Good morning, Katie,

Quick addendum to my comments below and wish I had picked up on this earlier. I recently had occasion to notice what appear to be numerical inconsistencies involving simple unit conversion in Tables 3 and 4 on breastfeeding activity (for example, see below). Unless I'm missing something, I hope/suspect this has already been noticed/corrected, but a more thorough quantitative audit of these tables may be in order, if not. Cheers, -Anthony

Table 3. Breastfeeding Activity Thresholds Assuming No Breastfeeding Interruption

RADIO-NUCLIDE	PHARMA-CEUTICAL	COLUMN 1 5 mSv (0.5 rem) Breastfeeding Activity Requiring a Record $Q_{B\|rec}$		COLUMN 2 1 mSv (0.1 rem) Breastfeeding Activity Threshold for Instructions $Q_{B\|ins}$	
		(GBq)	(mCi)	(GBq)	(mCi)
C-11	choline	2	60	0.5	10
Cr-51	EDTA	30	800	6	200
F-18	FDG	1	30	0.2	6
Ga-67	citrate	0.08	2	0.02	0.4
Ga-68	octreotate	9	200	2	50
I-123	MIBG	1	40	0.3	8
	OIH	2	40	0.3	8
	NaI[a,]	0.002	0.05	0.0004	0.01
I-124	NaI[a,b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
I-125	OIH	0.1	3	0.02	0.6
	NaI[a,b]	<1 μCi	0.002	<1 μCi	<1 μCi
I-131	OIH	0.08	2	0.02	0.4
	NaI[a,b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
In-111	octreotate	0.9	30	0.2	5
	WBC	0.08	2	0.02	0.4
Lu-177	octreotate	0.4	10	0.08	2
N-13	Any	10	400	3	70
O-15	water	10	300	2	60
Ra-223	Dichloride[b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
Rb-82	chloride	10	300	2	60
Tc-99m	DISIDA	0.2	6	0.05	1
	DTPA	50	1000	10	300
	DTPA aerosol	100	4000	30	700
	glucoheptonate	20	600	5	100
	HAM	0.2	7	0.05	1
	MAA	2	60	0.4	10
	MAG3	40	1000	8	200
	MDP	40	1000	9	200
	MIBI	30	800	6	200
	pertechnetate	0.5	10	0.1	3
	PYP	0.7	20	0.1	4
	RBC in vitro	50	1000	10	300
	RBC in vivo	40	1000	8	200
	sulfur colloid	0.5	10	0.1	3
	WBC	0.8	20	0.2	4
Tl-201	chloride	2	50	0.4	10
Zr-89	panitumumab	0.01	0.3	0.002	0.07

a. $Q_{B|rec}$ and $Q_{B|ins}$ are based on thyroid dose equivalent to nursing child or infant after patient release.

b. The calculated activity is less than 1 μCi. For these radionuclides, breastfeeding record retention is required, and instructions must be given.

From: Fotenos, Anthony
Sent: Wednesday, July 5, 2023 2:05 PM
To: Miller, Donald <Donald.Miller@fda.hhs.gov>; Katherine Tapp <Katherine.Tapp@nrc.gov>
Cc: O'Hara, Michael D <Michael.OHara@fda.hhs.gov>; Cindy Flannery <Cindy.Flannery@nrc.gov>
Subject: RE: [External_Sender] RE: RE: [EXTERNAL] Comments on Draft Regulatory Guide 8.39

Good afternoon, Katie,

I appreciated the opportunity to read the proposed revision to regulatory guidance 8.39, "Release of Patients Administered Radioactive Materials" (DG-8061 (RG 8.39 Rev. 2). From my perspective, the document is well written and clear, so I have no major edits to suggest and only the following highish level comment.

- Consider adding one or two examples under Appendix C that require use of Table 2, "Basic Measurement Thresholds for Radionuclides." In addition, my understanding is that the guidance generally intends for licensees to rely on Table 1 (activity thresholds) or Table 2 (count thresholds), but not both. Arguably, this intention could be read as a bit at odds with the following sentence excerpted from under Section 4.1 ("Activities and Dose Rates that Require Instructions", italics added for emphasis): "Licensees should use column 2 of table 1 to determine the administered activity or column 2 of table 2 for the corresponding dose rates at 1 m because *above these thresholds* instructions must be given in accordance with 10 CFR 35.75(b)." Perhaps ideally, an overview flowchart (along lines of those provided for licensees after they've decided to proceed down alternative Table 1 or Table 2 routes) would be provided earlier on to clarify intended relationship of options detailed under Table 1, Table 2, and Appendix B.

Please don't hesitate if you have additional questions about anything above, and I hope you enjoyed the July 4th holiday, cheers, -Anthony