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Rules, Announcements and Directives Branch (RADB),
Office of Administration,
Mail Stop: TWB-05-B01M,
U. S. Nuclear Regulatory Commission,
Washington, DC 20555-0001

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Subject: CORAR Comments on Draft NRC Regulatory Guide DG-8050, Applications of Bioassay for I-125 and I-131. Docket ID NRC-2011-0224

Reference: Federal Register Vol.76, No 186, September 26, 2011, Pages 59448-59449. Notice of issuance and availability of Draft Regulatory Guide DG-8050, "Applications of Bioassay for Radioiodine."

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹. CORAR manufacturers' and distributors' and our customers' operations involve occupational exposure to I-125, I-131, I-123 and I-129 mentioned in the draft guide, and I-126.

We appreciate the NRC providing guidance on bioassay for radioiodine. Since the last revision of Regulatory Guide 8.20 the NRC has expanded jurisdiction to include certain accelerator produced radionuclides. We see this update of RG 8.20 as a good opportunity to include the commonly used accelerator produced radioiodines. The title of the Draft RG still refers only to I-125 and I-131. However, if the NRC decides to expand the scope of this guidance to include I-123 and other commonly used radioiodines the title should be changed to "Applications of Bioassay for Radioiodine" as indicated in the public notice referenced above. This would be highly beneficial to licensees who possess both reactor and accelerator produced radionuclides. We appreciate having one uniform set of regulations and guidance for these licensed materials.

1. CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

SONSI Review Complete
Template = ADM-013

E-RIDS = ADM-03
Call = R.A. Jervay (195)¹
N. Cree (m5c)

CORAR appreciates the opportunity to submit comments and would be glad to provide clarification or additional information.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'L. R. Smith', written in a cursive style.

Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety.

Enclosure: CORAR Comments on Draft NRC Regulatory Guide DG-8050, Applications of Bioassay for I-125 and I-131.

**CORAR COMMENTS ON DRAFT NRC REGULATORY GUIDE DG-8050,
APPLICATIONS OF BIOASSAY FOR I-125 and I-131**

- 1. Page 2, Background, "The guide does not specifically address using other isotopes of radioiodine such as iodine-123...and iodine-129...¹²³I...would require specific considerations that are not detailed in this guide."**

I-123 is one of the most commonly used radionuclides in nuclear medicine. Since NRC now has jurisdiction over accelerator produced radioiodines, it would be very useful to licensees if I-123 and I-129 were also addressed in this guidance. It would be particularly useful to numerous licensees if the "specific considerations" for I-123 were addressed, and concise guidance for other radioiodines would also be useful.

- 2. Page 3, Section 1.b, "When quantities ... are greater than 10 percent of the Table 1 values, routine bioassay may be necessary under certain circumstances. A written justification for not performing such bioassay measurements should be prepared and documented for subsequent review during NRC inspections..."**

Please describe or provide examples of "special circumstances" that would apply in Section 1.b. Also, the requirement for a written justification documented for inspection for not performing measurements when bioassay is not performed if quantities handled exceed 10% of Table 1 values is unnecessary and potentially burdensome for some licensees. Licensees choosing to not perform routine bioassay would need to know the NRC justification for Table 1 values (and 10% of these values) in order to provide a different justification.

- 3. Page 3, "Table 1...Total Activity (mCi)..."**

Licensees have been traditionally challenged by regulatory agencies to justify the administrative action levels they establish. For licensees to adopt the values in Table 1, the justification or basis for these values should be explained in this guide. Also, the justification for using 10% of these values should be explained.

In this Regulatory Guide certain quantities are expressed in both traditional and SI units. To be consistent throughout shouldn't there be 2 more columns in Table 1 with the values expressed in MBq?

4. Page 3, Section 1.c., “bioassay is not required when process quantities handled by a worker are less than 10 percent of those values in columns 1 and 2 of Table 1.”

This statement is likely to be very confusing to licensees as it appears to contradict the Table 1 title: “Activity Levels above Which Bioassay for Radioiodine is Necessary”. What is the actual threshold for bioassay, the values in Table 1, or 10% of the values in Table 1? If it is the former, then remove Section 1.c. If the latter, then remove Section 1.c and reduce the values in Table 1 to 10% of the current values.

5. Page 3, Footnote below Table 1, lines 4 and 5, “...and diluted to concentrations less than 0.1 curie per gram (i.e., 3.7×10^3 Bq/g of nonvolatile agent.”

In this sentence it is not clear why there is a need to consider diluting nonvolatile radioiodine to below a specified concentration. Is the intent to limit airborne exposure from volatile forms that may be generated by chemical and physical degradation in more concentrated material?

Instead of “curie” shouldn’t it be “microcurie” to be compatible with “ 3.7×10^3 Bq/g”? Consider rewriting this phrase as “100 nCi/g (3.7 kBq/g).

6. Page 3, Footnote below Table 1, line 12, “50 mCi (1.8×10^9 Bq)”

Consider replacing “(1.8×10^9 Bq)” by (1.8 GBq).

7. Page 3, Footnote, paragraph 2 below Table 1, last line, “...face velocities of 0.5 meters per second or more.”

Most licensees use instruments to measure face velocities in linear feet per minute (LFM). Consider rewriting this phrase as “face velocities of 100 LFM or 0.5 m/s”. Also face velocities much greater than these will cause turbulence and be less protective, hence it is often necessary to characterize an adequately protective hood by a suitable range. Consider “100-150 LFM (0.5-0.75 m/s) or as otherwise determined to be effective”.

8. Page 4, Section 1.d., “Column 3 of Table 1...”

The columns with values in Table 1 were previously referred to as columns 1 and 2. So it is unclear where “column 3” appears in Table 1.

9. Page 4, Section 1.e., line 4, "...to verify the effectiveness of...with the respirator devices."

It might be clearer to licensees if the "effectiveness" was more explicit. E.g., consider "radioiodine removal efficiency"

Shouldn't "respirator devices" be "respiratory protection devices"? Consider replacing "with the respirator devices" by "when using a respirator".

Also, other guidance such as that from ICRP and NCRP, recommend a threshold based on percent of measured air concentration in the work area (e.g. DAC or ALI) to determine whether or not bioassay should be performed. This Regulatory Guide should also include guidance on applicability of air sampling results to a decision on whether bioassay should be performed.

10. Page 4, Section 2, "All workers who handle radioiodine substances or are sufficiently close to the process..."

This section should also alert licensees to consider bioassay when airborne radioiodine is potentially and/or inadvertently circulated to other occupied areas.

11. Page 5, Section 5.a, Biweekly or More Frequent Measurements

It would be helpful if the basis for the values of $1\mu\text{Ci}$ and $5\mu\text{Ci}$ as action levels for 5.a.(1) and 5.a.(2) were concisely explained at the beginning of section 5.

12. Page 5, Section 5. a. (2) B., lines 2 and 3, "1 μCi (3.7×10^4 Bq)...If a possibility exists of longer-term retention of I^{125} and I^{131} that requires evaluation,..."

Instead of " $(3.7\times 10^4$ Bq)" write "(37 kBq)".

It is not clear what is meant by longer-term retention, longer than what? Is the intent to recognize unusually high uptake in the thyroid which takes a long time to reduce below an administrative action level? Or is the intent to detect a radiochemical intake that has components with unusually long biological half-lives?

13. Page 5, Section 5. a. (2) B., line 6, "For all severe uptake incidences,..."

It would be helpful if the quantity of an uptake considered to be severe were indicated here. Also, in the last sentence of this paragraph that extends to page 6, thyroid blocking should be mentioned as an emergency provision in the event of a severe uptake and quantitative action levels specified or referenced.

14. Page 7, Glossary, ALI, last sentence, "...50 μ Ci...1- μ Ci..."

Add (1.85 MBq) after "50 μ Ci". Instead of "1- μ Ci" delete the hyphen and add (37 kBq) after "1 μ Ci".

15. Page 7, Glossary, intake, last 2 lines, "Common units used in this guide for intake are the microcurie μ Ci and bequerel (Bq)."

The most commonly used units in this guide should be "kBq" and "MBq" rather than "Bq" to be compatible with " μ Ci".

16. Page 7, Glossary, uptake, last line, "Common units used in this guide for intake are (μ Ci) and (Bq)."

The most commonly used units in this guide should be "kBq" and "MBq" rather than "Bq" to be compatible with " μ Ci". Delete "intake" and insert "uptake".

17. Page 7, Glossary.

Add the terms "nonvolatile agent," and "volatile" and provide definitions. The definition of nonvolatile agent could include examples of commonly used radiochemical compounds. The definition of volatile could include radiochemical forms such as iodide or free iodine as examples along with relative volatility. This would enable application of the guidance to common materials and practices used by most licensees.

18. GENERAL COMMENTS:

- Consider mentioning the need for different procedures for controlling and monitoring prenatal and nursing occupational exposure.
- Consider adding guidance on monitoring individuals who do not have thyroid glands or have abnormal thyroid function.