Staff Responses to Public Comments on Draft Regulatory Guide DG-4017
(Proposed Revision 2 of Regulatory Guide 4.16)

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Comments			NRC Comment Resolution
Originator	**DG-4017 Section**	**Specific Comment**	**NRC Staff Response**
NEI	2.0	This section states that periodic replicate grab sampling of liquid effluents should be done. It should be noted that this practice is not currently performed nor is it required by the rule.	Replicate sampling is a common aspect of quality assurance programs for environmental monitoring. The extent to which this has been performed is dependent on the quality assurance program in place at a facility. The draft guidance specifically utilizes the word "should" to note that the practice is desirable but not required. Licensees following this guidance should be able to justify deviance from the recommendation.
NEI	2.1	Section 2.1 states "Licensees should use this guidance (ANSI/HPSN13.1-1999) to establish sampling and monitoring methods for those gaseous effluent points that emit 90 percent or more of the total radioactivity released from the facility, as well as those points that generate 90 percent or more of the total estimated offsite exposure from facility releases." Application of the physical sampling equipment (shrouded probes, large diameter transport tubing, etc.) called for in ANSI/HPS N13.1-1999 will necessitate major sampling system retrofits across the industry, something that even the EPA has not recommended based on their extensive comparisons to systems designed to the 1969 standard. NRC's application of this technology	In 2002, the EPA amended the NESHAPs regulations to require new and modified sources to be sampled and monitored consistent with ANSI/HPS N13.1-1999. In contrast, NRC's guidance for acceptable methods for monitoring and sampling endorse the consensus standard but conformance with the standard is not required by regulation. While EPA does not require retrofitting of existing sources, neither does the NRC. However, staff recognizes that, as an established consensus standard, it is appropriate to design and operate to the

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		should be risk-based, for example, calling for the 1999 ANSI standard for stacks with a likelihood of exceeding a certain percent of a dose-based limit (50% of the 10 CFR 20 limits, for instance). The current wording would apply the 1999 standard to stacks emitting 90% or more of the facility's total release or generating 90% or more of the resultant offsite dose no matter how miniscule the concentrations and doses are. This gives no consideration to risk.	specifications contained in ANSI/HPS N13.1-1999. Staff also recognizes that it may not be practical to modify existing monitoring systems. The word “should” is specifically utilized in this section, as well as in the consensus standard, to denote that a practice is desirable but not required. Staff believes it appropriate that facilities be able to provide justification for not applying the consensus standard as per recommendations in the guidance at this time. A discussion of public risk due to facility emissions would be expected to be part of any justification for not conforming to the guidance. The recommendation is to utilize the consensus standard on release points cumulatively contributing 90% of the total activity released, as well as on those points cumulatively contributing 90% towards the total off-site exposure. This reflects staff opinion that the consensus standard should, at a minimum, be applied to those points that represent the highest public risk from gaseous emissions. Staff revised this paragraph slightly to assure that the 90% criteria is interpreted against cumulative emissions from all release points as opposed to emissions from a single emission point.
NEI	2.1	Use of the term "continuous monitoring" should be replaced with "continuous sampling," as continuous	Use of the term “continuous monitoring” in the guidance is meant to imply on-line or real time

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		monitoring can be interpreted to mean on-line or real time monitoring.	monitoring. For the passage in question, the draft guidance primarily discussed methods for high risk or low risk emission points and, through a lack of discussion, excluded methods for the more commonly encountered emission points. The draft guidance was reviewed and additional text inserted to assure the more common “continuous sampling” method is mentioned to clarify the difference between these methods.
NEI	2.1	In paragraphs 4 and 5,"could emit" and "has the potential to emit", respectively, should be replaced with "could be expected to emit" or something similar. The current wording could be interpreted as endorsing the "potential to emit" (or PTE) concept used by the EPA in some applications whereby the licensee is required to consider potential emissions from a source devoid of emission controls, e.g. giving no credit for HEPA filters. We do not believe this should be the NRC's intent in these paragraphs.	Change made as per comment.
NEI	2.1	In paragraphs 4 and 5 it also needs to be clear that we are not comparing in-stack concentrations to the Appendix B Table 2 limits that in actuality apply to radionuclide concentrations at the boundary of the restricted area. So rather than say "emit", it would be better to say (consistent with the prior comment) "could be expected to emit radionuclides such that environmental concentrations at the boundary of the restricted area are...."	As discussed in other guidance documents (e.g., Regulatory Guide 4.20), methods for demonstrating compliance with dose limits vary depending on the resources and needs of a facility. This may include use of in-stack concentrations when determining public exposures and may also be used to determine public exposures within the facility boundaries, if appropriate. Staff has revised paragraphs 4 and 5 to be consistent with language in paragraph 3 of this section, which is consistent with the intent of this comment.

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NEI	2.1	"If no radiological source can contaminate an effluent, sampling of the effluent for radionuclide concentrations is not necessary (e.g. a nonradiological stack). However, licensees should evaluate each effluent point periodically (e.g. quarterly) to verify that its radiological status has not changed." The frequency requirement is new and unneeded. Requirements for ISA and change management processes are considerable and offer a preferable basis for review. As the review process is related to change, the issues that might change the stack status if any are specifically addressed, instead of a generic review.	To be more consistent with the expected low risk of contamination in situations where no radiological source can contaminate an effluent, the draft RG's recommendation to perform evaluations of effluent points "quarterly" has been revised to "annually". Note that the comment's statement that the RG is establishing a new "frequency requirement" in this regard is not accurate. The guidance here utilizes the word "should" to denote a desirable practice, but RGs do not establish requirements. Licensees following this guidance should be able to justify deviance from the recommendation.
NEI	3.1	The concept of DQOs in place of fixed criteria (10% of concentration limits) adds much complexity to the process and will require even more accurate estimates of the measurement of uncertainty including sampling and measurement techniques in the absence of a safety concern.	The Data Quality Objectives (DQO) concept has already been incorporated into other related guidance such as Regulatory Guide 4.15 "Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment". Including DQOs in this Regulatory Guide instead of a fixed criteria provides consistency among various guidance documents. In addition, the emissions that are measured can be used, in part, to estimate public risk from operations, so the staff does not agree with the comment's view about "the absence of a safety concern." Staff believes a more accurate estimate of the measurement uncertainty may benefit affected parties by addressing the measurement capabilities of licensees and their estimates of releases. Staff feel these are

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			sufficient reasons to implement a DQOs process for evaluating uncertainty.
NEI	3.2	The section replaces a simple <10% MDC requirement with much more elaborate programmatic DQOs. The majority of licensees have low releases and very limited potential or actual public dose. Enhancing the complexity and requirements for monitoring low level releases does not seem productive. However as an alternative option for licensees with difficult monitoring issues or who are closer to release or public exposure limits, it seems reasonable. *Note that the additional effort for the more complex system is an additional and unidentified cost to the Licensee.*	The flexibility of the DQO process is such that, if appropriate, a licensee could select to maintain MDCs consistent with previous revisions of the guidance. Again, note the language utilizes the word “should” to denote a desirable practice but not a requirement. Also note that other guidance already in effect includes reference to the DQO process (see response to prior comment). Staff believes incorporating the DQO process into the monitoring and sampling of low level releases has value, as it will likely generate additional public trust with regards to the environmental and public impact of licensed operations.
NEI	3.3	Section 3.3 states "For example, in plants handling uranium, the licensee should perform a chemical or isotopic analysis for uranium at least quarterly on selected samples." Such analysis should not be necessary if the Table 2 environmental concentrations for each isotope are approximately the same, or if the limits are conservatively chosen, for example, based upon the most conservative isotope or a conservative mix of the isotopes.	The need for additional analysis extends beyond the quantification of released radioactive material. There are several QC applications: to independently verify the gross activity analytical method; to identify biases developing in the analytical methodologies, and; to verify the mixture of materials present (e.g., if gross analytical results change significantly relative to isotopic results, additional investigation is warranted as the mixture of materials may have changed). If other methods exist to verify the analytical methods employed and the identity of radionuclides present in samples, those methods may provide sufficient justification to deviate from the recommendations of this section. The draft guidance text was revised to

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			provide additional clarification of the purpose of supplemental analysis, and reflects the above response.
NEI	3.9	The section replaces a simple measurement error requirement with much more complex systemic error. The majority of licensees have low releases and very limited potential for actual public dose. Enhancing the complexity and requirements for monitoring low level releases does not seem productive. However as an alternative option for licensees with difficult monitoring issues or who are closer to release or public exposure limits, it seems reasonable. Licensees with releases greater than a percentage of dose limits might adopt the more complex error band. *Note that the additional effort for the more complex system is an additional and unidentified cost to the Licensee. To determine uncertainty in flow rate measurements could require a number of stack flow rate measurements through the monitoring period, as fluctuations in stack flow are a complex function of atmospheric conditions, heating and cooling, building enclosure, fan efficiency, and system resistance to name a few. For a stack with a long history, the use of year to year variance may be possible.*	The previous version of this guidance also requested an estimate of the systematic error that was to be reported separately from the measurement error (see section 5.2 of Rev 1). This revision only emphasizes the relative importance of the source of the error and requested the total error be estimated when reporting effluents so that the best estimate of measurement uncertainty is readily apparent to reviewers of the report. Staff do not believe that this revision constitutes a significant deviation from the guidance present in the prior revision.
NEI	3.9	Measurement uncertainty to include sampling errors would require replicate stack samples - a costly technique not currently performed or required.	Staff do not anticipate that estimates of the total uncertainty be analytically determined for each stack measurement. Rather total uncertainty should be determined periodically until a reasonable confidence is developed of the true measurement uncertainty for each effluent point. Afterwards, total uncertainty should be determined as needed to verify no significant system changes have occurred

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			affecting the measurement uncertainty. If guidance in the prior revision of the document has been followed, estimates of the total uncertainty should be readily available from the information already gathered.
NEI	6.5	The last sentence in the 1st paragraph of section 6.5 "The licensee should investigate significantly negative numbers less than 3 standard deviations below zero as it is unlikely that these values represent random uncertainties for a result near zero." Should read greater than 3 standard deviations below zero.	The “greater than” or “less than” issue becomes problematic when referring to negative numbers. In response to the comment, RG Text has been changed from “less than” to “more than” to improve the clarity of the discussion.
NEI	6.5	Section 6.5 discusses results less than minimum detectable concentrations. This section should be modified to explicitly include concentration determinations from other than counting techniques. For example, mass spectroscopy analyses could be used to determine isotopic concentrations and changes in voltage could be used to determine radon concentrations.	This section (6.5) has been modified to provide discussion relative to analytical reporting methods other than those associated with nuclear counting instrumentation. Staff believe the DQO process is the best tool available to establish an appropriate methodology for estimating concentrations when less than the detectable concentration is present and when using methods other than nuclear counting techniques.