Response to Public Comments on Draft Regulatory Guide (DG) -4018
"Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors"
Proposed Revision 1 of Regulatory Guide (RG) 4.20

A notice that Draft Regulatory Guide, DG-4018 (Proposed Revision 1 of RG 4.20) was available for public comment was published in the *Federal Register* on April 10, 2010 (75 FR 20645) and it was reopened for a 60-day public comment period on June 25, 2010 (75 FR 36445). Comments were received from the organizations listed below. The NRC has combined the comments and NRC staff disposition in the following table:

April 17, 2012

Greg Yuhas (GY) UC Berkeley 2199 Addison St Berkely, CA	US Army Corps of Engineer (USACE)	Council on Radionuclides and Radiopharmaceuticals, Inc (CORAR) 3911 Campolindo Dr. Moraga, CA 94556-1551

	Comments			NRC Comment Resolution
Item	Originator	DG-4018 Section	**Specific Comment**	**NRC Staff Response**
1	GY	General	The draft does not mention how this Regulatory Guide will apply to Agreement State and general licensees.	General licensees may, or may not, be exempt from 10 CFR 20 depending on the specific provisions in the general license. If exempt from the applicable regulation for which this guidance was developed, this guidance would not apply. Similarly, applicability of this guidance for Agreement State licensees is determined by the appropriate State authority.

2	GY	B	The term “sealed sources,” presented in paragraph three under As Low As Reasonably Achievable, lacks clarity. Revise the sentence to specifically apply to sources manufactured pursuant to an NRC or Agreement State issued Sealed Source and Device Registry (SSDR) number.	Sealed source is defined in 10 CFR 30 as follows: *Sealed source* means any by product material that is encased in a capsule designed to prevent leakage or escape of the byproduct material While staff could expand on this definition to state “any licensed radioactive material” instead of “byproduct material,” staff feel additional sealed source specification in this guide may only confuse users when the intent is otherwise apparent. No change made.
3	GY	B	Change the third sentence under “Constraints,” to read: “The constraint, in this case, may interpreted as that fraction of the public dose limit allocated to air emissions to assure exposures are ALARA through this particular release pathway.”	Staff agrees with the suggested comment and incorporated the suggested wording: “The constraint, in this case, may interpreted as that fraction of the public dose limit allocated to air emissions to assure exposures”
4	GY	C	Under C. Regulatory Position, item 1, second sentence should be changed to recognize that EPA approved models, such as COMPLY and CAP-88, are authorized for use without prior NRC granted exception.	Exceptions are evaluated or issued on a case by case basis and typically are applicable to regulatory requirements a licensee can justify as not applying. As use of these computer codes are not regulatory requirements, this comment is not applicable. This regulatory guide already states that use of these codes is an acceptable method of demonstrating compliance with 10 CFR 20.1101(d).
5	GY	C	Regulatory Position, section 1.b. introduces the term “sealed container.” The concept of sealed containers is important and should be discussed. For example: sealed containers are containers used to store radioactive materials that would not be expected to release their contents under conditions of normal use; normal use does not include fire, earthquake, floods, dropping onto an unyielding surface or exposure to environmental conditions that would be expected to challenge the integrity of the container during the year. A sealed steel paint and flame-sealed quartz vial would be expected to effectively contain dispersible radioactive material during conditions of normal use; however, both would fail if crushed or exposed to fire. A plastic bag exposed to direct sunlight would be expected to deteriorate during the year and should not be	Further specifying what is considered a sealed container would confuse the performance criteria for sealed containers stated in this section (i.e., unopened and not leaking). Staff believe that licensees have adequate control and knowledge of their facilities and radiation programs to understand when this performance criteria is applicable and would be able to determine an inventory that accurately, and/or conservatively, contributes to airborne effluents in the period under consideration. No change made.

			considered a sealed container under those circumstances.	
6	GY	C	Regulatory Position, Section 2.B. assumes the "air concentration measured at the point of release." In many cases, the air concentration is estimated, not measured, as permitted by 10 CFR 20. When calculating the fraction of material released, the licensee should be directed to Table 1 of ANSI/HPS N13.1-1999 or EPA 520/1-89-001 for acceptable release fractions from solid, liquid, or gaseous forms of radioactive materials.	Section 2 of the RG has been modified to include general discussion regarding estimation of a release of materials not based on measurement. This includes a reference to ANSI/HPS N13.1-1999.
7	USACE		The proposed change from 20% to 10% of the air effluent limit should be explained in more detail. As currently explained it would only be appropriate for radionuclides for which the stochastic limit is governing. If submersion is limiting the current explanation is inaccurate. Rather than adjust based on the age dependent factor (2, see note below), it may be appropriate to adjust the dose relationship factor of 50 to 500 (i.e. changes the derived limit from 0.1 rem to 0.01 rem). This would apply to both effluent limit calculation approaches, thus eliminating the submersion issue.	Staff debated this issue fully and concluded that the statement in Appendix B that essentially continuous ingestion or inhalation of the concentrations in Table 2 would result in 50 mrem annual dose to be accurate. As such, staff have decided to reinstate the 20% sum-of-fractions method which will be applicable to those radionuclides which are limited by the stochastic internal dose. Unfortunately, this does not resolve the difficulty staff identified that radionuclides which are submersion dose limited in the same table correspond to 100 mrem annual dose. Clarification has been added that if an effluent mixture contains radionuclides for which submersion dose is limiting, then use of the 10% inequality or computerized modeling may be necessary to demonstrate compliance.
8	USACE		USACE agrees with and appreciates the addition of CAP88 as a potential modeling option.	No response required.
9	USACE		More discussion should be added to the Guide to better facilitate understanding and compliance with the 10 CFR 20.1101(d) standard and the Clean Air Act. a. USACE has performed dose calculations from air emissions on many sites, for many years. Often the hypothetical maximum exposed individual is an adult worker (member of general public). To address this receptor, the modeled dose to that worker is then corrected for time of exposure (8 or 10 hrs per day rather than 24hr/day), effectively reducing the exposure. This	Staff have decided to include text describing the derivations of Table 2, Appendix B values as present in 10 CFR 20. Staff recognize that ICRP 30, on which the 10 CFR 20, Appendix B values are based, did not address age groups other than adults which is why the factor of 2 was utilized to account for these age groups as well as pathways other than direct inhalation or ingestion. However, more recent guidance has provided dose conversion factors for other age groups which could be utilized when justified. Also, it was not felt to be appropriate to discuss manipulating these derivations based on site specific parameters although doing so in practice may be justifiable.

			only corrects for the factor of 3 in the above notes. As discussed in the DG currently, it appears the limit for this receptor would equal to 5 mrem/yr. If the maximally exposed individual is an adult, the 10 CFR 20 Appendix B stated factor of 2 should also be addressed. These dose estimating issues should be discussed in the Guide, especially with regards to the computer models. b. The values presented in Tables 1, 2, and 3 of 10 CFR 20 Appendix B are rounded up to the nearest whole number. This rounding is not significant given a dose limit of 100 mrem/yr, but it may be significant given a dose constraint of 10 or 5 mrem/yr.	Given the above inclusion in the guide, staff do not feel it is warranted to discuss the bias introduced by rounding of the data in Appendix B. Staff recognize that there is considerable uncertainty in any dose conversion factor applied to a population but the values in 10 CFR 20 have been deemed acceptable for regulatory purposes.
10	USACE		Discussions should be added to the Guide addressing data QC and uncertainty to facilitate compliance with the standard. The 10% of air effluent value limits may be difficult to demonstrate for some radionuclides (e.g. Th-232), and meeting data QC requirements may also be difficult at these levels. Additionally, the measurement uncertainty at 10% of the air effluent limits may be significant. Modeling also adds uncertainty, however by accepting only certain models the uncertainty can be considered acceptable. At a minimum these issues should be discussed in the Guide.	Data uncertainty and Quality Assurance/Quality Control guidance are present in Regulatory Guides 4.16 “Monitoring and Reporting Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Cycle Facilities” and 4.15 “Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination) -- Effluent Streams and the Environment.” Staff have elected not to repeat this subject in this document. Staff do not address modeling uncertainty as the methods put forward are intended to deterministically arrive at an appropriately conservative estimate of potential public exposure. Conversely, probabilistic modeling could be expected to require justification of the distribution of each parameter utilized as being appropriate for the specific situation and the final distribution of the output reviewed to bound actual exposures. The cost and effort associated with developing this approach is such that few facilities have shown interest in performing probabilistic modeling.
11		C	An informal comment was received to consider including the code MILDOSE-AIR among those specifically called out in the guide. MILDOSE-AIR is a code utilized by mining/milling sites to assess	Staff considered this code for inclusion but determined that it would result in confusion as it is primarily utilized for modeling Rn emissions while Rn and it’s progeny are explicitly excluded from the regulation being discussed in

			public exposures due to radon emissions.	this regulatory guide.
12	CORAR	B	Page 3, lines 19-20, section B, Constraints, "The dose limit to members of the public includes doses from all pathways, including direct radiation, liquid effluents and gaseous effluents." Replace "gaseous" by "airborne" because airborne effluents may include liquid aerosols and solid particulates as well as gaseous materials. Consider specifying the public annual dose limit of 100 mrem (1 mSv) in this sentence or elsewhere in this section to ensure that readers understand the quantity being referred to.	Suggestion has been incorporated.
13	CORAR	C	Page 3, section C., REGLATORY POSITION, lines 3-5, "The NRC Staff considers the methods described below acceptable for use by its licensees other than power reactors to determine the exposure resulting from air emissions of radioactive material to the environment." Replace "exposure" by "dose".	Suggestion has been incorporated.
14	CORAR	C	Pages 3-4, section C.A., Applicable Exclusions to the Constraint on Environmental Air Emissions and section C.2., Calculation of Dose to the Member of the Public Likely To Receive the Highest Dose from Air Effluents. These sections appear to apply to airborne emissions from a licensed facility to an outside public area. However, licensees also need guidance on how to address airborne releases, through open doorways, windows or on rooftops, from a Restricted Area to an Unrestricted Area, occupied by members of the public that may be in an adjacent room or attached building. None of the methods in section C.2. are practical for demonstrating compliance in these situations. The guidance should be clearer in explaining that the 10 mrem (0.1 mSv) constraint rule applies to emissions	The methods proposed by staff in this guide are generically anticipated to be conservative in almost all situations. Situations involving transfer of airborne materials through doorways, windows, or HVAC systems are too site specific for guidance in this media. In that case, the licensee should perform due diligence by performing and documenting a site specific study to estimate the transference of materials to a receptor of interest and the resulting dose resulting from exposure. Staff believe the statement in C.1.e to effectively address that exposures need not be evaluated for nonresidents within the facility boundary. Materials that are of negligible quantity and/or low fractional release potential could be excluded if sufficient justification is present. Again, the methods presented are meant to generically be conservative and acceptable to staff but are not intended to limit licensees. Site specific modifications to these methods are outside the scope of this guidance but

			outside the facility and not to Unrestricted Areas within the licensee's facility. In section C.2., compliance can be conservatively demonstrated by assuming that all unsealed materials are release in airborne effluent. However, the guidance would be more useful if unsealed materials that are of negligible quantity and/or low fractional release potential are excluded from consideration.	may still be acceptable when justified.
15	CORAR	C	Page 4, section C.2., lines 8-11, "The following methods represent a graded approach, from the method involving the fewest site-specific data and, therefore, the most conservative to the more rigorous methods, with more realistic results, for demonstrating that the constraint has been met. All of these methods are acceptable for demonstrating compliance with 10 CFR 20.1101(d):" This guidance is not understood by some licensees. It would be helpful to explain whether the NRC expects licensees to implement a graded approach by starting with the most conservative method and using successively more rigorous methods until they find one that demonstrates compliance. Or can a licensee just select any of these methods to demonstrate compliance? We know of an Agreement State inspection action where a licensee was determined to be out of compliance when emission concentrations at the point of release were considered although they had adequately demonstrated compliance using the COMPLY Code indicating annual public dose to be less than 0.1 mrem (0.001 mSv).	Staff do not believe it is necessary to use a graded approach when demonstrating compliance. The graded approach discussed in the guidance is intended solely to allow users to pick the method that most closely corresponds to the amount of site specific information desired to be collected. The accuracy of the dose estimate should only increase as one utilizes more site specific information and the resulting dose estimate becomes less conservative…but not underestimated. Staff did not intend to force multiple conservative estimates before eventually arriving at a more accurate modeling method that demonstrates compliance. However, staff cannot think of a way to state this more explicitly than is already present in the guide.
16	CORAR		Page 5, lines 6-10, section C.2.a., "The concentrations assume a factor of 2 to account for the exposure parameters applicable to age groups other than adults such that the resulting exposure for these groups would be estimated at 100 mrem (1 mSv). The licensee can demonstrate that it	As previously discussed, staff debated this issue fully and concluded that the statement in Appendix B that essentially continuous ingestion or inhalation of the concentrations in Table 2 would result in 50 mrem annual dose to be accurate. As such, staff have decided to reinstate the 20% sum-of-fractions method which will be applicable to those

			meets the constraint if the radionuclide concentration at the point of release is less than 10 percent of the "air" values in Table 2." The use of a factor of 2 to account for the exposure parameters applicable to age groups other than adults is appropriate for setting the NRC's annual 100 mrem (1 mSv) limit. However, this factor is not applicable to the annual 10 mrem (0.l mSv) constraint. This is because the constraint was based on the EPA requirement to limit individual risk conservatively assuming a 70 year exposure period. (i.e. a total dose of the 700 mrem (7 mSv)). The extra risk incurred during the few years of exposure when not an adult may only increase the total lifetime risk by a factor of less than 1.25 and is consequently insignificant. Hence the 10 mrem (0.1 mSv) annual constraint is equivalent to about 20% of the 100 mrem (1 mSv) limit (consistent with USNRC Regulatory Guide 4.20-1996), not 10%. . Section 2a and b should be modified to ensure that the constraint is based on population risk criteria and the following changes made on page 5: Line 10: substitute "20%" for "10%". Line 18: substitute "<0.2" for "<0.1". Line 21: substitute "20%" for "10%".	radionuclides which are limited by the stochastic ALI. However, radionuclides which are submersion dose limited in the same table correspond to 100 mrem annual dose. Guidance has been revised to state that if an effluent mixture contains radionuclides for which submersion dose is limiting, then use of a 10% inequality or computerized modeling should occur to demonstrate compliance.
17	CORAR		Page 5, section C.2.b., last paragraph, lines 3-5, "Default values for f are 0.25 for long- and intermediate-term releases greater than 24 hours in duration and 1 for "puff" releases or releases of less than 24 hours." Manufacturing facilities typically experience multiple low-level short term releases each time they process a radionuclide such as ^{133}Me, ^{18}F and ^{3}H. When there are 50 to 1000 or more such processes a year the licensee should select f=0.25 for the default value. Extra guidance would be helpful here.	Staff understand the position presented and acknowledge the potential acceptability of the method. However, to adequately address this would require potentially lengthy and confusing discussion of site specific information applicable to the nature of the releases and meteorology. Staff do not believe it appropriate to discuss site specific variations when attempting to present generic acceptable methods for demonstrating compliance…especially when one does not have to utilize the default values for the modeling method discussed but can justify appropriate site specific values.

				No change
18	CORAR		Page 7, section C.3., Report to the U.S. Nuclear Regulatory Commission if a Constraint Has Been Exceeded. Information in the report should include the method used to estimate the dose to the member of the public.	Agreed, text was added to communicate this.