From:	STEVEN H BROWN
To:	Evans, Robert; Burrows, Ronald
Cc:	Von Till, Bill
Subject:	[External_Sender] Following our Discussion Earlier This Week - De minimus levels of source and Byproduct Materials
Date:	Friday, June 14, 2019 1:30:57 PM

Gentlemen – again, thanks very much to Bill and for reaching out to me and setting up the conference call the other day. We had agreed that the Atomic Energy Act does not directly define levels of 11 e (2) byproduct material that are “de minimus” or “below regulatory concern” since the definition of 11 e (2) byproduct material is based solely on origin. But I think we made some progress in trying to flush out precedence or examples where limits “ below regulatory concern” might be appropriate to apply to source and/or 11(e) 2 byproduct material. As I had mentioned, Bernadette’s presentation at the NMA U Recovery Workshop in Denver last week triggered some concerns by several attendees on the suggestion that worker urine samples and/or samples of environmental media, collected under a licensee’s routine operational environmental monitoring program, could be “licensed material”.

A few considerations, some of which we did discuss:

Source material: Suggested that 10 CFR 40.13 clearly defines concentrations and quantities of source material that are “below regulatory concern” as “unimportant quantities of source material”, e.g., 0.05 % by weight. Bernadette suggested that if a urine sample was “spiked” with U, this might constitute making it licensable. Would suggest that adding a few 10s of ug U to a urine sample would not result in a concentration > 500 ppm and the prepared standard U solution that was used did not represent source material removed from its “place of origin”.

Regards to environmental samples, even if potentially impacted by licensed activities (e.g., a few pCi / gram statistically verifiable above the baseline), this would not constitute > 0.05% nor would an air filter sample that indicated airborne concentrations statistically verifiable above the baseline concentrations at that location. Never thought of the average annual effluent concentrations permitted to be released to unrestricted areas (10 CFR 20, App B, Table 2, Column 1) as a demarcation of “licensed material?

Byproduct Material:

We discussed that 10 CFR 20, Appendix C does contain, for a lengthy list of radionuclides, limits (uCi) below which do not require labeling. In version of 10 CFR 20 of years ago that I grew up with, this table was used similarly for quantities that were exempt from requirements for specific licenses. That is, these are quantities that are “below regulatory concern”. Listed in this table are radionuclides that are in the uranium or actinium decay series and are the nuclides that constitute 11(e) 2 byproduct material. So it is suggested that there are in fact, for the nuclides that make up 11(e) 2 byproduct material, limits that NRC has defined as “below regulatory concern”.

But I think there are two better examples that we did not discuss on our call:

(1) If there was not a “de minimus” or “below regulatory concern” level for 11 e (2) byproduct material, we could never terminate UR licenses or release land in licensed

space for unrestricted use. Case in point: 10 CFR 40, Appendix A, Criterion 6(6). Not just referring to the 5 / 15 pCi per gram in soil radium criteria here (but which certainly is a nuclide specific example of an 11 e (2) byproduct material de minimus limit), but more broadly the requirement to perform a Radium Benchmark Dose (RBD) analysis. That is, once one has calculated the RBD for a given site using the 5 / 15 radium in soil criteria, the licensee or applicant is required to use the RBD to determine the equivalent concentration of any other nuclide present (determining the equivalent uranium concentration that would result in the RBD is standard but I have also had to do it for thorium). But theoretically, one could determine the RBD equivalent concentration for any radionuclide in the uranium or actinium decay chains which are all potential components of 11 e (2) byproduct material which would be by definition levels of byproduct material radionuclides below regulatory concern! (Recognizing that I am ignoring the "sum of fractions" rule requirement for mixtures to simply make my point).

(2) Using a similar thought process, if there was not a de minimus or below regulatory concern level for 11 e (2) byproduct material, we could never release equipment or materials from licensed space at UR facilities for unrestricted use in the public domain. Case in point, the historical table of contamination limits for unrestricted use (RG 1.86 from 1974; RG 8.30 from 2002, FC 83-23 latest from 1993? etc.) The categories of radionuclides and the associated contamination limits per 100 cm2 have never changed over all the years, regardless of where this table appears (including DOE 10 CFR 835 and/or applicable DOE orders). Recognizing there has been some disagreements over the years how to define "uranium and its decay products" for purposes of assigning the classification (i.e., which "row(s)" of the table are applicable), the fact is that virtually every nuclide that would constitute 11 e (2) byproduct material can be assigned an unrestricted use contamination limit from this table that would be below regulatory concern.

And more broadly:

1. Regards to urine (or any other human excreta), in my almost 50 years of experience as a licensee under 10 CFR Parts 40, 30-35, 50 and 70, I am unaware of any case in which worker bioassay samples were controlled / handled as "licensed material". I consulted with some colleagues last week who are RSOs at very large university hospital campuses and they confirmed that no restrictions are placed on the excreta from patients who have been administered licensed "byproduct material" for diagnosis or treatment. If the excreta from the human is licensed material, doesn't that make the human from whom it came a licensed material? What are the implications of this?
2. Regards to environmental samples, the licensee does not know the radiological content of samples until the lab analyzes it so how can the licensee make the lab "aware" or need to verify the lab "can accept" the licensed material if it is unknown what radiologically is in the sample until the lab has it in their possession?
3. Bernadette raised the concern that these types of samples (urine or environmental media) would need to be transported to labs per DOT

requirements. Difficult to imagine these types of samples would ever contain radioactivity above the DOT exemption limit – not Class VII RAM if < 0.002 uCi / gram (49 CFR 173.403)

Additionally, it is appropriate and necessary to consider the relative radiological risks associated with the handling of these potential, but certainly incredibly small, levels of 11 e (2) in these types of samples. Given the performance based, risk informed philosophy that NRC has appropriately incorporated into licensing and compliance matters in the UR program (e.g., NUREG/CR 6733), it would appear that having to manage these types of samples as licensed material would entail considerable level of effort and costs, with no discernible increase in the levels of worker or public safety.

Rob had mentioned the example of NRC's 1993 (?) ruling on mill tailings as the initiator of some of these concerns. Tailings that had been dispersed off the pile to unrestricted areas could pose a public safety risk if not controlled. Makes perfect sense. But this is a fairly well defined example in that the material is a discrete licensed entity in a specific licensed place and it was "relocated" (windblown?) to unrestricted areas. The material is easily distinguishable radiologically from the otherwise naturally occurring radioactive material in the environment that was there before humans were.

I think the circumstances that we are concerned with here are quite different, and would suggest that the examples referenced above do provide precedent that the implementing regulations of the AEA do in fact define levels of the 11 e (2) radionuclides that are below regulatory concern. I would hope that these examples be considered as relevant to some of the issues and questions Bernadette raised in her intriguing presentation, should NRC consider or move forward with potential new rule making.

Thanks again for the opportunity to contribute my two cents to these important matters. – all the best – Steve

PS: (1) Since you both indicated you are not members of the Health Physics Society and therefore do not receive the monthly Health Physics Journal, have taken liberty of attaching an article from the current July 2019 edition. Think you will find the paper of interest. Note that its Figure 2, "Basic approach to ISR uranium mining", was taken from and credited to the NRC U Recovery web site and was selected to appear on the cover of this months Journal. Enjoy

(2) Editorial comment – Particularly as CHPS, you guys should be members of the HPS - it does provide a lot of professional value

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