Staff Responses to Public Comments on Draft Regulatory Guide DG-8051
(Proposed Revision 2 of Regulatory Guide 8.22)
(Public comments have been edited for clarity)

Draft Regulatory Guide 8.22, "Bioassay at Uranium Mills," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110960333), was published for public comment in the *Federal Register* on March 13, 2012 as DG-8051 (77 FR 14837). The U.S. Nuclear Regulatory Commission (NRC) received and analyzed multiple comment submissions. The comments and the NRC staff's responses are presented in the following tables grouped by the person or organization that submitted the comments:

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No.	Comment or Basis	Recommendation	NRC Resolution
1	Comment on bioassay frequency in section C.3	You may want to consider an upper bound limit for a urinalysis sampling time frame, <90 hours, for uranium mill workers under the following conditions: a) Calcining to 1,200 °F in a multiple hearth dryer using a feed of ammonium diuranate $(NH_4)_2U_20_7$ (i.e., ADU).	The NRC agreed with the comment; ammonium diuranate (ADU) has been included in Section B, Background as well as in Section C.3.c. Special Bioassay sampling requirement is now 90 hours.
2	General input	Mill operating personnel were routinely rotated to each operating position, grinding and leach, CCD, solvent extraction, and precipitation and drying. That way, no one was placed at one operating position continually and all were trained at each position. Barreling was normally conducted on dayshift.	The comment was informative, but no changes to the regulatory guide (RG) were warranted.
3	General input	All in-vivo counting was conducted once annually for selected mill personnel with everyone counted during their first year of employment. Every count period included the mill person with the highest exposure potential (no credit was taken for respirator use) during the preceding year. The average annual counting data were all below the minimum detection limit.	The comment was informative, but no changes to the RG were warranted.
4	General input	Respirators were not worn for routine mill operation. "Airborne uranium sampling was crossed checked with NRC personnel on their inspections of the mill and the results were considered acceptable by the NRC."	The comment was informative, but no changes to the RG were warranted.
5	General input	There was an extremely low rate of turnover at this mill. The data reflect	The comment was informative, but

		a learning curve for the operators and the effect of engineering controls. There was no turnover in the radiation safety department, no change in mill analytical procedures or contract laboratory used for urinalysis data during this time frame.	no changes to the RG were warranted.
6	Comments on Table A-1	Had a 15 µg/liter lower limit of detection in-vitro uranium urinalysis been used after a >90 hour time off sampling time frame, most of these data would not have been observed (i.e., there are 24/7 rotating shifts that have 4 days, >192 hours, off). If the barreling operation is under control the amount of soluble uranium in the air could be missed entirely.	The NRC agreed with the comment; this revision of RG 8.22 is not including the 15 µg/liter lower limit of detection in-vitro uranium urinalysis. Instead is referencing the American National Standards Institute/Health Physics Society (ANSI/HPS) N13.30-2011, "Performance Criteria for Radiobioassay" which recommends detection methodology, for uranium and urine sample detection capability, which is acceptable to NRC.

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No.	Comment or Basis	Text of comment	Resolution
1	Comments on Section C.3.a (changed to C.4.a)	Frequency – reference to minimum monthly bioassay sampling: In light of the solubility study data (dissolution in lung fluid simulants) for modern UR products presented in Attachment 1, a monthly frequency may be inadequate to identify intakes of materials with dissolution /elimination half times of a few days or less. The NRC should consider minimum urinalysis specimen collection frequencies aligned with weekly shift schedules for workers in the yellowcake areas of mill.	The NRC agreed with the comment; Section C.4.a has been revised to indicate that monthly frequency is only acceptable for Class Y materials based in Table 1.
2	Comments on Section C.3.b	Frequency: The NRC should recognize here that although NUREG-0874 does represent appropriate and the most current guidance for the dosimetric model	The NRC agreed with the comment; this revision of RG 8.22 is aligned

	(changed to C.4.b)	basis of 10 CFR 20, both are based on ICRP 30 dosimetry models of over 30 years ago. The more recent lung and uranium dosimetry models of the ICRP, e.g., ICRP 66, 68 and 71 should at least be recognized here.	with Title 10 of the Code of Federal Regulations (10 CFR) Part 20, "Standards for Protection against Radiation." As suggested, the latest International Commission on Radiological Protection (ICRP) recommendations associated with uranium bioassay have been cited in this document. It should be noted that some of the recommendations issued by ICRP do not correspond to the requirements specified in the NRC's regulations. In such cases, the NRC's requirements take precedence.
3	Comments on Section C, Table 1	Table 1: As indicated under General Comments above, the uranium products being produced by most UR facilities in the US today are not represented in this table, e.g., UO_4 and hydrates of UO_4 and UO_3.	The NRC agreed with the comment; although UO_3 and UO_4 and uranium hydrates, as well as ADU are uranyl peroxides (UO_4 nH_2O) and were not represented in Table 1, they are discussed in detail in Section B "Background" of the guide. Also, the solubility issues are covered in Section C.3.c and C.5.c.
4	Comments on Section C, Table 1	Table 1 and discussions that follow regards to D, W and Y solubility classification system: Similar to comment above, it should be recognized that the F, M and S solubility types defined in ICRP 68 and 71 are generally considered equivalent to ICRP 30 D, W and Y solubility classes, respectively.	The NRC agreed with the comment; the equivalency of the ICRP-26 lung solubility classifications D/W/Y to that of ICRP-60 F/M/S has been applied in Table 1.
5	Comments on Section C.4.e	Reference to 1 µg/liter action level: Based on conversations with commercial radiochemical laboratories, it is doubtful that detection limits <about 5 µg/L are attainable with any statistical confidence. The 1 µg/liter value is also discussed in Section 8, Quality Control for urinalysis, but appears to be intended in that section to define a "blank" control. Nonetheless, it is doubtful that this can be analytically demonstrated with statistical confidence.	The NRC disagreed with the comment; the NRC staff has revised Section C.7, "Quality Control," to provide an endorsement of ANSI/HPS N13.30-2011 guidance where the 5 µg/L sensitivity is attainable as noted in Table 3 of the

			standard, indicating that the minimum testing level for indirect radiobioassay performance testing, for uranium is required at 1 µg in mass.
6	Commented in Section C.4.e	Reference to NUREG/CR-2268: The "short lived" compound discussed therein is uranium hexafluoride which is not relevant to uranium recovery facilities. However, see discussion under General Comments above and Attachment 1 as related to the uranyl peroxides typically being produced at modern uranium recovery facilities.	The NRC agreed with the comment; uranyl peroxides is now included in this guide based on the technical bases in NRPB-W22 "Industrial Uranium Compounds: Exposure Limits, Assessment of Intake and Toxicity after Inhalation" (2003), as referenced in the guide (Ref. 13).
7	Comments on Section C.6.c (changed to C.7.a.(2))	Section 7.c.: Prevention of Specimen Contamination, requirement that urine volume collected should be adequate for four analyses: (a) the licensee has little control over the urine volume provided by the worker. (b) If multiple analyses are required from the same specimen, minimum detection limits are impacted. (Particularly in consideration of the 1 µg/liter requirement. Under these requirements, it may be problematic to "see" the 15 µg/liter MQC defined in Section C.7.a and the 15 µg/liter action level in Appendix A. Furthermore, the 1 µg/liter action level of Section 5.e vs. the 15 µg/liter MQC described in this section is confusing and appears to be conflicting.	The NRC disagreed with the comment; a) the urine volume can be controlled and it is proportional to the water consumed in the body, and b) the original section C.7.c has been deleted and has been replaced by Section C.7, 'Quality Control," referencing Section 4.0 of ANSI/HPS N 13.30-2011, "Performance Criteria for Radiobioassay."

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No.	Comment or Basis	Text of comment	Resolution
1	Clarifications on Section C.2.	Workers Requiring Bioassay: A clear and concise definition of workers requiring bioassay should be incorporated in the glossary. Licensees should have no doubt as to who must be bioassayed at their sites. It is clear, based on how the draft guidance is written for example, that any worker that must don a respirator must be bioassayed following completion of work; however, the other	The NRC agreed with the comment, but a clear and concise definition of workers requiring bioassay to be incorporated in the glossary is not necessary. Current proposed document in Sections C.1, C.2, and C.3 clearly

		requirements are not that clear. The document states that, *"...workers who handle and work with uranium substances, or are sufficiently close to the process so that intake is possible"* must be bioassayed. The document does not discuss worker exposure time. Workers spending a very limited time with uranium substances are at very low risk of intake, and thus, bioassaying of them should not be required. An example would be a worker who spends an hour or less per week in proximity to uranium processing. In addition, infrequent visitors to a uranium recovery operation may be, for a very short time (minutes), *sufficiently close* to *the process* so *that Intake is possible,* if they are touring the grinding, leaching or counter-current decantation areas of a conventional mill. There should be no requirement that such infrequent visitors be bioassayed.	state who has to undergo a bioassay. The NRC staff also agreed with the comment about exempted bioassay conditions for those with very limited time exposure and those low-risk visitors who use respirators. Licensees may be able to request such an exemption under 10 CFR 20.2301, "Applications for Exemptions," subject to NRC approval.
2	Clarifications on Section C.1.d	Post Operational and Termination Bioassays: The guide should recognize that it is not always possible to collect a final bioassay sample from a worker upon termination of work involving exposure to uranium. In some cases, workers have failed to report to work and subsequently have been impossible to locate or contact making it impossible to obtain a final post-operational bioassay. This is especially true in the case of contract workers. Contract employees work for the contractor and the licensee may be unable to obtain a post-operational bioassay of a contract worker who fails to report for work and cannot be found. This contingency should be recognized in the document.	The NRC agreed with the comment; Section C.3.d of the guide states that licensees should develop a contingency plan to avoid or eliminate the failure to collect the last sample. This means an additional effort to collect a termination sample before the worker leaves the facility.
3	Comments for bioassays following use of respiratory protection devices	The draft guide states: Bioassay specimens should be collected and evaluated after a respiratory protection device is used to reduce intake of radionuclides. In some cases, respiratory protection must be donned for a very short period of time (often less than fifteen (15) minutes) to take a reading or perform some minor tasks in an area designated for respirator use. This very short duration exposure with its low associated risk, does not warrant a special bioassay. This is especially true for facilities on standby where very brief respirator use is required on an infrequent basis. In any event if a worker were required to don a respirator, even infrequently and for brief periods of time, that worker would still be subject to bioassaying on a monthly basis. The Regulatory Guide should be revised to recognize such	The NRC agreed with the comment; the guidance on respiratory uses shall be consisted with requirements in 10 CFR Part 20, Subpart H "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," requirements. In Section C.3.e a discussion on "Respiratory Protection Bioassay," is added for further clarification. All respiratory discussions have been consolidated in the Section B "Discussion" under

		infrequent short periods of respirator use.	"Background." Licensees may be able to request an exemption under 10 CFR 20.2301, for low-risk workers or visitors, subject to NRC approval.
4		All ISR (i.e., in-situ recovery) samples appear to exhibit solubility characteristics that meet the definition of absorption Type F as defined in ICRP 71. That is "generally equivalent" to solubility Class D from the older ICRP 26/30.	The NRC agreed with the comment; the proposed document indicates that ADU are uranyl peroxides (UO_4 nH_2O) and are classified as soluble chemicals, i.e., they can't belong to a Class-Y materials bioassay program.

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No.	Comment or Basis	Text of comment	Resolution
1	Clarifications on Section C.2d: Changed to C.2.c. The original Section C.2.e has been consolidated in Section B.	Dryer Operators use respirators on a daily basis… The requirement for special bioassay collection after respirator use should be limited to non-routine activities not covered by C.2.d.(1) or C.2.d.(2). Consistent with C.2.d.(1), for routine Dryer Operations, bioassay should be based upon air sampling results and/or residual contamination that may be found inside of the respirator…. the collection of a daily bioassay after routine respirator use pursuant to C.2.e. is redundant with C.2.d.(1). For this reason, CAMECO suggests C.2.e. be modified to address non-routine activities not covered under C.2.d.(1) or (2).	The NRC agreed with the comment; the guidance on respiratory uses shall be consistent with 10 CFR Part 20, Subpart H requirements. Also, Sections C.3.d and C.3.e have been deleted. The information is now reflected in C.3.d.(1) and C.3.d.(2).
2	Clarifications on the original Section C.2 and C.3. They are now in Sections C.2 and C.4, respectively.	It is not possible to implement a 36-hour delay to avoid uranium that is eliminated without uptake in kidney tissues. Does C.3.c. apply to C.2.e.? The language is unclear. Modifying 2.e to address non-routine activities would eliminate this problem.	The NRC agreed with the comment; the entire Sections C.1, C.2and C.3 have been revised for better clarification. "Does C.4.c. (formerly C.3.c.) apply to C.3.e. (formerly C.2.e.)" The answer is yes: It indicates that bioassay frequency and the type of bioassay are often closely related. The 36-hour time-frame is for dosimetry information only; it does not require implementing and the reference has

			been removed.
3	General comments	This would be a significant burden on the dryer operators who wear a respirator every day. Providing a bioassay daily would result in an approximate $ 18,250 ($25 per sample @365 days a year) increase in cost for bioassay analysis for two dryer operators.	The comment was informative, but no changes to the RG were warranted.

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No.	Comment or Basis	Text of comment	Resolution
1	Comments on Section C.1 that has been consolidated in Section C.2.	Section 1: Conditions Under Which Bioassay Is Necessary This section states that, "All workers who handle and work with uranium substances, or are sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material), should participate in the bioassay programs described below." This statement places further restriction on the necessity of internal exposure monitoring. 10 CFR 20.1502(b) requires monitoring if a radiation worker is "likely" to exceed the applicable annual limit on intake or committed effective dose equivalents. The statement within the regulatory guide removes the evaluation of the likelihood of intake and states that workers with only a possibility of exposure should be monitored, regardless of the magnitude of the intake, and should be reconsidered within the context of the regulations.	The NRC agreed with the comment; this statement has been deleted or reconstructed. The current Section C.1 "Participation" provides clarification stating that 10 CFR 20.1502(a) and (b) are the primary conditions for initiating a bioassay measurement.

2	Comments on Section C.2	Section 2: Types of Bioassay That Should Be Performed Part e of this section states, "Following use of respiratory protection devices. Bioassay specimens should be collected and evaluated after a respiratory protection device is used to reduce intake of radionuclides." As stated elsewhere in the regulatory guide, bioassay programs are confirmatory in nature. Collection of bioassay samples following the use of respiratory protection in no way reduces the intake of radionuclides. Furthermore, at some facilities, respiratory protection is donned on a near daily basis by many workers. Sampling at this frequency would negate the necessity for routine and special bioassay sampling in addition to resulting in an unsustainable quantity of bioassay sample analysis being performed. This increase in sampling does little to benefit the safety of the worker as history has demonstrated that an adequate routine sampling program remains sufficient to determine the occupational radiation exposure.	The NRC agreed with the comment; the original Section C.3., has been reconstructed. In the proposed document, the Respirator Protection Bioassay has been addressed in Section C.3.e.
3	Clarification of Section C.4.e.	Section 4: Action-Levels and Corresponding Actions Part e of this section state, "When short-lived components are anticipated in urinalysis. Licensees should use the recommendation in NUREG/CR-2268 (Ref. 8) to use two-action-levels: at 1 μg/L Monday morning urinary excretion rate and an exposure associated urinary output of 100 μg/L during the first 24 hours after the exposure." This is the only mention of a "Monday morning urinary excretion rate". There is no further description that defines this type of sampling protocol. Due to the dependence of the urinary excretion rate of soluble uranium on the time following the intake, it is unclear what type of action level is desired.	The NRC agreed with the comment; the proposed document excludes the two-action-levels method stated in NUREG/CR-2268.
4	Clarification	Section 8: Quality Control: Section C.8, now Section C.7. The section describes a recommended quality control program. Part a states, "The uranium urinalyses sensitivity and detection shall be achieved at a minimum quantifiable concentration (MQC) of less than 15μg/L." Although a specific value is defined for an MQC, no references or definitions are provided for the calculation of this value.	The NRC agreed with the comment; Section C.7 "Quality Control," has been revised referencing ANSI/HPS N-13.30-2011 guidance where the 5 μg/L sensitivity is attainable as noted in Table 3 of the standard, indicating that the minimum testing level for indirect radiobioassay performance testing, for uranium is required at 1μg in mass.

5	Clarification for the Appendix A	Table A-1 and A-2 refer to a "quarterly limit of intake." Current regulations are defined in reference to an annual limit on intake (ALI). It is recognized that this may be in reference to historic regulation. However, if a quarterly limit is intended, definition and reference to this limit is necessary.	The NRC agreed with the comment; the "quarterly limit of intake" is not a limit. It means 1/4 numerical value of the ALI, which is 5 rem, as stated in 10 CFR 20.1201. In addition, the word "quarterly limit" has been removed from Tables A-1 and A-2.