
U.S. Nuclear Regulatory Commission
Washington, DC
20555–0001
ATTN: Rulemakings and Adjudications Staff.

3 December 2017

RE: 10 CFR Part 30, [Docket No. PRM–30–66; NRC–2017–0159], Naturally-Occurring and Accelerator-Produced Radioactive Materials

This letter is in response to the NRC's request for comments (Federal Register, Vol. 82, No. 162, Wednesday, August 23, 2017, p 39971-39972) for the NRC to amend its existing regulations in appendix B to part 30 of title 10 of the Code of Federal Regulations (10 CFR), to specifically add the appropriate radionuclides and their corresponding activities to the list of ''Quantities of Licensed Material Requiring Labeling.'' The requirements in 10 CFR 30.35, ''Financial Assurance and Recordkeeping for Decommissioning,'' refer to the list in appendix B to 10 CFR part 30 to determine the need for a decommissioning funding plan and the amount of financial assurance required for sealed and unsealed sources. This letter represents input from PharmaLogic Holdings Corp. and its subsidiaries listed below:

Pharmalogic, Ltd.	Williston VT
PharmaLogic Penn Ltd.	Sayre, PA
PharmaLogic WV, Ltd.	Bridgeport and Huntington, WV
PharmaLogic MI, Inc.	Traverse City, MI
PharmaLogic Syracuse, LLC	Syracuse and Albany, NY
PharmaLogic WY, Inc.	Casper, WY
PharmaLogic MT, Inc.	Missoula, MT
PharmaLogic ME, Inc.	Augusta, ME
Clinical Pharmacy Services, Inc.	Gray, TN
Blue Ridge Isotopes, LLC	Salem, VA
Precision Nuclear LLC	Gray, TN
Precision Nuclear of Virginia, LLC	Salem, VA
Diagnostic Laboratories, LLC	Gray, TN
Mid-America Isotopes, Inc.	Ashland, MO
RadioPharmacy, Inc.	Evansville, IN and Dix, IL
Radiopharmacy of Paducah, Inc.	Paducah, KY

Pharmalogic Holdings Corp. is grateful to the petitioner to have raised the issue as this was recently experienced with our organization related to the Germanium-68 generator and the NRC's request for comments to address this issue is greatly appreciated.

Pharmalogic Holdings Corp. comments are addressed in the 4 bullet points as specified in the above mentioned Federal Register notification.

1. *What products or technologies, other than the germanium-68 generators cited in the petition, are being or could be negatively affected because the radioactive materials required for these products or technologies are not currently listed on the table in appendix B of 10 CFR part 30?*

Products or technologies that are not currently listed on the table in appendix B of 10 CFR part 30 that are being or could be negatively affected are listed below. These include emerging technologies / products / isotopes for imaging, therapy, and by-products formed in cyclotron target windows.

No.	Products or technologies	Decay Mode	Half Life	Suggested 10 CFR Part 30 Appendix B Quantity (µCi)	Anticipated Use of Nuclide
1.	Actinium-227	α	21.77 y	1	Radiocontaminant in Ac-225 or as a potential generator; parent for Th-227 ($t_{½}$ of 18.7 d) and Ra-223 ($t_{½}$ of 11.4 d).
2.	Aluminium-26	β^+	7.17e5 y	1	Activation byproduct from Aluminum target bodies and target windows
3.	Cobalt-57	ε	271 d	1	Activation byproduct from HAVAR cyclotron windows
2.	Lutetium-177m	IT	160 d	1	Contaminant from production of Lu-177 for therapeutic use
3.	Titanium-44	ε	60 y	1	Potential generator; parent for Sc-44 ($t_{½}$ of 3.9 h)
4.	Tholium-228	α	1.91 y	1	Potential generator; parent for Ra-224 ($t_{½}$ of 3.6 d) and Pb-212 ($t_{½}$ of 10.6 h) and Bi-212 ($t_{½}$ of 1 h)
5.	Rhenium-184m	IT	165 d	1	Activation byproduct from HAVAR cyclotron windows
6.	Silicone-32	β^-	153 y	1	Potential therapy agent
7.	Sodium-22	β^+	2.60 y	1	Positron source

2. *Please provide specific examples of how the current NRC regulatory framework for decommissioning financial assurance has put an undue hardship on potential license applicants. Explain how this hardship has discouraged the development of beneficial new products, or otherwise imposed unnecessarily burdensome requirements on licensees or members of the public (e.g., users of medical diagnostic or therapeutic technologies) that depend on naturally-occurring or accelerator-produced radioactive materials (NARM).*

   An example of how the current NRC regulatory framework for decommissioning financial assurance has put an undue hardship on potential license applicants is the Germanium-68 generator issue that has raised this petition. The financial hardship and time required to secure the money for decommissioning was projected to amount to $225,000 per licensee and had delayed the implementation (and use) of the Germanium-68 generators in 13 of the Company's markets.

   Another example is if Co-57 (accelerator-produced (side product) radioactive material in Havar target windows). With Co-57 not being mentioned in the list, the default value for the isotope on site is 0.1 microcuries and as small amounts are produced in the target windows, the amount of the bond required escalates.

   A third example that speaks to the potential stifling of medical diagnostic or therapeutic technologies if another Germanium-68 scenario was to play out for up and coming isotopes such as Lu-177m, Ti-44 (to name a few) where innovative smaller companies are kept out of the market with burgeoning high fees. This further impacts patient care in remote / smaller markets where single owners / smaller companies cater to the local patient need.

3. *Given NRC's current regulatory authority over the radiological safety and security of NARM, what factors should the NRC take into account in establishing possession limits for any of these materials that should be listed in appendix B of 10 CFR part 30?*

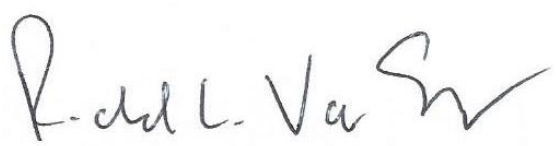
   For establishing possession limits it is important to consider what the isotopes is to be used for. Isotopes currently used only for sealed sources (e.g. Ge / Ga-68) could become relevant as generator produced isotopes in the future and the same for isotopes to be used in therapy. The limits for sites performing many therapy doses will be more than microcuries.

   1. One possible solution for the factors the NRC could take into account in establishing possession limits for any of these materials that should be listed in appendix B of 10 CFR part 30 would be a more frequently review (maybe 3-5 years) of appendix B of 10 CFR part 30 to ensure industry input and hence keeping the list up to date with relevant / emerging isotopes.

4. *Does this petition raise other issues not addressed by the questions above about labelling or decommissioning financial assurance for radioactive materials? Must these issues be addressed by a rulemaking, or are there other regulatory solutions that NRC should consider?*

One possibility is for 10 CFR 30.35 ‘‘Financial Assurance and Recordkeeping for Decommissioning,’’ refer to updated quantities in the list published in NRC Regulations, Title 10, Code of Federal Regulations, Part 20 – Standards for protection against radiation, Appendix C to Part 20 - Quantities of Licensed Material Requiring Labeling (https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-appc.html).

Sincerely,



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