COMMENTS ON THE JANUARY 28, 1994 DRAFT OF EPA 40 CFR PART 194

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1 GENERAL OBSERVATIONS

1.1 NATURE OF THE CONTENT OF COMPLIANCE APPLICATIONS

Despite the implications of its title, the proposed regulation primarily addresses the content of compliance applications, rather than criteria, per se. By criteria, it is meant the specific standards which U.S. Environmental Protection Agency (EPA) will use to determine (judge) whether U.S. Department of Energy (DOE) has provided adequate measures to assure public health and safety and environmental protection. In addition to the sections beginning on pages 8 and 11 that are specifically called out as addressing "content," the introductory phrases to essentially every subsequent section require that the section define what the "compliance application must include." EPA may find it useful to: (i) restructure the proposed regulation to group all content information together and (ii) add criteria to the draft rule. This will clarify EPA's intent regarding compliance and will reduce redundancy.

1.2 FORMAT AND CONTENT OF DOE'S COMPLIANCE APPLICATION

The proposed regulations should consider any specific requirements for the format and content of DOE's Compliance Application.

1.3 QUALITY ASSURANCE

Citation: page 13, Quality Assurance

The current provisions appear to address only after-the-fact assessment of the quality assurance (QA) program that has been developed and implemented by the DOE. U.S. Nuclear Regulatory Commission (NRC) has found it prudent to become familiar with, review, and assess applicants' QA programs as early as possible. EPA should consider its role with respect to evaluation of DOE's QA program in the time period preceding submittal of a compliance application. (Suggest Office of General Council consider this, as well.)

1.4 INTENDED PURPOSE, SCOPE, AND APPLICABILITY

Citations: page 2, Purpose, Scope and Applicability; page 5 and 6, paragraphs (b)(4)(A and C); page 10, paragraph (3).

The scope of the proposed 40 CFR Part 194 is ambiguous. The title of the proposed rule indicates that it addresses "certification and determination of ... compliance with environmental standards for ... management and disposal..." [emphasis added], which leads to confusion. The "Purpose, scope, and applicability" section (page 2) indicates that it addresses only "disposal regulations at [of] 40 CFR part 191," where the definition of "Disposal regulations" limits the scope of the review of DOE's compliance application to only those items regarding waste disposal (i.e., 40 CFR Part 191, Subparts B and C only). This would not appear to include waste storage and management, which are addressed in 40 CFR Part 191, Subpart A.

Another area of ambiguity may include paragraph (b)(4)(A), of page 5, which appears to be most relevant to an operating facility at which emplacement operations are ongoing, which by definition

in 40 CFR 191.02(m) refers to a waste "management" activity. The criterion in (b)(4)(C), of page 6, also appears to be written for waste management.

In paragraph (3), of page 10, EPA's use of "assessments performed under 40 CFR part 191" may appear to require compliance with Subparts A, B, and C, since radiation safety assessments will be performed for the storage and management of wastes. It is our understanding that this rule will only apply to Subparts B and C.

Clarify whether the scope of the proposed regulations is to address the process of disposal as well as the performance of the repository subsequent to disposal of wastes.

1.5 ACTIVE AND PASSIVE INSTITUTIONAL CONTROLS

Citation: page 24 and 26, Active Institutional Controls and Passive Institutional Controls

The NRC assumes that active institutional controls will not be effective in preventing human intrusion for more than 100 years after facility closure. This assumption appeared to be prudent for a repository because no practical method has been identified to assure which active institutional controls will persist or will continue to be effective. Passive institutional controls, such as monuments, markers, and land use records, are likely to persist and be effective in deterring future human intrusion into a repository. Concerns about the scientific predictability of human intrusion are reflected in the Energy Policy Act of 1992 identification of postclosure oversight and human intrusion as subjects for the National Academy of Sciences (NAS) Committee on the Technical Bases for Yucca Mountain Standards (TYMS) Committee review. Predicting the probabilities of rare geologic events, such as volcanic activity at Yucca Mountain (YM), could prove nearly as challenging as predictions of human intrusion. Therefore, the NRC believes that rare geological events, along with human intrusion, should be included when considering whether it is possible to make scientifically supportable predictions of potential repository disruptions.

Since the TYMS Committee is currently examining the regulatory aspects of both active and passive institutional control, it is suggested that EPA reserve this section until the TYMS Committee has completed its studies and finalized its recommendations.

1.6 EXPERT JUDGEMENT (ELICITATION)

Citation: page 19 and 20, Expert Judgement

The requirement that "...any expert judgment processes shall be peer-reviewed" does not appear to be well founded and is certainly outside of currently accepted practice in this area. It is tantamount to requiring experts to review the results of experts. This process is not logically justified, since selection of the original expert panel should have drawn upon the best available talent in the pertinent disciplines. Any subsequent group of peer reviewers could be less competent to the task than were the members of the original panel of experts. In most circumstances, review in the open literature should be sufficient, assuming the authors attempt to publish the study. Alternatively, review by agency staff would suffice. The expert elicitation process for probability judgements is currently well established and not undergoing much change.

1.7 MISCELLANEOUS

The EPA is not encouraged to publish the proposed 40 CFR Part 194 without further solicitation of informal comments. The comments contained herein reflect significant questions and areas of concern, which appear to require more than editorial fixes.

The draft document may be unbalanced in the treatment of different key areas. For example, sections on expert elicitation, QA, peer review, and Complementary Cumulative Distribution Function (CCDF) construction may be detailed to the point of fixing how DOE will conduct its business. In contrast, the issue of alternative conceptual models is omitted in this document.

The role of the EPA is unclear in regards to determination of compliance. The compliance criteria that the EPA proposes should be concerned with the evaluation and determination or whether or not the DOE Compliance Application has demonstrated compliance with the regulatory requirements. The EPA should give the DOE latitude to use the best methods available or encourage the DOE to develop improved methods for demonstrating compliance. In most cases, the EPA should avoid telling the DOE how to conduct its compliance demonstration, especially in areas which have a history of standard practices (e.g., QA programs, design, peer reviews, or expert elicitations).

2 SPECIFIC OBSERVATIONS

2.1 § 194. DEFINITIONS

Citation: page 3, Definition of Quality Assurance

Quality assurance may not be defined in sufficiently objective terms to provide a sound basis for DOE development and implementation of an effective QA program nor for EPA to assess the adequacy of such a program. Another approach would be to base the quality program on items important to safety and important to waste isolation. Companion definitions of these terms would form a sound basis for development, implementation, and assessment of an appropriate QA program.

10 CFR Part 50, Appendix B provides a definition of QA that may be suited for site characterization, design, construction, and monitoring of a radioactive waste facility. The 10 CFR Part 50, Appendix B definition seems to be more consistent with definitions found in other quality standards, and does not appear to be narrowly focused (e.g., as specific to environmental monitoring).

2.2 § 194. CONDITIONS OF COMPLIANCE CERTIFICATION AND DETERMINATION

Citation: page 4, Conditions of Compliance Certifications and Determination

Historically, NRC has found it useful to provide in its rules the possibility of placing "conditions" or "restrictions" on the licenses granted to nuclear facility operators. NRC's regulation for disposal of spent fuel and high-level nuclear waste includes a section on this topic (see 10 CFR 60.43). Analogous provisions in 40 CFR Part 194 would augment those established for initially granting a certification of compliance, which are already provided in the draft rule (page 4). EPA should consider the appropriateness of including such provisions in 40 CFR Part 194.

2.3 § 194. CONTENT OF COMPLIANCE CERTIFICATION APPLICATION

Citation: pages 8-11, Content of Compliance Certification Application

Although the introductory paragraph [page 8, paragraph (1)] notes that this section addresses the "description of the disposal system and those features ... that may affect ... performance," it does not emphasize engineered components of the system. Rather, the focus is on various natural components of the disposal system. Likewise, the companion section on "design" [page 9, paragraph (2)] appears to focus on "materials of construction" and "codes and standards" used in the design. There appear to be no explicit requirements for: (i) design information regarding engineered features important to waste isolation, (ii) use of site characterization data in design, (iii) QA plans used in the characterization and design processes, and (iv) similar information that is needed to provide a basis for evaluating the assessments that will be provided in accordance with paragraph (3) of page 10.

The intent of paragraph (6) of page 10, regarding future drilling rates, appears to contradict the intent of the section "Consideration of Human-Initiated Processes and Events."

2.4 § 194. INSPECTIONS

Citation: page 12, paragraph (a); page 13, paragraphs (c)(1 and 2)

The EPA appears to have rather board latitude in obtaining access to any areas that they wish to inspect, including "other locations performing activities which provide information used to support any compliance application(s) to which the Department has access." It is not clear whether such access is necessary and how access to any facilities, including contractor, research, and administrative facilities, will be useful in determining the acceptability of the site under consideration.

The provisions for "unfettered and unannounced access" and the access during emplacement operations appear to be more related to the safe storage and management of wastes than to disposal performance assessment (PA). Clarify whether EPA desires such access within the scope of this regulation.

2.5 § 194. QUALITY ASSURANCE

Citation: pages 13-15, Quality Assurance

Paragraph (a), of page 13, seems to suggest requirements for QA plans for each of the eight functions listed. A single QA program may be appropriate for the full range of Waste Isolation Pilot Plant (WIPP) functions and activities, and should not be precluded. Also, a "quality assurance plan" suggests a plan to control future activities. At the time of the compliance application, most, if not all, of these activities will be completed.

Citation: page 14, paragraphs (a)(1) through (a)(8)

10 CFR 60.151 has taken an approach of applying QA requirements to the various phases of the repository program (i.e., site characterization, facility and equipment construction, operations, performance confirmation, and permanent closure), while 40 CFR Part 194 is much more specific to certain activities and functions. The major difference seems to be in lack of applicability of 40 CFR Part 194 QA criteria to facility construction and operations, and some aspects of site characterization. For example, (a)(3) does not comprehensively include important geological aspects such as stratigraphy and structural geological features. Furthermore, although "design" is noted in (a)(7), companion requirements related to aspects of construction, testing, and performance evaluations of engineered systems (e.g underground repository, shafts, boreholes, seals, waste forms, etc.) that may be important to the performance of the disposal system are not addressed.

Citation: page 14, paragraph (a)(6)

EPA may want to consider citing NUREG-1298, "Qualification of Existing Data for High-Level Waste Repositories," which provides appropriate guidance for addressing data not collected under an approved QA program, consistent with the level of guidance provided in NUREGs -1297 and -0856.

Citation: pages 14 and 15, paragraphs (b)(1) to (b)(5)

The criteria provided for QA programs appear only to address activity (a)(2), environmental monitoring, sampling, and analysis. Criteria are not provided for the other seven functions/activities listed in (a), nor are criteria provided for "planning, implementation, assessment, reporting, and quality improvement" as provided in the definition of QA (page 3).

The 18 criteria of 10 CFR Part 50, Appendix B, which are also applied through 10 CFR Part 60 to the High-Level Waste program, may provide requirements that cover the range of activities and items important to waste isolation at WIPP.

2.6 § 194. MODELS AND CODES

Citation: page 15, Models and Codes

The discussion provided here is not totally consistent with the definitions of "verification" and "validation" that are documented in the cited NUREG-0856. Despite the introductory statement that identifies what follows as "verification", the items delineated in (a)(2) are a mixture of verification and validation activities and criteria. In addition, the requirement that models, codes, and data be "subjected to peer review" [page 16, item (2)(E)] appears to be unduly restrictive. Neither the cited NUREG-0856 nor generally accepted practice support the need for such wide-spread peer reviews. It is also noted that there is a high degree of redundancy between sections (a) and (c) of this portion of the proposed rule (e.g., user's manuals, licenses, etc.).

Citation: page 15, paragraph (a)(2)(A)

This paragraph does not address alternate models, hence it fails to address a key area of regulatory concern.

Citation: page 16, paragraph (b)

This paragraph references NUREG-0856, which appears to be redundant with the comprehensive list of compliance application submittals required (paragraph 1) and the explicit list of documentation required in (c). NUREG-0856 adds nothing to these requirements, and may unnecessarily complicate the issues related to codes and models due to its applicability to: (i) high-level waste (HLW) (versus transuranics), and (ii) codes intended to be provided to NRC (versus being provided to EPA).

2.7 § 194. WASTE CHARACTERIZATION

Citation: page 17, paragraph (b)

The requirement that the DOE provide information on "each radionuclide" appears to be excessive. EPA should consider establishing levels (e.g., percentage of the inventory or total curie contribution) below which radionuclides need not be considered in PAs. A risk-based approach to establishing such criteria is suggested. In addition, EPA's proposed requirement that the applicant "quantify" the "waste form" is not clear in paragraphs [(b)(i) and (b)(i)(4)].

Citation: page 17, paragraph (b)(i)

The term to be generated appears to mean the wastes that do not exist today but will be generated by future activities. This term also be interpreted to mean the wastes generated by isotopic decay and daughter ingrowth or wastes to-be-generated by chemical decomposition of organic wastes as time proceeds. The term may require clarification.

Citation: page 18, paragraph (c)(1)

EPA should reconsider the requirement for "physical sampling to verify waste characterization." The radiological risks attendant to such sampling may not be warranted by the modest reduction in uncertainty that may be achieved regarding the characteristics of the waste form. Such actions are particularly difficult to rationalize given that paragraph (c)(2) requires the applicant to provide an extreme worst case analysis. A risk-based approach to assessing the need for such sampling is suggested.

2.8 § 194. FUTURE STATE ASSUMPTIONS

Citation: page 19, Future State Assumptions

EPA's address of "Future state assumptions" is an important step forward in addressing this difficult matter. However, the current language is somewhat confusing in its expression of what is not included. Suggest that this be revised to clearly indicate (i) how geologic, hydrologic, and climatic conditions should be addressed (e.g. based on the Quaternary record) and (ii) how other conditions (and what those conditions are) should be addressed (e.g. an assumed static biosphere).

2.9 § 194. EXPERT JUDGEMENT

Citation: page 19 and 20, paragraph (a)

A potential problem with this requirement is the determination of what constitutes reasonable effort to obtain information through data collection or experimentation. The elicitation approach permits the formal incorporation of subjective expert judgement into the decision process. This information supplements other sources, including the results of experiments and observations and modeling of physical and geochemical processes. The role of experts is not to create knowledge, instead it is to summarize and interpret the available information and to express what is known and what is not known."

It is suggested that this requirement provide more specific guidance on when expert elicitations are appropriate. For example, formal expert elicitations could be conducted under the following circumstances:

(i) Unobtainable data - extensive, noncontroversial data directly relevant to a problem are lacking

(ii) Importance of the issues - expert judgement will have a major impact on the judgement and/or the issue is receiving considerable scrutiny

(iii) Complexity of the issues - a problem is very complex or several experts are required for a judgement

(iv) Level of documentation required - formal methods promote complete and consistent documentation

(v) Extent of the use of expert opinion - expert judgements are used extensively in the decision making process

The EPA could cite reports that address these points.

Citation: page 20, paragraph (b)

It is suggested that EPA consider adding the following items to the listing of documentation associated with expert elicitations: (i) training and preparation received by the experts, (ii) statements and reports prepared by the experts in preparation for the elicitations, and (iii) statements and reports prepared in response to the elicitations.

Citation: page 20, paragraph (c)(1)

This may be unduly restrictive. The generalists recruited for the elicitation team in an expert elicitation should be fully aware of the reasons for the elicitation and the use of the product of the elicitation. Their input is fundamental to the design of the elicitation, and they play a very large role in understanding and interpreting the elicitation results. Generalists oversee completion of the PA and provide quality control for the PA models and resulting analyses. Hence, generalists are usually selected from among the professionals within the organization responsible for the PA.

Citation: page 20, paragraph (c)(2)

Again, this seems unnecessarily restrictive given the argument for paragraph (c)(1) and since conflict of interest is addressed in paragraph (c)(5)

Citation: page 20, paragraph (c)(3 to 5) and paragraph (d); page 21, paragraph (h)

These statements appear appropriate for a properly conducted expert judgement elicitation. However, the following are suggested wording changes. In paragraph (c)(3), suggest changing "At least one-half of the membership..." to "A majority of the membership...." In paragraph (c)(4), suggest changing "including <u>all</u> areas of expertise..." to "including <u>the scientifically prominent</u> areas of expertise...."

Citation: page 21, paragraph (f)

This requirement states one of the critical principles of all scientific research: any measurement should represent the underlying theoretical construct. Any expert elicitation should have high construct validity in that the data collected accurately reflects the issue under test. It is difficult to ensure construct validity outside of an experimental situation. However, this is a reasonable guideline, which any properly documented elicitation should provide.

Citation: page 21, paragraph (g)

This seems reasonable for any one parameter. However, in complex simulation models, it is difficult to determine *a priori* which value of any given parameter would contribute to the overall worst case scenario. Therefore, it might be more scientifically sound to incorporate the most likely values into a simulation and then place bounds of uncertainty around the outcome of that scenario. Therefore, it is suggested that this paragraph be deleted, since it may be inappropriate to dictate exactly how data obtained in an elicitation should be used in an analysis, which appears to be more within the discretion of the DOE.

Citation: page 21, paragraph (h)

It is suggested that the requirement for providing "an opportunity for presentation to the expert(s) ... views of groups and individuals other than those affiliated with the Department" be satisfied by the public hearing process or public meetings of appropriate federal advisory committees. Established practice for expert elicitations does not provide for public interactions of the sort described here, since they are not conducive to the thoughtful deliberative process that has been shown to be effective in eliciting the views of experts.

2.10 § 194. PEER REVIEW

Citation: page 22, paragraph (a)

In the HLW program, peer review is presented as a QA requirement. This paragraph implies that peer reviews are to be used (liberally) for expert elicitations, processes and events, QA programs, models and codes, and waste characterization. NUREG-1297 provides criteria for applying peer reviews that appear much more narrowly focused than in this paragraph. While verification of technical adequacy (e.g., technical review) is common, peer reviews are only necessary when there are significant uncertainties in data, methods, or interpretations.

Suggest "conforming to accepted scientific practices" may be a more reasonable approach, and in the absence of accepted scientific practices, peer review is warranted.

Citation: page 22, paragraph (b)

NUREG-1297 leaves considerable latitude in the structure of a peer review. It is primarily concerned with ensuring the quality of the peer reviewers and documentation.

2.11 § 194. CONSIDERATION OF HUMAN-INITIATED PROCESSES AND EVENTS

Citation: pages 22 to 24, Consideration of Human-Initiated Processes and Events

There have been technological and demographic changes over the past 50 years which may be reflected in the detailed historical record of the rate of intrusion in the Delaware Basin. The method chosen for establishing the drilling rates in the performance calculations may not be well founded. First, experience in the area during the last 50 years may not be relevant to practices that would be expected

under conditions of active and/or passive controls. Second, the suggested method does not distinguish between the types of drilling that have historically occurred in the area. The potential impacts of relatively shallow drilling (e.g., local water wells and potash exploration boreholes) are expected to be much different and less severe than those for deep drilling activities (e.g., oil and gas exploration). Also, without documented justification it may appear arbitrary to set the rate of future intrusion at an average value established over the previous 50 years.

Clairify the intent of the phrase "both natural" [page 22, paragraph (a)] in regard to this section.

The EPA may wish to consider changes in the compliance criteria that account for the level of drilling activity. The level of drilling activity should reflect the presence or lack of institutional controls. The NRC would suggest that an approach that is more flexible than the current choice might be appropriate, even though it may appear to be more challenging to incorporate into the compliance certification process. In implementing such an approach, the EPA may require an analysis that indicates the impacts of the assumptions made in the analysis of the human intrusion. This would provide EPA and other interested parties with information, such as the future level of drilling activity that would more clearly illustrate the level of confidence in achieving compliance.

The text vacillates between a very broad phrase "human-initiated processes and events" and the specific term "drilling," clarification on this point is requested.

2.12 § 194. COMPLIANCE

Citations: page 24, Compliance

There are several implications to specifying "At least 300" CCDFs in this rule that need to be carefully considered.

(i) This rule ties the compliance demonstration to a particular method (i.e., the Monte Carlo Method) with some sampling technique (e.g., Latin Hypercube). This method is currently favored by DOE and organizations associated with other waste programs but requires excessive computing time. To apply the method with a reasonable computing time, either the models are simplified, or the number of samples are limited, or both. Other techniques (e.g., importance sampling) are currently under investigation and may be adopted in the future. It may be preferable not to specify use of a particular method.

(ii) Strictly speaking, 40 CFR Part 191 requires the DOE to determine only two points on the CCDF—at probabilities of 0.1 and 0.001. The CCDF beyond (less than) these values is immaterial for compliance determination. With the Monte Carlo Method, obtaining these two points is no less expensive than obtaining many other points, and hence the full CCDF is usually plotted. It is possible to devise a method (one such was proposed in DOE's Yucca Mountain Site Characterization Plan) to determine just the two points, in which case not even a single CCDF will be obtainable.

(iii) The current compliance demonstration method followed by WIPP uses the following steps:

(a) Select a set of disjointed scenarios (what can happen) that are suitably parameterized; some of the parameters being uncertain

(b) Assign probabilities of occurrence to each scenario such that they add up to one

(c) Draw N samples (i.e., sample N equally likely future happenings)

(d) Assign probability distributions (multivariate if needed) to the uncertain parameters

(e) Draw M equally likely vectors from the parameter distributions

(f) Simulate system behavior (what may happen) for the first parameter vector for all of the N samples (scenarios or happenings) will result in N consequences being calculated

(g) Plot a CCDF from the N consequences calculated above

(h) Repeat the above steps M times for each parameter vector to plot M CCDFs

Note that each of the CCDFs is a complete representation of the system. The proposed language in the compliance rule implies that M has to be at least 300.

The above sequence of steps is not unique for obtaining a CCDF. For example, an alternate and more common sequence is as follows:

(i) Select a set of N scenarios and assign them probabilities

(ii) Parametrize the scenarios and select those that will be assigned statistical distributions

(iii) Draw M sample vectors (most commonly equally likely) from the parameter distributions

(iv) Simulate a scenario for each of the M vectors to obtain M consequences for that scenario

(v) Plot a CCDF for the scenario which is conditional on the scenario occurring and is called the conditional CCDF

(vi) Repeat steps (iv) and (v) to obtain conditional CCDFs for each of the N scenarios

(vii) Obtain a mean CCDF through a weighted sum of the conditional CCDFs, the weights being equal to the probabilities of the scenarios

The mean CCDF obtained this way and the mean of the M CCDFs obtained as explained above (first sequence of steps) are equivalent. However, by the alternate sequence of steps, 300 CCDFs would imply that 300 scenarios have to be considered.

If the EPA ties itself not only to a method, but also to a sequence of steps in that method, the number 300 will have no unique meaning.

(i) Two types of uncertainties are explicitly considered in the methods described above: uncertainties in defining the scenarios and uncertainties in the parameters. Not included in these methods are conceptual model uncertainties. The proposed requirement for at least 300 CCDFs does not address the exclusion of these uncertainties.

(ii) The number of parameter vectors required to obtain a 'converged' CCDF by either of the sequence of steps outlined above depends on: (i) the number of uncertain parameters, (ii) the extent to which consequences depend non-linearly on the sampled parameters, and (iii) the sensitivity of the CCDF to certain of the parameters. No unique way of calculating the minimum number of vectors required for a converged CCDF is known today. The EPA should require that the mean of the CCDFs has converged. The mean has converged when the rate at which the CCDF changes by the addition of more vectors is small.

The approach described by EPA in choosing the sample size for the number of CCDFs to generate is related to the subject of tolerance limits. Tolerance limits for continuous distributions describe a random interval within which a specified proportion q of a univariate population lies with a given probability $1-\alpha$ that the stated interval actually contains the proportion. They are based on transforming the sample order statistics (i.e., the endpoints of the tolerance interval), which depend on the unknown continuous distribution, to order statistics of a random sample of size N from a uniform distribution over the interval (0,1). This produces a distribution-free result.

Following EPA's argument it is possible to use tables for tolerance limits to determine the needed sample size to assure that at least 99 percent of the population for a univariate distribution is less than the maximum sampled value with 0.95 probability. From Conover (1980) the required sample size is 299. EPA rounded this value to 300 and used it in their compliance requirements.

The problem with this approach is that it assumes samples are taken from a univariate distribution. In this compliance area, the distributions are generally multivariate in nature and the CCDFs are often derived using many candidate variables. As such, the required sample sizes are necessarily based on the number of variables used in modelling the CCDF. Constructing tolerance limits for such a multivariate sample is much more complex, and more research would be needed to see whether multivariate tolerance results could be applied in this type of problem.

A second potential problem is the questionable value of tolerance limits in assessing the needed sample size for this type of problem. The issue of sample size for the CCDFs is much more complex than that of constructing a simple interval. There are other issues such as the efficiency of the sampler to generate the data, the various uncertainties (some subjective and some stochastic), the choice of variables in the models, etc. Sample size determination should somehow account for these variations.

Citation: page 24, paragraph (b)

If Latin hypercube sampling is chosen as the sampling method, this implies at least 300 sample elements will be generated. Since the use of a Latin hypercube sampler is known to be very efficient, it is questionable whether such a large sample size is always necessary. It is important that the number of sample elements (i.e., simulations) exceeds the number of variables, but, it is not clear that the number of variables will always be so large that 300 sample elements will be required. For example, if only 3 variables are available, the use of at least 300 CCDFs would far exceed those necessary to obtain good

estimates of the CCDFs. It appears a better approach would be to relate the required number of CCDFs to the number of potential variables. Whatever is chosen, justification for the selected number of CCDFs is suggested.

Another concern is over the fact that this large sample size is only helpful in tightening the confidence intervals for the family of CCDFs rather than the mean CCDF. The confidence interval for the mean would be controlled by the number of replicate samples as this uncertainty is associated with variation in the mean estimate.

Citation: page 24, paragraph (c)

This part relates to the use of the mean CCDF for determining compliance. The mean CCDF is only one of several ways for obtaining a single CCDF. Another popular statistical summary might be the median CCDF, as it could be argued that it would be less influenced by extreme values in the family of CCDFs. It is the concept of risk that drives this argument. Use of the mean curve implies an interest in the average risk, while use of the median implies an interest in the median risk. Regardless of what approach is chosen, loss of information on uncertainty is a consequence of taking a single curve to represent many different curves.

In the literature on risk, the average risk has historically been chosen as the best summary measure. There are many reasons for its popularity and these are tied to the usefulness of the mean as a measure of the central value of a distribution of many possible values.

2.13 § 194. ACTIVE INSTITUTIONAL CONTROLS

Citation: pages 24 and 25, Active Institutional Controls

Considering the statement in paragraph (b), "Performance assessments that assess isolation ... shall not consider any contributions from active institutional controls for more than 100 years after disposal," requiring "detailed descriptions of proposed active institutional controls" and "Assumptions pertaining to their effectiveness," in paragraph (a), appears unnecessary.

2.14 § 194. MONITORING

Citation: page 25-26, Monitoring

The monitoring program described here identifies actions that are potentially disruptive of the integrity of the natural and engineered systems that are intended to isolate the wastes. The parameters to be sampled under paragraph (c) would require, as a minimum: (i) boreholes and signal cables intruding the site, and (ii) development of potentially unfavorable local hydraulic gradients (due to extraction of brines and gases for analysis). It is not clear whether the added confidence in waste system performance that may be obtained from such a monitoring program offsets the added risks of compromising the long-term integrity of the natural and engineered systems.

2.15 § 194. PASSIVE INSTITUTIONAL CONTROLS

Citation: page 27, paragraph (b)

Considering the uncertainties associated with passive institutional controls and human behavior, clarify the intended purpose of having detailed descriptions of the period of time the controls are expected to endure and be understood. The requirement for DOE to include "detailed descriptions of the proposed passive institutional controls, their locations and the period of time the controls are expected to endure and be understood" appears to be in conflict with the Section "Consideration of human-initiated processes and events," in regards to assessing the potential for human intrusion.

2.16 § 194. ENGINEERED BARRIERS

Citation: pages 27 to 29, Engineered Barriers

The phrase "substantially delay" may require further clarification or guidance.

Citation: pages 28, paragraph (c)(1 to 10)

Some items listed as those to be considered in evaluating engineered barrier alternatives may be incomplete or questionable. Criteria are not given for making judgements of acceptability for items numbered (1) to (6) and (10). Although programmatically important, items (7) to (9) do not appear to be directly related to radiation or environmental safety.

In paragraph (4), clarify the intent as to whether to require that a waste package must be removable.

Citation: page 29, paragraph (d)

Explain how individual and various combinations of the engineered barriers (subsystem performance components) are determined to be adequate to assure meeting subsystem and overall system performance objectives.

2.17 § 194. CONSIDERATION OF THE PRESENCE OF RESOURCES

Citation: page 29, Consideration of the Presence of Resources

Statements, such as "likelihood of future human intrusion ... take into account the presence of resources" appear to be in conflict with the Section "Consideration of human-initiated processes and events," in regards to assessing the potential for human intrusion by drilling.

Citation: page 29, paragraph (c)

Considering the very specific nature of "assessing the likelihood and consequences of human-initiated processes and events" in paragraph (c), of page 23, there may be an inconsistency in the requirement to "consider human intrusion into the controlled area in search of all known resources" on page 29, paragraph (c).

2.18 § 194. REMOVAL OF WASTES

Citation: page 29, Removal of Wastes

The required plan for removal of wastes does not address any need to design and operate the facility to preserve the option for removal of wastes.

It appears the required plan for removal of wastes does not have to show that wastes could be removed within a reasonable time frame, since a period of removal is not defined. With the known salt creep rates at WIPP, a reasonable time for removal of wastes should be defined. Clarify whether the time period of assured removal of wastes should extend through the period of active institutional control.

The required plan for removal does not appear to indicate: (i) whether the potential removal of only a portion of the emplaced wastes, and (ii) whether placing backfill around the waste packages during emplacement are allowed.

2.19 § 194. CONSIDERATION OF PROTECTED INDIVIDUAL

Citation: page 30, Consideration of Protected Individual

Radiation protection for individuals should be applied in a reasonable manner. Individual protection standards should not attempt to protect all individuals, under all conceivable circumstances, at all times in the future. A standard should protect critical groups based on reasonable, realistic exposure scenarios. A fundamental dose standard would be acceptable, provided that such a standard could be implemented using some type of reference biosphere. A standard should not permit unlimited speculation about human locations, lifestyles, societal conditions, and worst-case exposures.

2.20 § 194. CONSIDERATION OF EXPOSURE PATHWAYS

Citation: page 30, Consideration of Exposure Pathways

Estimation of the maximum individual dose is strongly dependent on the rate of release of radioactive material to the environment, since the rate of release will largely determine the concentrations of radioactive material ultimately reaching an individual. The relative timing of releases of different radionuclides will also be important, since simultaneous release of two or more radionuclides will cause higher doses than would sequential releases. Finally, the estimated doses will depend strongly on whether the location and characteristics of the exposed individual are taken to be projections of current demographics and lifestyles or are defined in a manner that maximizes the doses that reasonably could be hypothesized to occur in the future.

The EPA should carefully consider whether the maximum individual dose or a critical group's exposure should be evaluated. The EPA may want to delay this section until the results of the TYMS Committee are available.

2.21 § 194. CONSIDERATION OF UNDISTURBED PERFORMANCE

Citation: page 31, Consideration of Undisturbed Performance

Clarify whether the "categories of events or processes" are to be considered the same as a series of events in a scenario, where four independent but sequential events with a 50 percent probability of occurrence during 10,000 years are excluded from consideration, because their combined probability ($0.5^4 = 0.0625$) would be less than one in 10?