Response to Public Comments on Draft Regulatory Guide DG-8050
"Applications of Bioassay for Radioiodine"
(Proposed Revision 2 of Regulatory Guide 8.20)
(Public comments have been edited for clarity)

Draft Regulatory Guide 8.20 titled "Applications of Bioassay for I-125 and I-131," was published for public comment as DG-8050 (ML102800439) in the *Federal Register* in September 26, 2011. Based on the public comments the title of the guide has been changed to "Applications of Bioassay for Radioiodine." The comments and the NRC staff's response are set forth in the following table by organizations:

(1) Comments were received from the Division of Public Health, State of Wisconsin.

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ADAMS Accession Number ML11334A057

No.	Comment or Basis	Recommendation	NRC Resolution
1	Clarification for Table 2 (the original Table 1 is Table 2 now, because of a new table inserted calls Table 1)	The columns in Table 2 should be numbered. Column 3 in Part C.l.d and Column 2 in Part C. 1.c appear to reference the same column.	The NRC agreed with the comment; the columns in Table 2 are numbered as suggested. Clarification is made in sections C.l.b and C.1.c about the use of Table 2.
2	Support NRC proposed action level values	Wisconsin State supports the 1 microcurie and the 5 microcurie action level in Part 5.	Thank you for your comment.

(2) Comments were received from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR).

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ADAMS Accession Number ML11334A063.

No.	Comment or Basis	Recommendation	NRC Resolution
1	General recommendation	"…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. … 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.	The NRC agreed with the comment; as suggested I -123, I-124, and I-129 have been added in this guide and the title of the guide has been revised to "Applications of Bioassay for Radioiodine."
2	Clarification for Section C.1.b.	"…describe or provide examples of special circumstances" that would apply in Section C.1.b.	The NRC agreed with the comment; two examples are provided in Section C.1.b., "Conditions under which Routine Bioassay May Be Necessary." Relevant examples are also provided in the guide.
3	Clarification for Table 2	"… 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."	The NRC agreed with the comment; Section C.1.b, indicates that licensees could choose either an exemption or alternative bioassay frequency, but the conditions must satisfy the requirements in 10 CFR 20.2301, "Applications for Exemptions."
4	Clarification for Table 2	"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 ... the justification for using 10% of these values should be explained."	The NRC agreed with the comment; the ten percent (10%) is an administrative upper limit used in this guide. However, an exemption could be obtained to use an alternative bioassay frequency or dosimetry models due to medical, prenatal, or other reasons, but the conditions must satisfy the requirements in in 10 CFR 20.2301"Applications for Exemptions."

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5	Clarification for Table 2	"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?"	The NRC agreed with the comment; Table 2 has been revised as suggested using dual units.
6	Clarification for Table 2	"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."	The NRC agreed with the comment; the ten percent (10%) is an administrative control used in this guide. However, an exemption could be obtained to use an alternative bioassay frequency or dosimetry models due to medical, prenatal, or other reasons, but the conditions must satisfy the requirements, in 10 CFR 20.2301, "Applications for Exemptions."
7	Clarification for Table 2	Footnote of Table 2: "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?"	The NRC agreed with the comment; the footnote in Table 2 has been revised to indicate that radioactivity in process is always chemically bound and in such a way that radioiodine remains in nonvolatile form and diluted to concentrations less than 100 mCi/g (3.7 GBq/g) of nonvolatile agent.
8	Clarification	Footnote of Table 2: "Instead of curie shouldn't it be "microcurie" to be compatible with $3.7x10^3$ Bq/g? Consider rewriting this phrase as 100 nCi/g (3.7 kBq/g)."	The NRC agreed with the comment; changes have been made as suggested.
9	Clarification	Footnote of Table 2: "Consider replacing (1.8x109 Bq) by (1.8 GBq)".	The NRC agreed with the comment; changes have been made as suggested.
10	Technology update in Section C.1.c.	"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."	The NRC agreed with the comment; the footnote in Table 2 has been revised. The term of "face velocity of 100 LFM…" has been eliminated and replaced with "ventilated fume-hood with face velocities that meet the designed criteria."
11	Clarification.	Numbering of columns in Table 2 are not clear.	The NRC agreed with the comment; all columns in Tables

No.	Comment or Basis	Recommendation	NRC Resolution
			2 have been clearly marked.
12	Clarification in Section C.1.f.	It might be clearer to licensees if the "effectiveness" was more explicit, e.g., consider "radioiodine removal efficiency"	The NRC agreed with the comment; changes have been made as suggested and shown in the second paragraph of Section C.1.d.
13	Clarification	Shouldn't "respirator devices" be "respiratory protection devices"?	The NRC agreed with the comment; all changes have been made as suggested.
14	Suggestion	"… ICRP and NCRP, recommend a threshold based on percent of measured air concentration in the work area (e.g. DAC or ALl) 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."	The NRC agreed with the comment; air sampling in workplace is an acceptable method and described in RG 8.25 (1992). Section 1.9 of RG 8.25 states that when working with tritium, iodine, or other materials that are easily and effectively detected by bioassay, it could be appropriate to eliminate all air sampling and when working with tritium, iodine, or other materials that are easily and effectively detected by bioassay, it could be appropriate to eliminate all air sampling and rely completely on bioassays to measure intakes and verify confinement.
15	Suggestion in Section C.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.	The NRC agreed with the comment; the suggestion has been addressed in Section C.2.
16	Suggestion in Section C.5.a	"It would be helpful if the basis for the values of 1 μCi and 5 μCi as action levels for 5.a.(1) and 5.a.(2) were concisely explained at the beginning of Section 5.	The NRC agreed with the comment; the Predetermined Action Level (PAL) for thyroid protection is based on NUREG/CR-4884, "Interpretation of Bioassay Measurement." The technical bases for these PAL values are provided in footnote 2 of Section C.5.
17	Suggestion	Section C***5.***a.: Instead of "($3.7x10^4$ Bq)" write "(37 kBq)".	The NRC agreed with the comment; a change has been made as suggested.
18	Clarification	"It is not clear what is meant by longer-term retention, longer than what? Is the intent to recognize unusually high	The NRC agreed with the comment; the phrase "longer-term retention" has been removed.

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		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?"	
19	Suggestion	Section 5.b.: "It would be helpful if the quantity of an uptake considered to be severe was 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."	The NRC agreed with the comment; both severe intake consideration and thyroid blocking methods are provided in Section C.5.b (2).
20	Suggestion	In Glossary, ALl, last sentence: Add (1.85 MBq) after "50 μCi." Instead of "1-μCi" delete the hyphen and add (37 kBq) after "l μCi".	The NRC agreed with the comment; a change has been made as suggested.
21	Suggestion	The most commonly used units in this guide should be "kBq" and "MBq" rather than "Bq" to be compatible with "μCi".	The NRC agreed with the comment; a change has been made as suggested.
22	Suggestion	Delete "intake" and insert "uptake".	The NRC agreed with the comment; a change has been made as suggested. In addition, both terms have been incorporated in the Glossary Section of this guide.
23	Suggestion	"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."	The NRC agreed with the comment; the terms “volatile” and "nonvolatile agent," have been incorporated in the guide.
24	General Comment	"Consider mentioning the need for different procedures for controlling and monitoring prenatal and nursing occupational exposure."	The NRC agreed with the comment; the licensee could choose an exemption to use an alternative bioassay frequency or dosimetry models due to medical, prenatal, or other reasons, but the conditions must satisfy the

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			requirements, in 10 CFR 20.2301, "Applications for Exemptions."
25	General Comment	"Consider adding guidance on monitoring individuals who do not have thyroid glands or have abnormal thyroid function."	The NRC agreed with the comment; the licensee could choose an exemption to use an alternative bioassay frequency or dosimetry models due to medical, prenatal, or other reasons, but the conditions must satisfy the requirements, in 10 CFR 20.2301, "Applications for Exemptions."

(3) Thirty three (33) comments were received from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) members that was collected and forwarded as one package via a NRC internal email dated January 25, 2012.

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Dated: January 4, 2012
Accession Number ML14056A070.

No.	Comment or Basis	Recommendation	NRC Resolution
1	Comment	"I have only one mechanical comment … the words should precede the acronym the first time it's used in a document and should be "derived air concentration (DAC).""	The NRC agreed with the comment; the DAC is spelled out.

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Dated: January 7, 2012
ADAMS Accession Number ML14056A083.

No.	Comment or Basis	Recommendation	NRC Resolution
2	Comment/Input	"Since the title of Section C was changed, I found the use of "Regulatory Position" confusing in the document. That's why I suggest changing "Position" to "Guidance.""	The NRC agreed with the comment; all "position" words used in Section C of this guide have been eliminated.
3	Comment/Input	"I would like to see a table listing the CDE dose conversion factors (mrem/μCi; mSv/Bq) NRC staff use to calculate thyroid dose from thyroid bioassay measurements. Does NRC staff use the information from NUREG/CR- 4884? Would it be possible to have that NUREG available on NRC website?"	The NRC agreed with the comment; NUREG/CR-4884 is available in NRC website and can be obtained via the link as shown in Reference 12 of this guide at http://pbadupws.nrc.gov/docs/ML0734/ML073400289.pdf.
4	Comment/Input	"I also agree with Pat Zanzonico that I-123 and I-124 should be included, as well as I-129."	The NRC agreed with the comment; I -123, I -124, and I-129 have been incorporated in the guide.
5	Comment/Input	"I looked at NUREG 1556 Vol 9 Rev 2 App M concerning bioassay program guidance as I reviewed this draft guide. I recommend when NRC staff next work on that NUREG document they include reference to Reg Guide 8.20 (same comment for NUREG 1556 Vol. 11)."	The NRC agreed with the comment; this suggestion has been made available to the appropriate NRC staff for follow-up.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A072.

No.	Comment or Basis	Recommendation	NRC Resolution
6	Comment/Input	"…for including I-123 (as well as I-124 & 129) in the document. By this, I do not mean to imply that additional regulation is required, but that at a minimum, some guidance should be given to aid in the local development of policies and procedures and "action levels at an equivalent level of response" as indicated in the draft guide."	The NRC agreed with the comment; I-123, I-124, and I-129 have been incorporated in the guide as suggested.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A073.

No.	Comment or Basis	Recommendation	NRC Resolution
7	General Comment/Input	"I find the document too general for iodine, and should be useful for all unsealed sources - the concepts are the same …. Such assay protocols should probably be established and standardized for most nuclides, and not limited to the iodine's. I also agree with the inclusion of all iodine's, and other nuclides."	The NRC disagreed with the comment; this guide is limited to iodine referring to five iodine isotopes. Further, the RG title has been revised to "Applications of Bioassay for Radioiodine."
8		"Creating a short, effective document (with a long list of references) is better than subjecting the professional, so desperate to learn something, to such confusing documents, is just not right."	The NRC agreed with the comment; the staff made an effort to keep this guide short and effective.
9	Specific Comment	"Traceability to NIST would be helpful, True	The NRC agreed with the comment; the NIST

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		calibration should be required, not just QC testing." And, "… a role the NRC needs to plug, ensuring such measurements are accurate. The word "bioassay" implies accuracy."	traceability is part of QA and QC laboratory analysis but it is not applicable to this guide.

ACMUI Members
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Dated: January 6, 2012
ADAMS Accession Number ML14056A074.

No.	Comment or Basis	Recommendation	NRC Resolution
10	General Comment/Input	"Attached please find my annotated version of the clean copy of Draft Regulatory Guide (DG-8050) – annotated with my comments in the right-hand margin and with some minor editorial revisions. Among my comments is that iodine-124 as well iodine-124, although not by-product materials should be included in the RG."	The NRC agreed with the comment; all editorial updates were incorporated. In addition, I-124 is incorporated in this version.
11	Comment - title of this document.	"I know they are NOT by-product materials but shouldn't I-123 and I-124, both widely used in Nuclear Medicine, be included as well."	The NRC agreed with the comment; I-123 and I-124 are incorporated in this version.
12	Clarification	"Does the term, "unsealed" materials, included CAPSULES, a very commonly used form of radioiodine in the clinic? If it is NOT intended to include capsules – and I think it should NOT – that should be stated explicitly to avoid potential confusion among Licensees."	The NRC agreed with the comment; clarifications regarding the iodine capsules have been added and examples are provided as suggested.
13	Clarification	"…does "compliance" with Regulatory Guides assure compliance with the applicable regulations? If so, I think that should be stated explicitly."	The NRC agreed with the comment; this guide provides a method that the NRC staff considers acceptable in implementing 10 CFR Part 20 regulations but each specific licensee may include conditions in their license that could impose additional requirements. Also, Regulatory Guides are not substitutes for regulations and compliance with them is not required.

No.	Comment or Basis	Recommendation	NRC Resolution
14	Clarification the "activity" word used	"What is meant by the term, “kinds of activities”? If it refers to the physical and chemical forms of radioactivity, this latter term should be used. In any case, I do not think the term, “kinds of activities,” is rigorously correct, since “activity” is a quantity."	The NRC agreed with the comment; this suggestion has been made throughout the entire document.
15	Clarification for Section C.1.	"I find Item C.1.b. confusing. My inference from Table 1 and Item c. is that bioassay is required for cumulative activities equal to or greater than those in Table 1, not required for cumulative activities less than 10% of those in Table 1, and recommended for cumulated activities between the two preceding values – Is that correct? If so, that should be stated explicitly to avoid potential confusion among Licensees?"	The NRC agreed with the comment; the original Section C has been reworded and reorganized so that there will be no confusion between Table 2 and Section C.1. Section C.1.b states that routine bioassay may be necessary to be performed when quantities handled in unsealed form are greater than 10 percent of Table 2 values.
16	Clarification for Section C.1.	"I also find Item C.1.c. confusing. Table 1 refers to a 3-month time frame while Item d. refers to a 40-hour time frame. These different time frames should be reconciled."	The NRC agreed with the comment; the 3-month time frame in Table 2 is required to assess the total radioactivity. The 40 hour time frame is based on 10 CFR Part 20, Appendix B, Table 2, footnote 3 requirement for weekly accumulation of radioactivity in air.
17	Clarification for Section C.4.	"I find this - a different time frame than the previous two – confusing as well."	The NRC agreed with the comment; Section C.4 has been revised to clearly indicate the time frame for thyroid content.
18	Clarification for Section C.5.	"Chelation" is appropriate, I think, for radiometal but not for radioiodine contamination, regardless of its chemical form."	The NRC agreed with the comment; the proposed guide uses now the terms “chelation and decorporation agents” as shown in the Section C.5.b.
19	Clarification for the Glossary Section for ALI	"I don’t think the term, “deterministic,” is appropriate in this context – 50 uCi of internalized radioiodine would deliver a committed dose equivalent of ~50 rem to the Standard-Man thyroid, below the threshold dose of any deterministic effect."	The NRC agreed with the comment; the term “deterministic” has been replaced by “non-stochastic” (Table 1).

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A066.

No.	Comment or Basis	Recommendation	NRC Resolution
20	General Comment/Input	"I do not believe there is added value to including isotopes of iodine other than I-131 and I-125 to this regulatory guide."	The NRC agreed with the comment; however, the majority of ACMUI members are in favor of adding I-123, I-124 and I-129.
21	Clarification in Section C.1.a	Undefined "open form", consistently use "unsealed"	The NRC agreed with the comment; "open form" is changed to "unsealed."
22	Clarification in Section C.1.b	"About word "circumstance": an example would be helpful"	The NRC agreed with the comment; two examples are provided in Section C.2.b.
23	Clarification in Table 2	"Perhaps a fume hood standard should be referenced"	The NRC agreed with the comment; footnote 2 of the Table 2 states that "superficial velocity of fume hoods should be consisted to meet the design criteria..."
24	Clarification	Undefined "non-free form", consistently use "unsealed"	The NRC agreed with the comment; the term "nonfree form" is changed to "sealed forms" as suggested.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A064.

No.	Comment or Basis	Recommendation	NRC Resolution
25	Clarification in Section C.5.	"Item 5, suddenly activities are in microCi with Bq in parenthesis. It probably would be best to have the two sets of units throughout the document, but better with the SI units as primary and the conventional in parenthesis. Also, the values such as 1.8 x 10^5Bq would make more sense to readers who know the units	The NRC agreed with the comment; both English traditional and SI units are used throughout the guide.

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		as 180 kBq or 0.18 Mbq.	
26	General Comment/Input	In C.5.b.(2), "should be taken immediately" should be read. That is “the auxiliary verb and the main verb should not be separated (except for a few special adverbs.)”	The NRC agreed with the grammatical comment; the sentence has been revised.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A065.

No.	Comment or Basis	Recommendation	NRC Resolution
27	Recommendation	"… I-123 & I-124 should be included."	The NRC agreed with the comment; three new nuclides have been incorporated in this version, including I-123 and I-124.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A078.

No.	Comment or Basis	Recommendation	NRC Resolution
28	General Comment/Input Clarification	"iodine is much more volatile than sodium iodide, from the notes of a chemistry class"	The NRC agreed with the comment but a change to this guide is not warranted.
29	General Comment/Input for footnote in Table 2	"Operations involving the routine use of ^{125}I and ^{131}I in an open room or bench are discouraged… adequate face velocities of 0.5 meters per second or more."	The NRC agreed with the comment; all technical concerns have been addressed. Clarification for open room/bench and superficial velocity were made in this revision.
30	General Comment/Input for	"Capsules (such as gelatin capsules given to patients	The NRC agreed with the comment; the footnote in

No.	Comment or Basis	Recommendation	NRC Resolution
	clarification on footnote in Table 2	for diagnostic tests) may be considered to contain the radioiodine in non-free form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed)."	Table 2 has been revised as suggested.
31	Recommendation	"If there is a breech in normal procedures during the administration of I-131 (e.g. spillage from the vial that exceeds the capacity of the absorbent pad) a bioassay would be necessary."	The NRC agreed with the comment; the suggested language has been incorporated in the footnote of the Table 2.
32	General Recommendation	"Additional flexibility of conditions should be included to further reduce the burden of a bioassay program … For example, for licensees whose thyroid bioassay program does not produce any results of thyroid content equal to or less than 0.1 μCi (a tenfold reduction of the current amount) during a 3 month period."	The NRC agreed with the comment; this guide provides a method that the NRC staff considers acceptable in implementing 10 CFR Part 20 regulations but each specific licensee may include other methods that are consistent with the NRC regulations. Also, Regulatory Guides are not substitutes for regulations and compliance with them is not required.

ACMUI Members
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Dated: January 8, 2012
ADAMS Accession Number ML14056A082.

No.	Comment or Basis	Recommendation	NRC Resolution
33	General Comment/Input	"NRC staff should drop the guidance that fume hoods should have face velocity of 100 LFM. New hood designs can safely function with lower face velocity. Staff should change this guidance to ensure the face velocity meets the fume hood design criteria."	The NRC agreed with the comment; the revised statement is listed in the footnote 2 of Table 2, which states, "Whenever practicable, sealed bottles or containers holding radioiodine should be placed in a well-ventilated area (e.g., ventilated fume-hood with face velocities that meet the designed criteria.)"