November 6, 2017

Secretary, U.S. Nuclear Regulatory Commission
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301-415-1677

ATTN: Rulemakings and Adjudication Staff

Re: Docket No. NRC–2017–0159

Dear Ms. Vietti-Cook

I agree with the Organization of Agreement States (OAS) petition for rulemaking. The basis for updating 10 CFR 30 Appendix B was discussed in the Addendum to the Advisory Committee on the Medical Use of Isotopes (ACMUI) Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report of August 12, 2015 (ACMUI Ge-68 report, https://www.nrc.gov/docs/ML1523/ML15231A047.pdf).

The following excerpts from the ACMUI report describe the origin of the Part 30 App B Table and impact it has on the example of the Ge-68/Ga-68 generator.

"*1. What purpose do the labeling values for Appendix B of Part 30 serve?*

The labeling values for those licensed materials with half-lives greater than 120 days are used to determine whether the possession limits approved for a license require the licensee to maintain financial assurance for decommissioning, and if so, what amount of financial assurance is required (§ 30.35). The labeling values for those licensed materials with half-lives less than or equal to 120 days serve no purpose."

"2. Where did values for Appendix B of Part 30 come from?

Prior to 1994, Appendix B of Part 30 did not exist. Instead, the requirements in § 30.35 referenced the old Appendix C of Part 20 which first appeared in the regulations in 1970. The regulatory history for Appendix B of Part 30 listed at the bottom of that table is the regulatory history of the old Appendix C of Part 20 prior to 1994.

The current decommissioning funding plan (DFP) regulations in § 30.35 are based on values that were established 45 years ago."

"3. How were values for the old Appendix C of Part 20 derived?

Description of how the values for the old Appendix C of Part 20 were chosen is specified in the proposed changes to Part 20 and Part 303 published in 1968 (33 FR 11414, August 10, 1968):

> 'Two basic criteria were used in deriving the quantities. Since inhalation is considered the most likely route of entry into the body, the quantity that would be inhaled by a standard man exposed for 1 year at the highest average concentration permitted in air (by 10 CFR Part 20) for members of the general public was computed. If the radioisotope emits gamma radiation, the quantity that, from a point source, would produce a radiation level of 1 milliroentgen per hour at a distance of 10 centimeters was also computed. The smaller of these two quantities was then logarithmically rounded to the nearest decade, in microcuries, and entered in § 30.71, Schedule B.' "

"4. Why was Ge-68 not included in the old Appendix C of Part 20?

The air concentrations of licensed materials permitted in air were based on the International Commission on Radiological Protection Committee II (ICRP 2) recommended values for maximum permissible concentrations [4]. ICRP 2 was published in 1959; Ge-68 was not included in the list of radionuclides. The current Appendix B of Part 30 does not include a specific value for Ge-68 because data published 56 years ago did not include that radionuclide."

"8. If Ge-68 had been specifically listed in Appendix B of Part 30, what would the labeling value be?

One option to choosing the labeling value for Ge-68 is to use the specific labeling value listed in the updated Appendix C of Part 20. This value for unsealed Ge-68 is 10 µCi. Another option is to calculate the value using the criteria specified in 1968 (see Question 3) and the highest average concentration of Ge-68 permitted in air (by Appendix B Part 20, Table 2, Column 1) for members of the general public, which is 5×10^{-9} µCi/ml. The first criteria calculation is:

$V_1 = 5 \times 10^{-9}$ µCi/ml x 20,000 ml/min x 60 min/hr x 24 hr/day x 365 day = 53 µCi

Considering that the Ge-68 in a Ge/Ga-68 generator is not your typical unsealed source, but is practically a solid within a sealed source, a calculated value based on air concentrations is very conservative.

[4] "'Report of Committee II on Permissible Dose for Internal Radiation (1959),' Health Physics Journal, Vol 3, Issue 1, April 1959."

The second criteria calculation involves use of a gamma exposure calculation. Germanium-68 does not decay by emission of gammas, but its daughter, Ga-68, decays with photon emissions.

The exposure rate constant [5] for Ga-68 is 5.43 R-cm^2/mCi-hr. The second criteria calculation is:

$$V_2 = (0.001 \text{ R/h} \times 100 \text{ cm}^2 \times 1000 \text{ µCi/mCi}) / 5.43 \text{ R-cm}^2\text{/mCi-hr} = 18 \text{ µCi}$$

So, logarithmically rounding to the nearest decade for the smaller of these two values, V_2, would mean the labeling value for Ge-68 should be 10 µCi.

This is the same value that was listed for labeling unsealed Ge-68 in the new Appendix C of Part 20 in 1994. Hence, 10 µCi would seem to be the appropriate labeling value for Ge-68."

"9. If 10 µCi is proposed for the specific labeling value for Ge-68 used in a Ge/Ga-68 generator meant for medical use, then that means the labeling value used would increase by a factor of 100 and the DFP trigger level would increase from 10 mCi to 1 Ci. Is that safe?

Yes. Remember, the labeling values in Appendix B of Part 30 are only used to determine the level of financial assurance needed for decommissioning. These values are not used for any other regulatory requirement, and definitely are not used as any kind of radiological criteria for allowing a formerly licensed site to be released for unrestricted use under § 20.1402.

Also, the substantial safety inherent to a Ge/Ga-68 generator (see Question 7) makes its use will far less likely to result in residual contamination than the unsealed uses allowed for other radionuclides [6] listed in Appendix B of Part 30 which also have a labeling quantity of 10 µCi. The cost for decommissioning a Ge/Ga-68 generator would not warrant the need to greatly increase the financial assurance needed by the medical licensee."

Based on points raised in the ACMUI report as applied to the whole of Appendix B of Part 30, please consider my comments to the four specific questions contained in the petition for rulemaking (82 FR 39971, August 23, 2017).

[5] "Smith, D.S and Stabin, M.G., 'Exposure Rate Constants and Lead Shielding Values for Over 1,100 Radionuclides,' Health Physics Journal, Vol 102, No 3, March 2012."

[6] "Examples of other radionuclides (half-life) with 10 microcurie labeling value in Appendix B of Part 30: Sb-125 (2.8 years), Ba-133 (10.6 years), Ca-45 (163 days), Cs-137 (30 years), Cl-36 (300,000 years), Mn-54 (312 days), Ni-63 (101 years), and Zn-65 (244 days)."

Question 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 on the table in appendix B of 10 CFR part 30?

When proposing the changes to the current 10 CFR 20 Appendix C (51 FR 1120, January 9, 1986), the NRC stated the following.

> "The quantities listed in Appendix C were derived by taking one-tenth of the ,most restrictive occupational annual limit of intake listed in Appendix B, rounding to the nearest factor of ten, and arbitrarily constraining the values listed between 0.001 and 1,000 pCi. These quantities are comparable, but not identical to the existing Appendix C listings and the byproduct material listings in § 30.71, Schedule B, 10 CFR Part 30. Conformity between Appendix C, 10 CFR Part 20, and § 30.71, 10 CFR Part 30, is not considered essential. Further, such conformance would involve addition of a large number of radionuclides to § 30.71, and would constitute a substantive change in the radionuclides available to persons exempt pursuant to § 30.18,10 CFR Part 30. No change in § 30.71 is proposed at this time."

Perhaps it is now time to change some of the values associated with § 30.71. If the values used for § 30.71 were updated to again reference the current Part 20 Appendix C values for licensed materials with half-life greater than or equal to 120 days, the attached tables show the impact on the radionuclides specifically listed in the current Part 20 Appendix C table. Because the establishment of the original § 30.71 values listed in the old Part 20 Appendix C table was arbitrarily chosen, I suggest that the rulemaking be made to update the § 30.71 values to all the increased values (highlighted in green) so that any products or technologies which involve these radionuclides are no longer negatively impacted by use of old values or generic values.

Question 2. Please provide specific examples of how the current NRC regulatory framework for decommissioning financial assurance has put an undue hardship on potential license applications. 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).

The NRC has recognized a hardship with its Ge-68/Ga-68 generator DFP exemption for medical use (https://scp.nrc.gov/asletters/program/sp16083_1.pdf). I ask why specific examples beyond this one must be provided. I would think that the NRC's policy on establishing performance-based regulations should be all that is needed to ensure that licensing for radionuclides with similar values listed in Part 20 Appendix C are considered consistently when determining decommissioning financial assurance.

Question 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?

I suggest that the NRC consider radionuclide generators as their own separate category when considering decommissioning. The design of a generator, especially those approved by FDA regulations, are closely evaluated and tested to ensure the long-lived parent radionuclide remains in the generator. Decommissioning is thus easily done by shipping the generator for disposal, with little need for significant financial assurance.

Question 4. Does this petition raise other issues not addressed by the questions above about labeling 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?

The attached tables also identified some radionuclides which currently have § 30.71 values which are higher when compared to their Part 20 Appendix C values (highlighted in yellow). Due to the arbitrary nature of choosing § 30.71 values and to approximately 30 years of use for determining DFP and financial assurance requirements, I would suggest those values be kept as they are now.

I would think that the NRC would choose to do rulemaking rather than issuing exemptions to change the § 30.71 values. I do not know enough about other alternative regulatory solutions that the NRC could consider to provide a suggestion to that question.

Thank you for your consideration of my comments.

Susan M. Langhorst, Ph.D., CHP

Information on Part 30 App B Licensed Materials with Half-Lives Greater than 120 Days

Licensed Material	Part 30 App B Quantity (µCi)	Half-Live*	Part 20 App C Quantity (µCi)	Decay Mode*
Sb-125	10	2.76 y	100	β-
Ba-133	10	10.6 y	100	EC
Ca-45	10	162.6 d	100	β-
C-14	100	5700 y	100	β-
Ce-144	1	284.9 d	1	β-
Cs-134	1	2.07 y	10	EC,β-
Cs-135	10	2.3e6 y	100	β-
Cs-137	10	30.1 y	10	β-
Cl-36	10	3.01e5 y	10	EC+,β+,β-
Co-60	1	5.29 y	1	β-
Eu-152	1	13.5 y	1	EC+,β+,β-
Eu-154	1	8.6 y	1	EC,β-
Eu-155	10	4.75 y	10	β-
Gd-153	10	240 d	10	EC
H-3	1000	12.3 y	1000	β-
In-115	10	4.41e14 y	100	β-
I-129	0.1	1.57e7 y	1	β-
Fe-55	10	2.74 y	100	EC
Kr-85	100	10.7 y	1000	β-
Mn-54	10	312 d	100	EC,β-
Ni-59	100	7.6e4 y	100	EC+,β+
Ni-63	10	101 y	100	β-
Nb-93m	10	16.1 y	10	IT
Pt-193	100	50 y	1000	EC
Pu-239	0.01	24100 y	0.001	α
Po-210	0.1	138 d	0.1	α

Licensed Material	Part 30 App B Quantity (µCi)	Half-Live*	Part 20 App C Quantity (µCi)	Decay Mode*
Pm-147	10	2.62 y	10	β-
Ra-226	0.01	1600 y	0.1	α
Rb-87	10	4.81e10 y	100	β-
Ru-106	1	372 d	1	β-
Sm-151	10	90 y	10	β-
Sr-90	0.1	28.8 y	0.1	β-
Tc-97	100	4.21e6 y	1000	EC
Tc-99	100	2.11e5 y	100	β-
Tl-204	10	3.78 y	100	EC,β-
Th (nat)	100	1.41e10 y	100	α
Tm-170	10	129 d	10	EC,β-
Tm-171	10	1.92 y	10	β-
U (nat)	100	4.47e9 y	100	α
U-233	0.01	159 y	0.001	α
U-234	0.01	2.46e5 y	0.001	α
U-235	0.01	7.04e8 y	0.001	α
Zn-65	10	244 d	10	EC+,β+
Zr-93	10	1.61e6 y	1	β-

If § 30.71 were to reference part 20 App C again

value increases

value decreases

*** http://www.nndc.bnl.gov/mird/**

Information on Part 20 App C Licensed Materials with Half-Lives Greater than 120 Days

Part 30 App B generic value = 0.1 µCi

Non-Alpha Emitting Licensed Material	Half-Live*	Part 20 App C Quantity (µCi)
Cd-113m	14.1y	0.1
Hf-182	8.90e6y	0.1
Ra-228	5.75y	0.1
Be-10	1.51e6y	1
Si-32	153y	1
Ti-44	59.1y	1
Fe-60	2.62e6y	1
Nb-94	2.03e4y	1
Ag-108m	438y	1
Pm-146	5.53y	1
Eu-150	36.9y	1
Tb-158	180y	1
Ho-166m	1.2e3y	1
Hf-172	1.87y	1
Os-194	6y	1
Hg-194	444d	1
Np-236	153e3y	1
Na-22	2.6018y	10
Al-26	7.17e5y	10
Ge-68	270.95d	10
Mo-93	4.0e3y	10
Tc-98	4.2e6y	10
Rh-101	3.3y	10
Rh-102m	3.7y	10
Rh-102	203.7y	10
Pd-107	6.5ey	10
Sn-123	129.2d	10
Sn-126	2.30e5y	10
Te-121m	164.2d	10
La-137	6e4y	10
Pm-144	363d	10
Tb-157	71y	10

Part 30 App B generic value = 0.01 µCi

Alpha Emitting Licensed Material	Half-Live*	Part 20 App C Quantity (µCi)
Gd-148	74.6y	0.001
Ac-227	21.772y	0.001
Th-228	1.9125y	0.001
Th-229	7340y	0.001
Th-230	7.538e4y	0.001
Pa-231	3.276e4y	0.001
U-232	68.9y	0.001
U-234	2.455e5y	0.001
U-235	703.8e6y	0.001
U-236	2.342e7y	0.001
Np-236	153e3y	0.001
Np-237	2.144e6y	0.001
Pu-236	2.853y	0.001
Pu-238	87.7y	0.001
Pu-239	24110y	0.001
Pu-240	6561y	0.001
Pu-242	3.73e5y	0.001
Pu-244	8.11e7y	0.001
Am-242m	141y	0.001
Am-243	7364y	0.001
Cm-243	28.9y	0.001
Cm-244	18.11y	0.001
Cm-245	8423y	0.001
Cm-246	4760y	0.001
Cm-247	1.56e7y	0.001
Cm-248	3.48e5y	0.001
Bk-247	1380y	0.001
Cf-249	351y	0.001
Cf-250	13.08y	0.001
Cf-251	898y	0.001
Cf-252	2.645y	0.001
Pb-210	22.2y	0.01
Pu-241	14.290y	0.01

Information on Part 20 App C Licensed Materials with Half-Lives Greater than 120 Days

Part 30 App B generic value = 0.1 µCi

Non-Alpha Emitting Licensed Material	Half-Live*	Part 20 App C Quantity (µCi)
Lu-173	1.37y	10
Lu-174m	142d	10
Lu-174	3.31y	10
Lu-177m	160.44d	10
Re-184m	169d	10
Re-186m	2.0e5y	10
Ir-194m	171d	10
Au-195	186.01d	10
Bi-207	31.55y	10
K-40	1.248e9y	100
Ca-41	9.94e4y	100
Co-57	271.74d	100
Se-79	3.26e5y	100
Cd-113	8.04e15y	100
Sn-119m	293d	100
Sn-121m	43.9y	100
La-138	1.02e11y	100
Ce-139	137.641d	100
Pm-143	265d	100
Sm-145	340d	100
Dy-159	144.4d	100
Lu-176	3.76e10y	100
Ta-179	1.82y	100
Pb-205	1.73e7y	100
Ar-39	269y	1,000
V-49	330d	1,000
Mg-53	3.7e6y	1,000
Kr-85	2.29E+05	1,000
Re-187	4.33e10y	1,000

Part 30 App B generic value = 0.01 µCi

Alpha Emitting Licensed Material	Half-Live*	Part 20 App C Quantity (µCi)
Cm-242	162.86d	0.01
Cf-248	333.5d	0.01
Es-254	275.7d	0.01
Bi-210m	3.04E+06	0.1
Bk-249	330d	0.1
Sm-146	10.3e6y	1
Pm-145	17.7y	10
Gd-151	124d	10
Pb-202	52.5e3y	10
Sm-147	1.07e11y	100
Th-232	14.0e9y	100
U-238	4.468e9y	100
Np-235	396.2d	100

If § 30.71 were to reference Part 20 App C again

value increases

value decreases

*** http://www.nndc.bnl.gov/mird/**

From:	Susan M. Langhorst, LLC
To:	RulemakingComments Resource
Subject:	[External_Sender] Comments for Docket No. PRM-30-66
Date:	Tuesday, November 07, 2017 12:02:55 PM
Attachments:	Comments on OAS petition for rulemaking.pdf

Thank you for considering my comments.

Susan M. Langhorst, Ph.D., CHP