RulemakingComments Resource

From: John Tauxe <jtauxe@neptuneinc.org>
Sent: Friday, July 24, 2015 4:58 PM
To: Gallagher, Carol
Cc: pblack@neptuneinc.org
Subject: [External_Sender] RE: comments submittal
Attachments: NRC Comments Neptune 2015-07-24 - 10 CFR 61.pdf; NRC Comments Neptune 2015-07-24 - NUREG-2175.pdf

Ms Gallagher -

Neptune is submitting the two attached memoranda in response to NRC's call for public comment on 10 CFR 61 and NUREG-2175.

Please see to it that these are appropriately entered into the NRC Docket.

Thank you!

- John

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24 July 2015

Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Rulemakings and Adjudications Staff

Subject: Comments on Proposed Revisions to Low-Level Waste Disposal Requirements 10 CFR part 61, 10 CFR part 20, and NUREG/BR-0204

Reference: Docket IDs NRC–2011–0012 and NRC-2013-0035

Dear Ms. Vietti-Cook:

Neptune and Company, Inc. (Neptune) is submitting the attached comments in response to the notices published in the 26 Mar 2015 Federal Register Vol. 80, No. 58, pp. 15930 *et seq*. and 16082 *et seq*. We appreciate the opportunity to comment on the proposed language for 10 CFR part 61 and 10 CFR part 20. We are also including comments on the associated *Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest* (NUREG/BR 0204, Rev. 2) of July 1998, as requested by NRC staff.

We believe that the revision to 10 CFR 61 and associated documents is a worthwhile endeavor that will lead to radioactive waste disposal decisions that are more beneficial for and protective of current and future generations.

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to Dr. Paul Black at (720) 746-1803 ext 1001 (pblack@neptuneinc.org), or Dr. John Tauxe at (505) 662-0707 ext 15 (jtauxe@neptuneinc.org).

Sincerely,

John Tauxe, P.E., Ph.D. and Paul Black, Ph.D.
Neptune and Company, Inc.

Comments on Proposed Revisions to Low-Level Waste Disposal Requirements 10 CFR part 61 and 10 CFR part 20, and to Possible Revisions to NUREG/BR-0204

Neptune and Company, Inc. (Neptune) appreciates the opportunity to provide comments on the U.S. Nuclear Regulatory Commission (NRC) proposed language for Code of Federal Regulations Title 10 Part 61 *Licensing Requirements for Land Disposal of Radioactive Waste*, on 10 CFR part 20 *Standards for Protection Against Radiation*, and on NUREG/BR-0204, *Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest* (Rev. 2, July 1998). We believe the NRC efforts are timely, and that revisions to these documents are sorely needed.

Comments on Proposed Revisions to 10 CFR Part 61

The document entitled *Comparison between Current Rule Language and Rule Language in Proposed Rule, "Low-Level Radioactive Waste Disposal" (80 FR 16082)* was provided for comment, and it contains sections of proposed revisions to the text of Part 61. Revisions are indicated in the document by the use of underlined text, and changed or omitted text is identified with strikeout. The proposed revisions have implications for most of the rule, and so we consider the entire rule to be "proposed". Some of the following comments therefore are oriented toward parts of 10 CFR 61 that are not proposed for revision, but are nevertheless in need.

Neptune has provided comments on previously proposed revisions to 10 CFR 61, in a memo dated 7 January 2013. While many of the issues raised in that submittal remain, we are pleased to see that many suggestions were adopted in the current proposed changes. This submittal focuses on the latest proposed revisions, but in some cases reiterates issues that were pertinent in 2013 and remain so today.

The comments below are organized into a General Comments section, with application to the overall rule, and a Specific Comments section, with comments following the same order as they appear in the proposed revisions document.

General Comments

Neptune is pleased to see most of the proposed changes to the regulation. We applaud the invocation of site-specific technical analyses and WAC development, and the incorporation of the structure of compliance and performance periods. While we still see little value in intruder assessments in supporting decision making, we are glad to see that these are no longer part of the performance assessment. Splitting these into separate analyses allows decision makers to more cleanly evaluate each on its merits.

The language of Part 61 could still use tightening up. A significant example of this is in the definition of the performance objectives, which apply in the title of §61.41 to the "general population", but in the text of the same subsection refer to "any member of the public". These terms are quite different from each other, but are sprinkled throughout Part 61 as if they were equivalent. Protection of the “general population” implies that a population risk assessment should be developed, and protection of “any member of the public” implies protection of anyone, including the most vulnerable members of the public. This is different from protecting an “average” member of the public, such as the “reference man” that is commonly used. It is good that the regulation strives to protect both the general population and any member of the public, and this can be done in a site-specific performance assessment, but the language needs to be cleaned up so that the two concepts are made to be clear and distinct. While the dose to any member of the public can be assessed against the performance objective of an annual maximum of 0.25 mSv, the population dose must be expressed differently. Note also that the term “general population” needs to be better defined in terms of the potentially affected population. The “general population” is too vague. That said, it may be that with the proposed site-specific performance assessment analysis both the individual and population doses can be assessed together. A population dose assessment will be required at any rate in order to assess whether doses are as low as reasonably achievable (ALARA).

We are encouraged to see explicit references to site-specific analysis of features, events, and processes, (FEPs), but would like to suggest that rather than FEPs being used to define exposure scenarios, that such possible scenarios be included in the analysis itself, making it an analysis of features, events, processes, and scenarios (FEPSs). Not all exposure scenarios results from an analysis of FEPs—some need to developed at the same fundamental level, rather than being an outcome of the FEPs analysis. Please consider adoption of the acronym “FEPS” in place of “FEP,” in recognition of the evolution of this concept.

Other items relevant to radioactive waste disposal under the purview of the NRC include the effects of the disposals on the environment. Since NRC is tasked with “protecting people and the environment”, one might expect that the analyses required in 10 CFR 61 would include ecological risk assessment as well as assessments of human health effects.

We also note that this is intended to be a regulation, but also contains guidance that should be removed to the supporting guidance document. The proposed regulation would benefit from being concise with supporting guidance in a separate document, instead of interspersing the regulations with text that is, essentially, guidance. Some examples are provided in our comments below.

Specific Comments

§61.2 Definitions.

Several terms are used in the existing and the proposed rule language that require definition in this section. These are

- member of the public
- general population
- reasonable assurance
- unacceptable risk

- disposal facility, disposal site, disposal unit (though these are covered in §61.7(a))
- low-activity waste
- high-activity waste
- radiation from the waste

The following existing definitions are proposed for revision, with specific comments following each. We note, again, that if a proper risk assessment is applied, then some of these terms are unnecessary, and the regulation could be simplified and brought in line with modern risk assessment practices.

Proposed definition:

Inadvertent Intruder means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, resource exploration or exploitation (e.g., well drilling) or other reasonably foreseeable pursuits that might unknowingly expose the person to radiation from the waste.

Comments:

We maintain that the distinction between an inadvertent intruder and any other member of the public should be dissolved. It is a completely unhelpful distinction that obfuscates a proper risk assessment.

The separation of the analyses for site-specific performance assessment and site-specific intruder assessment has ameliorated the problems introduced by previous use of generic intruder scenarios, but the definition of the inadvertent intruder remains troublesome for the following reasons.

Use of the word "person" (twice) becomes immediately problematic when the definition of "person" is considered:

> *Person* means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department of Energy (except that the Department of Energy is considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to law), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

Given this definition of "person", it is hard to imagine that this is all to be considered in the definition of inadvertent intruder, or anyone receiving a dose. A clarification is in order, perhaps by substituting another word for "person".

What is the meaning of the word "occupy" in this context? Does it mean that someone must set up residence on the site, or is a temporary visitation of the site considered an occupation? If a recreational hunter, for example, crosses the site and is unknowingly exposed to waste, or radionuclides that migrated from the waste, is that considered an occupation? Is such a visitor considered an inadvertent intruder? How is an analyst to consider the case where an intruder occupies the site, and while not receiving exposures, causes changes to the site that would expose some other member of the public? This could happen if the intruder triggers an erosional event that could expose waste and subsequent off-site migration of radionuclides that could result in exposures to a member of the public. The intruder is not exposed, but the member of the public is exposed due to actions of the intruder. This could potentially all be accounted for as a scenario (see FEPSs issue above) in a site-specific performance assessment, but it would not come to light in an intruder assessment.

Use of the terms “reasonably foreseeable” and “might” makes this definition quite vague in practice. Is it left up to the applicant to determine what constitutes “reasonable foreseeable pursuits”, and what “might” means in this context? Is an inadvertent intruder one who “might occupy the disposal site”, or one who actually “occupies the disposal site”? Our recommendation is that the “foreseeable future” should be defined site-specifically by the local (potentially affected) population and by considering economic arguments. This is how society operates in practice in our everyday lives.

Finally, the phrase “radiation from the waste” remains problematic in the context of inadvertent intrusion. Does this mean radiation only from the waste that is still in place as it was disposed? What if the waste has migrated, or what if the radionuclides that originated in the waste have migrated to a location where the intruder might come into contact with it, or at least be irradiated by it? Consider that radionuclides from the waste may have migrated to the ground surface, or to surface waters, and that such radionuclides would irradiate anyone who might traverse the area. Is such an individual to be considered an inadvertent intruder?

Ultimately, the distinction between an inadvertent intruder and other members of the public, or the general population, becomes blurred. We recommend that the concept of the inadvertent intruder be abandoned, replaced by a performance assessment that assesses risks to populations of individuals that are expected to occur at any given site. Such an approach would be far easier to communicate to the stakeholders, which is very important to gain approval and hence be able to open a disposal facility.

Proposed definition:

Intruder assessment is an analysis that (1) assumes an inadvertent intruder occupies the site or contacts the waste and engages in normal activities or other reasonably foreseeable pursuits that might unknowingly expose the person to radiation from the waste; (2) examines the capabilities of intruder barriers to inhibit an inadvertent intruder’s contact with the waste or to limit the inadvertent intruder’s exposure to radiation; and (3) estimates an inadvertent intruder’s potential annual dose, considering associated uncertainties.

Comments:

Given our views on the concept of the inadvertent intruder (above) it will be no surprise that we feel that the definition of an “intruder assessment” as distinct from a “performance assessment” is still not needed. If a performance assessment examines all site-specific exposure scenarios, then it will naturally account for all receptors as part of the general population, be they “intruders” or “members of the public”. This is overcomplicating what should be a straightforward problem.

Proposed definition:

Long-lived waste means (1) waste where more than ten percent of the initial radioactivity remains after 10,000 years (e.g. long-lived parent), ...

Comments:

We are glad to see that this definition has been clarified to the point where it can be clearly included in a technical analysis.

Proposed definition:

Site closure and stabilization means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

Comments:

It is not clear how such assurance can be provided. The language should be softened to explain the true intent. It is not possible to guarantee (assure) that stability will be maintained and that ongoing active maintenance will not be needed. Inserting the word “reasonably” in front of “assure” would at least make this consistent with other language in the rule.

Proposed definition:

Stability means structural stability.

Comments:

This definition is self-referential, and not particularly useful, even though we realize that the proposed revision is simply to correct a spelling error. The definition begs for discussion. What is the issue, actually? Is it exposure of the waste that is of concern? What about structural changes that do not release waste? What if waste is exposed to the environment through a structural failure but no one is exposed, and there is no dose or risk? Is the concern about stability simply for stability’s sake?

This issue is raised again in §61.7(f)(1) below, which further defines stability as minimizing contact with water (not really a structural stability issue), and also states that stability “isn’t necessary from a health and safety standpoint for most waste...” Well, if it is not necessary, what is the need for stability?

Since the regulation is supposed to support risk-informed decision making, it seems that the subject of site stability should also be framed in terms of risk. The basic definition in §61.44 indicates that the intent is to “eliminate to the extent practicable the need for ongoing maintenance of the disposal site following closure, so that only surveillance, monitoring, or minor custodial care are needed”. This, by itself, is a far better definition of site stability. Although it would be better again to regulate such that measures of site stability correspond to risk (dose).

§61.7 Concepts.

Proposed language:

§61.7(a) The disposal facility. [The contents of (1) and (2) are not reproduced here.]

Comments:

Sections 61.7(a)(1) and (2) clearly define the terms "disposal facility", "disposal site", and "disposal unit", but the use of these terms in the entire Part 61 seems to be inconsistent at times. Inconsistencies are identified in the comments below as they are identified. The entire text should be carefully reviewed to assure consistency in the use of these terms.

Proposed text:

§61.7(a)(2) ... In choosing a disposal site, site characteristics should be considered in terms of the indefinite future, take into account the radiological characteristics of the waste, and be evaluated for at least a 500-year timeframe [in order] to provide assurance that the performance objectives can be met.

Comments:

It is not clear what this means. How does this relate to the concept of a Compliance Period or a Performance Period? If a performance assessment is to estimate doses or risks for 10,000 years into the future, why would site characteristics be evaluated for only a 500-yr time frame?

§61.7(b) Performance objectives. Disposal of radioactive waste in land disposal facilities has the following safety objectives: protection of the general population from releases of radioactivity, protection of inadvertent intruders, protection of individuals during operations, and ensuring stability of the site after closure. Achieving these objectives depends upon many factors including the design of the land disposal facility, operational procedures, characteristics of the environment surrounding the land disposal facility, and the radioactive waste acceptable for disposal.

Comments:

We think that the concept of an inadvertent intruder should be removed, and the performance assessments should be aimed at doing a reasonable risk assessment. Protection of individuals during operations is handled through worker safety, and site stability can be folded into the risk assessment. Presumably a site would be judged sufficiently stable if the risks are low enough, or is there another reasonable approach to evaluating site stability?

Protection of the "general population" is called for, but, as pointed out above, this is different from protection of "any member of the public", which is required in §61.41. Again, a clarification of terms is needed. This seems to imply that the performance assessment should perform a population risk assessment, as opposed to (or perhaps in addition to) an assessment of dose to an individual. This is in concordance with the title of §61.41: Protection of the general population from releases of radioactivity. That title also seems to suggest that a population dose assessment is in order. As discussed in the comments below for that section, however, this is in conflict with the text within that section, which mentions dose to "any member of the public". The point of this comment is that the "general population" is in practice quite different from "any member of the public". Since §61.7 discusses concepts, it would be good to clarify the intent of the rule here as well as in §61.41.

Note that we support the need to perform a population risk (dose) assessment to support decision making, whether performed using the principles of ALARA or otherwise. Ultimately, siting of disposal sites was done by considering population risks.

The proposed text also neglects to identify the significance of human behavior and demographics in the assessment of risk to the general population and inadvertent intruders. These are among the "many factors" that should be mentioned specifically.

Proposed text:

§61.7(c)(3) ...some form of intruder barrier that is intended to prevent contact with the waste.

Comments:

This phrase appears at the end of the paragraph for (3). The problem here is that "receiving radiation exposure" is different from "contact with the waste". A future human could be some distance from the waste, at least from where it was originally placed, and still be exposed to radiation, while being exposed to radionuclides that have migrated away from the waste, or the progeny of those radionuclides. This begs the question of what is meant by "waste". Is it the waste form itself as disposed, or is it the radionuclides that were at one time part of the waste? This lack of firm definition plagues the bulk of part 61. These details may seem trivial to the casual reader, but they are critical to the analyst who must develop assessments that address the performance objectives in detail.

This could be perhaps rephrased, "...some form of intruder barrier that is intended to prevent contact with the disposed radionuclides."

Proposed text:

§61.7(f)(1) A cornerstone of the waste classification system is stability of both the waste and the disposal site, which minimizes the access of water to waste that has been emplaced and covered. Limiting the access of water to the waste minimizes the migration of radionuclides, which may avoid the need for long-term active maintenance and reduces the potential for release of radioactivity into the environment. While stability is desirable, it isn't necessary from a health and safety standpoint for most waste because the waste doesn't contain sufficient radionuclides to be of concern.

Comments:

This seems contradictory, in saying that stability is both a cornerstone of the waste classification system and that stability is not necessary. It also extends the original definition of "stability" (in §61.2, which says that stability means "structural stability") to claim that stability minimizes the access of water to waste. This seems to be confusing different concepts. Structural stability means that the site will not collapse, as in subside or erode—that it will retain its shape and strength. That really has little to do with keeping water out. Further, this focus on water belies a humid site bias—that water is universally the most significant process for contaminant transport in radioactive waste disposal. There are sites where water has a minor or even insignificant role to play—where, for example, biotically-induced transport or gas phase diffusion is of far greater significance than waterborne transport.

Structural stability has another unspoken but much more significant role: It keeps the waste from being exposed to the environment and especially from being directly exposed to human receptors. That function of stability is not even mentioned in this section.

It is somewhat jarring to read that "most waste ... doesn't contain sufficient radionuclides to be of concern." If that is the case, when what is all the fuss about in creating regulations for it in the first place? Perhaps this is just a confusion generated by poor presentation of context, however, as this section eventually seems to identify the waste under discussion as Class A waste, in the next part.

Why is site stability an issue? If it's tied to potential risk (dose), then that could make sense. But requiring stability with no metrics does not make sense, and the metrics should be dose (or release of radionuclides to the environment), which should be evaluated against the long term costs. Note that the Utah rule contains language that essentially suggests the intent of the stability requirement is to ensure that long-term maintenance is not needed—this suggests the need to evaluate risk and cost, which makes sense. The language in §61.44 already provides the necessary impetus for framing site stability in the context of risk (dose): "The disposal facility must be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required."

Proposed text:

§61.7(f)(1) [continued] This lower-activity waste (e.g. ordinary trash-type waste) tends to be unstable. If unstable waste is disposed with the waste requiring stability, the deterioration of unstable waste could lead to the failure of the system. The failure of the system could permit water to penetrate the disposal unit, which may cause problems with the waste that requires stability.

Comments:

This further confuses concepts. The real concern seems to be stability, which again is couched in terms of water even though it should not be assumed that water is the principal mode of contaminant transport at any given site. But, water aside, stability of the system (meaning the site, one presumes) may be compromised by unstable waste. Fair enough—so the operator should not mix structurally unstable waste with structurally stable waste. Activity has nothing to do with it, except that apparently we are not to be overly concerned with unstable low-activity waste, since it is not "of concern". If the classification of waste is driven by stability, which this section seems to imply, then let it be defined by stability, and not by concentration of specific radionuclides. Having classification tables based on radionuclide concentrations does not make sense if the real driving factor is structural stability of the wastes. Also, a properly formed risk assessment would take care of all of this, since it should factor in stability of waste.

Isn't "ordinary trash-type waste" what goes in a municipal landfill? This term is undefined and potentially misleading.

The language in this section goes on to discuss unstable Class A waste as opposed to stable Class

A waste, but makes no formal definitions of what "stability" means. §61.2 defines stability only as "structural stability", which is insufficient. Here, at least somewhat more of a definition is provided ""to maintain gross physical properties and identity [for] over 300 years." And, is this "stability" meant to apply to the waste form itself, or to the disposal unit (or perhaps even disposal site) as a whole?

It's interesting that 300 years is chosen. What is the basis for this value? Why is this different from other periods of concern in the proposed regulation? Consideration of dose to humans beyond 200 to 300 years has been documented as inappropriate in some articles. Is this the basis? Or, is the basis more simply that guaranteeing sufficient engineering for longer is not possible. This raises a few issues: Stability should be evaluated through risk, and if we cannot guarantee stability for more than 300 years, then why is a dose assessment needed much further out than that? An approach that is based on a revolving window of evaluation of shorter time frames would be preferable. Such an approach implicitly would acknowledge discounting, but in a reasonable way, and would need to be tied to funding guarantees.

Proposed text:

§61.7(f)(3) Waste that will not decay to levels which present an acceptable hazard to an intruder within 100 years is typically designated as Class C waste. Class C waste must be stable and be disposed of at a greater depth than the other classes of waste so that subsequent surface activities by an intruder will not disturb the waste. Where site conditions prevent deeper disposal, intruder barriers such as concrete covers may be used. The effective life of these intruder barriers should be at least 500 years.

Comments:

If it is true that "waste that will not decay to levels which [sic—should be "that"] present an acceptable hazard to an intruder within 100 years is designated as Class C waste", how is DU not a Class C waste? It decays to levels that are increasingly hazardous for over 2 million years. "Decay" does not imply a reduction in hazard.

It is also not clear why Class C waste must be disposed at greater depth. This statement is too general. A performance assessment should be performed, no matter the waste stream, to determine if a waste stream can be disposed in a given disposal configuration or engineered system. This also seems to presume that the pathway of interest is unvaryingly upwards. This might not be the case—for example, it is not clear that disposing deeper in a system that has potable groundwater at, say 5 meters below ground surface, would make sense.

Proposed text:

§61.7(g)(3) During the period when the final site closure and stabilization activities are being carried out, the licensee is in a disposal site closure phase. Following that, for a period of 5 years, the licensee must remain at the disposal site for a period of post-closure observation and maintenance to assure that the disposal site is stable and ready for institutional control. The Commission may approve shorter or require longer periods if conditions warrant. At the end of this period, the licensee applies for a license transfer to the disposal site owner.

Comments:

In the context of a 10,000-year Compliance Period, it is not clear how it is helpful to have a five-year post-closure period. In general, the language in §61.7(g) is very vague. Time frame is not well defined, and the nature and intent of the monitoring program is not well defined. It would be better to use some of the concepts from the DOE and from NUREG/CR-6948 on long-term PA maintenance, reduction in uncertainty, etc. to provide a technical framework and basis for long term monitoring and maintenance.

Proposed text:

§61.7(g)(4) After a finding of satisfactory disposal site closure, the Commission will transfer the license to the State or Federal government that owns the disposal site. If the U.S. Department of Energy is the Federal agency administering the land on behalf of the Federal government the license will be terminated because the Commission lacks regulatory authority over the Department for this activity. Under the conditions of the transferred license, the owner will carry out a program of monitoring to assure continued satisfactory disposal site performance, perform physical surveillance to restrict access to the site, and carry out minor custodial activities. During this period, productive uses of the land might be permitted if those uses do not affect the stability of the site and its ability to meet the performance objectives. At the end of the prescribed period of institutional control, the license will be terminated by the Commission.

Comments:

In this section, a “program of monitoring to assure continued satisfactory disposal site performance” is specifically mentioned. NRC would do well to broaden the concept of monitoring to encompass more than simply sampling for radionuclides that are headed for the fence line. As pointed out in NUREG/CR-6948, monitoring can and should include key elements of those processes that are known to be sensitive in the performance assessment in contributing to migration of radionuclides, and ultimately to receptor exposures. This could include, for example, monitoring for excessive water content in unsaturated materials, or a particularly dense population of deeply-rooted plants, if these are known to contribute to human exposures. This is addressed further in §61.12(l).

If a decision analysis structure based on a properly formed risk assessment were required, then all decisions concerning disposal of radioactive waste could be optimized (disposal, closure) and long term monitoring programs could be designed with stopping rules. Otherwise, long-term monitoring could continue indefinitely. As such, the performance assessment would become the decision document that it should be.

What happens to the site after the license has been “terminated by the Commission”? Is it assumed that the site poses no further risk to the public? How can the license ever be terminated in a case where radioactivity concentrations continually grow in time, such as for the disposal of DU?

§61.12 Specific Technical Information

Proposed text:

§61.12(a) A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description must include geologic, geotechnical, geochemical, geomorphological, hydrologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

Comments:

The second sentence should also include the word "demographic". We also suggest adding this sentence: "These features, events, processes, and exposure scenarios (FEPSs) must be related to their respective roles in both migration of and human exposure to radionuclides originating in the disposed waste."

Proposed (existing) text:

§61.12(b) ... For near-surface disposal, the description must include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; ...

Comments:

Somewhere in there should also be added "occurrence and activity of biota;".

Proposed (existing) text:

§61.12(l) A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration of radionuclides is indicated.

Comments:

As mentioned above in the discussion of §61.7(g)(4), NUREG/CR-6948 demonstrates that monitoring can and should include key elements of those processes that are known to be sensitive in the performance assessment in contributing to migration of radionuclides, or more to the point, risks to future humans.

The change to §61.12(l) that we would recommend, then, is to include more than simply monitoring for the migration of radionuclides. Once a sensitivity analysis of a probabilistic performance assessment is completed, the most significant features, events, processes, (FEPs) and exposure scenarios (FEPSs) in contaminant transport and human exposure can be identified, and it is these FEPSs that can be monitored (perhaps indirectly) to flag conditions that would lead to migration of radionuclides. It is best to mitigate migration pathways before migration has occurred. Language to this effect could be added to this section.

§61.13 Technical Analyses

Proposed text:

§61.13 The specific technical information must also include the following analyses needed to demonstrate that the performance objectives of subpart C of this part will be met. The technical analyses are one of the elements of the safety case. Licensees with licenses for land disposal facilities in effect on the effective date of this subpart must submit these analyses at the next license renewal or within 5 years of the effective date of this subpart, whichever comes first.

Comments:

We agree strongly that including all existing LLRW facilities in the regulatory update is important. If a facility is not able to demonstrate compliance with performance objectives as outlined in part 61, then they must engage in remedial actions that will bring about compliance, even if (or especially if) the facility is poised to be closed. Anything short of that is not fully protective of human health and the environment.

Proposed text:

§61.13(a)(1) Consider only features, events, and processes that might affect demonstrating compliance with §61.41(a).

Comments:

This language implies a scoping analysis, commonly known as a FEPs analysis. We would modify the language to include phenomena related to human exposures, as in "features, events, processes, and exposure scenarios": FEPSs. As discussed above, the inclusion of human exposure scenarios should be considered at this fundamental level of laying out the groundwork for the technical analyses, rather than developing scenarios based on just the features, events, and processes at work. Many scenarios do not naturally result from an analysis of FEPs alone, and are foundational in their own right, and they deserve a place in the expanded acronym, FEPS.

Proposed text:

§61.13(a)(5) Provide a technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes (e.g., of the engineered barriers, waste form, site characteristics) and interactions between the disposal facility and site characteristics that might affect the facility's ability to meet the performance objective in §61.41(a).

Comments:

It's not clear why this is being separated out, as this is a natural part of the FEPs scoping process. It could be eliminated because it is already covered by the FEPs process additions, and because Part 61 is meant to be regulation, not guidance. This entire section has become guidance it seems. The regulation would be better served by requiring a reasonable risk assessment (which should naturally include a scoping analysis) and providing performance objectives for comparison. This type of technical guidance should be removed.

If it is to remain, the word "naturalization" should replace "degradation, deterioration, or alteration", since it does not have a negative connotation. As discussed extensively during the NRC Workshop on Engineered Barriers in August 2010, the change of engineered barriers (and other parts of the system) to move toward natural conditions is not always detrimental to performance, and in any case must be recognized.

Proposed text:

§61.13(a)(4) Provide a technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models or empirical observations (e.g., laboratory testing, filed investigations, and natural analogs).

Comments:

This is a surprise as well. Why is this in the regulation? It is worthwhile, but not as part of the regulation. This is technical guidance.

It also would be good to specify what sorts of models are meant, here. It seems that it would mean computational models, but it could apply to conceptual models or mathematical models as well. Perhaps it should.

Proposed text:

§61.13(a)(7) Evaluate pathways including air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals.

Comments:

There is a mix of categories, here. Some of these are contaminant transport processes (plant uptake and exhumation by burrowing animals) but the others (air, soil, ground water, and surface water) are environmental media, rather than pathways or processes. Contaminant transport processes within these media might be diffusion, advection, chemical partitioning, etc. This distinction could be made. One drawback to include these, and only these, is that the list may become dated. As we learn more about the world of radionuclide contaminant transport, we find previously unknown or at least underappreciated mechanisms. For example, the only biotic pathways mentioned here are for plants and animals, but the potentially significant roles of mycological and microbiological entities are only now beginning to be appreciated.

Again, this is technical guidance and not regulation (it opens the door to dealing with biota, which is a good thing, but should be in guidance rather than regulation). As such, its presence in the regulation may not be appropriate. If it is retained, it should use more general language, rather than calling out specific mechanisms or materials.

Change “groundwater” to “ground water” in keeping with established NRC style.

Proposed text:

§61.13(a)(6) Account for uncertainties and variabilities in the projected behavior of the disposal system (e.g., disposal facility, natural system, and environment).

Comments:

This implies that the performance assessment be probabilistic. However, nothing else in the regulation explicitly requires this accounting for uncertainty. Obviously, we think this is needed, but some other adjustments to the regulation are really needed to go along with this.

As a companion section, we would also propose the following (to follow §61.13(a)(6):

§61.13(a)(8½) Account for uncertainties and variabilities in the projected demographics and behavior of human receptors.

Since the principal performance objectives for future humans is one of dose (or risk) to any member of the public (and/or to the general population), uncertainties and variabilities in the human element must be considered. These have the potential to be of greater significance than disposal system behavior in determining the risk and its uncertainty.

Proposed text:

§61.13(a)(9) Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding, and evaluate the effects that alternative conceptual models have on the understanding of the performance of the disposal facility.)

Comments:

In addition to alternative conceptual models, alternative implementations as mathematical models could be considered (e.g. various representations of porous medium tortuosity). This could further be extended to alternative computational modeling implementations. The same system could be modeled as a system model, or as a process model using finite-difference, finite-element, or some other discretization paradigm. Solutions could be implicit, explicit, or hybrid. All of these variations could produce somewhat different results, and all will no doubt evolve as better technologies are developed. The question is how far do we want to take this evaluation of alternative approaches? Perhaps the proposed language is sufficient.

At any rate, this is guidance, not regulation. It is not useful for the regulation to instruct analysts to merely "consider" an approach, but it would also be inappropriate to here require that specific approaches be tried.

If this section is to remain, then we would further suggest that "features and processes" be expanded to "features, events, processes, and exposure scenarios" so that alternative conceptualizations of events and of the human element would be considered.

Proposed text:

§61.13(a)(10) Identify and differentiate between the roles performed by the natural disposal site characteristics and design features of the disposal facility in limiting releases of radioactivity to the general population.

Comments:

While this is an important activity to be performed as part of performance assessment, this is again guidance, not regulation.

Proposed text:

§61.13(b) Inadvertent intruder analyses that demonstrate there is reasonable assurance that:

(1) the waste acceptance criteria developed in accordance with § 61.58 will be met,

(2) adequate barriers to inadvertent intrusion will be provided, and

(3) any inadvertent intruder will not be exposed to doses that exceed the limits set forth in § 61.42 as part of the intruder assessment. An intruder assessment shall:

(i) Assume that an inadvertent intruder occupies the disposal site at any time after the period of institutional controls ends, and engages in normal activities including agriculture, dwelling construction, resource exploration or exploitation (e.g., well drilling), or other reasonably foreseeable pursuits that are consistent with activities in and around the site at the time of closure and that unknowingly expose the intruder to radiation from the waste.

(ii) Identify adequate barriers to inadvertent intrusion that inhibit contact with the waste or limit exposure to radiation from the waste, and provide a basis for the time period over which barriers are effective.

(iii) Account for uncertainties and variability.

Comments:

NRC is moving in the wrong direction with respect to assessing inadvertent intrusion. It’s not that inadvertent intrusion should not be evaluated—it must be—but rather that it be considered fundamentally different from other types of site occupation. Rather than develop or suggest particular scenarios as done in (i) above, and rather than develop a separate “intruder assessment,” a site-specific performance assessment can cover all of this by evaluating likely future scenarios of who might occupy the site and what they might be doing. It must be recognized that agriculture, dwelling construction, and resource development are not universally normal activities. There could be disposal sites where none of these would be considered likely enough to survive a scoping analysis, let alone become part of a model. On the other hand, there are sites where all of these could happen, although with some likelihood that is probably less than 1 every year for in 10,000 years. There are still other activities that could lead to future waste releases or exposures, but would not of themselves be considered intrusive—consider the recreationalist who may intrude into the site and, while not being exposed, causes future failures of waste containment that might expose others in the future. The variation in likely activities between sites is part of what makes them different, and is important information for a site-specific performance assessment to incorporate.

Future humans who would intrude inadvertently into the waste should be considered just as any future member of the public would be considered, and with the same dose or risk metrics. However, the likelihood of any activity should also be considered, as the risk to future individuals is consolidated into a composite risk for the general population. There will be some individuals who experience greater exposures through their behavior or the activities of others, and there will be differences in how each individual responds to a given exposure. The language of risk to the general population and to any member of the public has been in Part 61 all along, but it has never been adequately spelled out. More of this discussion follows in comments to §61.41 below.

Under our recommendation it would still be possible to distinguish between receptors that are deemed MOP or IHI, but only for the purpose of comparison to the appropriate performance objective. This would, however, assume that an inadvertent intruder should not be as protected as a MOP, which might not make sense when performing a proper risk (dose) assessment.

In the proposed construction of both a PA and an IA, the decision making driver is not clear. How will the IA be used to support decision making? Since an IA is by design likely to be highly conservative, it is important that the results of the IA be used to provide insights into the disposal system, rather than to supplant, or even append to, the decisions that are supported by a properly formed PA. Too often in the past intruder analyses have been used to set WACs, for example. This is very unfortunate, since it unnecessarily limits disposal capability, and disposal systems are a precious commodity under current regulation and licensing requirements.

Proposed text:

§61.13(e) Analyses that assess how the disposal site limits the potential long-term radiological impacts, consistent with available data and current scientific understanding. The analyses shall be required for disposal sites with waste that contains radionuclides with average concentrations exceeding the values listed in table A of this paragraph, or if necessitated by site-specific conditions. For wastes containing mixtures of radionuclides found in table A, the total concentration shall be determined by the sum of fractions rule described in paragraph 61.55(a)(7). The analyses must identify and describe the features of the design and site characteristics that will demonstrate that the performance objectives set forth in §§ 61.41(c) and 61.42(c) will be met.

Table A - Average Concentrations of Long-lived Radionuclides Requiring Performance Period Analyses

Radionuclide	Concentration (Ci/m^3)[1]
C-14	0.8
C-14 in activated metal	8
Ni-59 in activated metal	22
Nb-94 in activated metal	0.02
Tc-99	0.3
I-129	0.008
Long-lived alpha-emitting nuclides[2]	[3] 10
Pu-241	[3] 350
Cm-242	[3] 2,000

[1] Values derived from § 61.55 Class A limits.
[2] Includes alpha-emitting transuranic nuclides as well as other long-lived alpha-emitting nuclides.
[3] Units are nanocuries per gram.

(f) Analyses that demonstrate the proposed disposal facility includes defense-in-depth protections..

Comments:

Clarification is needed for use of the term "waste" in the phrase "waste that contains radionuclides with average concentrations exceeding the values listed in table A of this paragraph". Is the waste to be the waste that was originally disposed, but has gone through 10,000 years of decay and ingrowth? Or is it the concentration of radionuclides that remain in the waste zone (that volume where the waste was originally disposed) at 10,000 years, or something else? This requires clarification for analysts to be able to implement it properly.

With respect to Table A formatting: In other parts of part 61, the NRC has adopted metric units, as it should by Executive Order 12770 (56 FR 35801, 1991), but switching dose units from rem to Sieverts. The same approach needs to be taken here, replacing Curies (which are not SI) with

Becquerels (Bq, or GBq, as appropriate.) For reference, 1 Ci/m^3 = 37 GBq/m^3. It may be permissible to include units in Ci for transitional use, as is done with mrem. Further, to have part of the table in volumetric concentration units GBq/m^3 (or Ci/m^3) and part in mass concentration units Bq/g (or nCi/g) with the title in volumetric units is confusing. A clearer version of this table follows, though our preference would be to remove the decremented Ci units altogether:

Table A - Average Concentrations of Long-lived Radionuclides Requiring Performance Period Analyses

Radionuclide	Concentration[1]
C-14	30 GBq/m^3 (0.8 Ci/m^3)
C-14 in activated metal	300 GBq/m^3 (8 Ci/m^3)
Ni-59 in activated metal	810 GBq/m^3 (22 Ci/m^3)
Nb-94 in activated metal	0.74 GBq/m^3 (0.02 Ci/m^3)
Tc-99	11 GBq/m^3 (0.3 Ci/m^3)
I-129	0.3 GBq/m^3 (0.008 Ci/m^3)
Long-lived alpha-emitting nuclides[2]	370 Bq/g (10 nCi/g)
Pu-241	13,000 Bq/g (350 nCi/g)
Cm-242	74,000 Bq/g (2,000 nCi/g)

[1] Values derived from § 61.55 Class A limits.
[2] Includes alpha-emitting transuranic nuclides as well as other long-lived alpha-emitting nuclides.

§61.41 Protection of the general population from releases of radioactivity

Proposed text:

§61.41(a) Concentrations of radioactive material that may be released to the general environment in ground water, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 0.25 milliSievert (25 millirems) to any member of the public within the compliance period. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable during the compliance period. Compliance with this paragraph must be demonstrate[d] through analyses that meet the requirements specified in §61.13(a).

(b) Concentrations of radioactive material that may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall be minimized during the protective assurance period. The annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(a).

(c) Effort shall be made to minimize releases of radioactivity from a disposal facility to the general environment to the extent reasonably achievable at any time during the performance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(e).

Comments:

This is a welcome direct invocation of ALARA, which is appropriately applied to assessments of dose (or risk) to the general population. But while the term “general population” is used in the title, the text of this section uses the phrase “any member of the public”. These are conceptually different. If we are to accept the phrase “any member of the public” at face value, then this implicitly means that the most vulnerable members of the public should be protected. This would include children, for example, who generally incur higher risks from exposure to radionuclides in the environment than do adults, due to both behavioral and physiological differences.

In performing a risk assessment of the general population, such members of the public should be considered, as should anyone else deemed to be exposed to radionuclides disposed at the site. This is where the so-called “inadvertent intruder” can be included as well, as a member of the public (i.e., as a potential receptor), rather than couched in some distinct assessment. The proper way to go about doing a population risk assessment is to consider who the receptors would be, what activities they would be pursuing, and what exposures they would encounter. Each receptor has its own likelihood of encountering radioactivity, for different amounts of time, in different exposure media, and with different physiological responses based on age, for example, as outlined in ICRP documents. This approach evaluates risks to each individual member of the public as well as the general population, and is required to satisfy the language of the title and text of this section.

The same comments (see response to §61.13(a)(7)) about using language that considers only part of the biotic spectrum applies here as well.

An additional problem is presented with the use of the term “effluents” in §61.41(a). It seems to be assumed that the only mechanisms for the migration of radionuclides from the waste into the larger environment involves effluents, but this is not the case. Plants translocate chemicals (including radionuclides) within their tissues, though the fluids in plant tissues might be considered effluents. Burrowing animals move bulk soils, which are not effluents. Erosion can cause bulk movement of solid materials as well—again, not effluents. Atmospheric dispersion transports radionuclides from the ground surface that are not “effluents”. Perhaps this language can be remedied by substituting something like “...effluents and other mechanisms of contaminant transport...”. Alternatively, a sentence structure could be used that does not use the word “effluents” at all, as in §61.41(c).

This is another instance of guidance being included in the proposed regulation.

§61.42 Protection of inadvertent intruders

Proposed text:

§61.41(a) Design, operation, and closure of the land disposal facility must ensure protection of any inadvertent intruder into the disposal site who occupies the site or contacts the waste at any time after active institutional controls over the disposal site are removed. The annual dose must not exceed 5 milliSieverts (500 millirems) to any inadvertent intruder within the compliance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(b).

(b) Design, operation, and closure of the land disposal facility shall minimize exposures to any inadvertent intruder into the disposal site at any time during the protective assurance period. The annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(b).

(c) Effort shall be made to minimize exposures to any inadvertent intruder to the extent reasonably achievable at any time during the performance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(e).

Comments:

This language clarifies the allowable dose to an inadvertent intruder, but still we have members of the public who might be considered intruders who “fall through the cracks”. Consider the case where an initial visitor to the site causes a disturbance to the engineered or natural barriers, and a later visitor is exposed to radioactivity. The initial visitor is not considered an intruder by the definition in this part, since s/he does not actually come into contact with the waste. Assume that this initial disturbance, however, compromises the integrity of the site in such a way that it causes radioactivity to be released after some time. A later visitor to the site, who would be a member of the public because s/he would cause no disturbance of the site, could be exposed to that released radioactivity, or conceivably to the waste itself. How is this case to be considered given the definitions of “inadvertent intruder” and “member of the public” in this part? Here we have what seems to be an inadvertent intruder who is not exposed and a member of the public who could come into direct contact with the waste.

As described in comments made above, it would be far more straightforward to dispense with these definitions, and consider this receptor as someone who should be protected to the standard presented in §61.41.

§61.50 Disposal site suitability requirements for land disposal.

Comments:

Neptune has only two editorial comments for this section:

§61.50(a)(1)(ii): Change “which” to “that”.

§61.50(a)(4)(i): Remove the superfluous phrase “Within the region or state where the facility is to be located,”.

§61.58 Waste Acceptance

Proposed text:

§61.58(b) Waste characterization. Each applicant shall provide, for Commission approval, acceptable methods for characterizing the waste for acceptance. The methods shall identify the characterization parameters and acceptable uncertainty in the characterization data. The following information, at a minimum, shall be required to characterize waste:

(1) Physical and chemical characteristics;
(2) Volume, including the waste and any stabilization or absorbent media;
(3) Weight of the container and contents;
(4) Identities, activities, and concentrations;
(5) Characterization date;
(6) Generating source; and
(7) Any other information needed to characterize the waste to demonstrate that the waste acceptance criteria set forth in § 61.58(a) are met.

Comments:

This gets to the practical approach of defining a methodology. It is good to require "acceptable methods for characterizing waste for acceptance", and the data required are reasonable for supporting development of a WAC, in addition to a site-specific performance assessment. Since these data will change as disposal operations proceed, however, it is not sensible to require the data itself as part of a license application. It is reasonable to indicate that these data could be made available, and it is reasonable to indicate how the data would be used in developing a WAC.

Section 61.58 (b)(7) asks for "any other information", leading to two issues that we think need to be addressed in waste manifesting. Those are lower limits of detection (LLDs) and an estimate of uncertainty in reported values. The lack of uncertainty information frustrates the ability of a probabilistic performance assessment to "provide reasonable assurance of compliance with the performance objectives of subpart C of this part," as required in §61.58(a). Further discussion of these issues is developed in our comments on NUREG/BR-0204 included in this submittal.

Proposed text:

§61.58(c)(1-4) Waste certification. Each applicant shall provide, for Commission approval, a program to certify that waste meets the acceptance criteria prior to receipt at the disposal facility. ...

Comments:

We interpret this as asking for a program that will need to be statistically based in order to justify that the waste that is accepted is properly characterized for disposal. We are pleased that NRC encourages better characterization and specification of waste concentrations so that disposal can be more effectively managed. With improved characterization and manifesting, including appropriate reporting of LLDs, radioactive waste disposal resources can be better utilized.

This concludes comments from Neptune and Company, Inc. on the proposed revisions to 10 CFR part 61.

Comments on Proposed Revisions to 10 CFR Part 20

Neptune has but one substantive comment on the proposed changes to 10 CFR part 20. We encourage NRC to consider the inclusion of language regarding uncertainty in the characterization of radioactive wastes manifested for disposal. Uncertainty in reported estimates is certainly present, and understanding the degree of uncertainty is critical to efficient use of disposal resources and to estimations of risks to workers and to the public.

Other issues that seem to be unaddressed include the role of LLDs in determining compliance with WACs, and methods for establishing WACs based on a probabilistic performance assessment. If WACs are based on mean concentrations (for example) from a PA, then it is not clear that all manifested waste needs to meet the WAC, but only that on average the waste needs to meet the WAC. Perhaps the intent is to determine a WAC such that satisfying the WAC for each waste manifest guarantees that the mean will be less than the WAC, but the guidance is not clear on this issue.

This concludes comments from Neptune and Company, Inc. on the proposed revisions to 10 CFR part 20.

Comments Regarding Revisions to NUREG/BR-0204

Neptune and Company, Inc. (Neptune) appreciates the opportunity to provide comments on possible changes to the U.S. Nuclear Regulatory Commission (NRC) *Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest* (NUREG/BR-0204, Rev. 2) of July 1998. Comments were requested by NRC as part of the *Public Workshop to Discuss Potential Revisions to NUREG/BR-0204 Rev. 2* on 1 March, 2013, in Phoenix, AZ. This seems to be associated with Docket ID NRC-2013-0035.

The comments below are organized into a General Comments section, with application to the overall document, and a Specific Comments section, with more specific and editorial comments.

General Comments

Definition and use of the lower limits of detection

Comment:

Discussion of using the lower limit of detection (LLD) occurs on page 12 of the Brochure. This discussion is a bit confusing in that the LLDs get reported in different ways, but the larger problems are 1) how the values reported on the manifests are used by radioactive waste disposal operators, and 2) how the LLDs are defined in the first place.

It is our understanding that some operators enter the LLD values, as reported, into their waste inventory databases, and other enter values of zero for reported LLD values. This has the potential of introducing error and uncertainty into the waste inventory for a disposal site, which runs counter to the efficient use of the site. Uncertainties in this case are difficult to quantify, and so must be overestimated. This obfuscates effective decision making on the part of the disposal site operator and regulator.

There are other issues that need to be addressed in manifesting or reporting waste concentrations. These include the number of samples that need to be taken on a waste stream, and when and where in the waste cycle those samples should be collected. This could be framed in terms of EPA's DQO process. This could also address scaling (which should be done statistically between lab data and screening measurements so that uncertainty is honored, and the necessary relationships can be formed – single values for scaling factors are insufficient).

The main focus of the changes to BR-0204 is the "phantom four", and issues that arise when measuring low quantities, or counts. An apparent challenge for the environmental/waste industry is understanding the power of statistical methods, and how they should be used. Chemists tend to censor data, essentially making datum-based decisions (this is natural since chemists are trained to think about each individual sample). However, it is rare that decisions are made on a datum rather than on data. Enough data should be collected for a waste stream to evaluate the data collectively. This is also appropriate from the perspective of supporting risk (dose) assessment, which is based on averages (i.e., data, not datum). If this approach were taken, then the need for LLDs for low-level radioactive measurements could be removed. Radioactivity data include ambient background subtractions, which can cause negative responses. Statistical methods can account for this properly. In fact, statistical methods are better suited to handle such uncensored data than censored data. Censoring implies loss of information, which is difficult to overcome. So, an option is to abandon LLDs in favor of straightforward waste characterization.

Otherwise, if LLDs continue to be entertained, the approach that Currie first described for estimating LLDs is reasonable, but was not adequately implemented in NRC's NUREG/BR-0204. The challenge, which Currie addressed, is that multiple samples of LLDs should not be combined.

The more complicated situation is waste that is characterized through scaling factors. Low counts then present different challenges, because the regression between lab data and (field) screening data can depend on the relationship at low counts, and the screening instruments are not usually set up for ambient subtractions. In effect, applying scaling at the sensitivity of the methods is unlikely to work very well.

In general, these types of statistical issues need to be addressed, and, based on this research, some simple, better, rules for manifesting are needed that will better support Performance Assessment.

Specific Comments

Existing text, p. 3:

Note: The NRC requires all uses of the Uniform Manifest forms to report information in metric units, and all the forms have been developed for the use of metric units.

Comment:

The manifest forms themselves go so far as to specify use of SI units in many cases, which is even more strict than "metric". This is all to the good, and we appreciate that NRC has adopted metric and SI units (and metric units, where SI is impractical, such as the use of "yr" rather than "s" for time) in its work. This needs to be extended into the revisions of 10 CFR part 61 and part 20 as well.

Existing text, p. 9:

13. Transport Index – See DOT regulations at 49 CFR 173.403. This is a dimensionless number which, for nonfissile material packages, is equivalent to the radiation dose in millirem per hour at one meter from the surface of the package.

Comment:

This is inconsistent with NRC's use of SI (or metric) units, and is also somewhat nonsensical. Rather than being dimensionless, this number indeed has dimensions of dose rate, and even specifies the units as millirem per hour. However, it is recognized that this may stem from a DOT regulation, and that the linkage to 49 CFR 173 needs to be maintained. Unfortunately, if the "Transport Index" is enshrined in that regulation and is reported as a dimensionless number, (even though it is not) then changing its basis from millirem per hour to milliSieverts per hour would introduce significant confusion. So, it may be best left alone. At any rate, NRC could provide in this brochure the SI equivalent to millirem, as in "...millirem per hour (equivalent to 10 microSieverts per hour) at one meter..."

Existing text, p. 11:

1. Manifest Totals - ... and the total net weight (kilograms).

Comment:

Kilograms are not a unit of weight, but rather mass, so the text should be changed to "...and the total net mass (in kilograms)." This error is repeated in several places in the Brochure, including two in the second paragraph on page 12. Just search on "weight" and find the others. This is also incorrectly referred to as "weight" on Forms 540 and 541, even when the units of "kg" are specified.

Existing text, p. 18:

15. Radiological Description – This information may be presented in either of two ways. First, list all significant radionuclides...

Comment:

The definition of "significant" is provided on p. 20, with several trigger concentrations that make it so. But all these trigger values are given in terms of activity concentration, such as MBq/cm^3. It needs to be clarified what is in the denominator of this calculation—that is, cm^3 of what, exactly? Is it a local concentration within the larger package, or is it a bulk concentration considering the entire volume of the shipped package?

Existing text, p. 19:

[15. Radiological Description – continued] **OR**, alternatively, for container containing a single waste type, enter the total megabequerels [sic] in the container ... and enter the percentage of each radionuclide.

Comment:

The problem here is that what is not specified is percentage by *what*? These values could have radically different values depending on if they are reported as percentage by volume, percentage by mass, or percentage by activity. This needs to be clarified.

Also, "megabecquerels" is misspelled in the Brochure.

This concludes comments from Neptune and Company, Inc. on revision of NUREG/BR-0204.

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24 July 2015

Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Rulemakings and Adjudications Staff

Subject: Comments on Guidance for Conducting Technical Analyses for 10 CFR Part 61 (NUREG-2175, Draft Report for Comment)

Reference: Docket ID NRC–2015–0003

Dear Ms. Vietti-Cook:

Neptune and Company, Inc. (Neptune) is submitting the attached comments in response to requests for comment on the proposed *Guidance for Conducting Technical Analyses for 10 CFR Part 61*, NUREG-2175 (Draft Report for Comment).

We believe that the revision to 10 CFR 61 is a worthwhile endeavor that will lead to radioactive waste disposal decisions that are more beneficial for and protective of current and future generations, and that the supporting guidance is important for achieving consistent and effective implementation of part 61.

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to Dr. Paul Black at (720) 746-1803 ext 1001 (pblack@neptuneinc.org), or Dr. John Tauxe at (505) 662-0707 ext 15 (jtauxe@neptuneinc.org).

Sincerely,

John Tauxe, P.E., Ph.D. and Paul Black, Ph.D.
Neptune and Company, Inc.

Comments on Guidance for Conducting Technical Analyses for 10 CFR Part 61 (NUREG 2175)

Neptune and Company, Inc. (Neptune) appreciates the opportunity to provide comments on the U.S. Nuclear Regulatory Commission (NRC) proposed *Guidance for Conducting Technical Analyses for 10 CFR Part 61* (NUREG-2175), provided as a draft report for comment.

The comments below are organized into a General Comments section, with application to the overall rule, and a Specific Comments section, with comments following the same order as they appear in the proposed revisions document.

General Comments

This guidance for technical analyses required by the proposed revisions to 10 CFR 61 is welcome. The bulk of the document is well written, and it is clear that the authors put a lot of thought and care into its development.

The draft NUREG-2175 suffers from occasional redundancy, and some disconnects in the flow of development of concepts, especially in the early sections, but these shortcomings could be addressed with some additional careful technical editing.

Specific Comments

§ 1.1.2 Safety Case

It remains unclear how the safety case is to be constructed. It seems that this is a collection of documents and analyses required to demonstrate adequate protection of public health, but the mechanics of how all these analyses are to be collected into a Safety Case is lacking. Admittedly, this is a new concept (for US regulators) and will require vetting and the development of examples. Is the Safety Case a document that serves as a wrapper for the performance assessment (PA), intruder assessment (IA), defense-in-depth analysis, etc.? Please provide clarity on what is expected in terms of a license applicant's submittal.

§ 1.1.4.1 and 3.0 Performance Assessment

Bullet (8): Uncertainty addresses the contaminant transport part of a PA, whereas the exposure part is better addressed through variability (population characteristics per EPA's description of probabilistic risk assessment). Variability should not be used directly in the projected behavior of the system except to inform the uncertainty in the mean estimates.

An issue with section 1.1.4.1 is that it addresses modeling for the sake of modeling. Modeling should be performed in some context of the decisions to be made. Compliance decisions are insufficient for evaluating the efficacy of a disposal system and optimizing disposal, which are critical for maximizing use of these precious resources (disposal systems). Modeling should be performed to evaluate options, in which case a framework for options analysis is needed within which the modeling implied here should be performed. The beginnings of addressing this appear in Item (10) of Section 1.1.4.1, but this does not go far enough.

§ 1.1.4.2 and 4.0 Inadvertent Intrusion Assessment

Consider this text from p. 1-5: “Because there is no scientific basis for quantitatively predicting the probability of a future disruptive human activity over long timeframes, an inadvertent intruder assessment does not consider the probability of inadvertent intrusion occurring.”

This simply is not true. This has been done before and can be done again (at NNSS and WIPP, for example). We are not in the role of prediction, we are in the role of modeling. We are modeling a reasonable facsimile to provide insights into what might happen, while conditioning on current knowledge of the system. Otherwise, a dose assessment beyond a few decades (let alone hundreds of years, or even thousands) is futile.

We do not know what the future holds—we know that it will be different from today, but all we can do for decisions that depend on the long term future is to project current conditions as we best understand them. This applies just as much to inadvertent intrusion scenarios as the environmental system.

Using IA to establish WACs is a mistake. This will not allow the nation to effectively use the limited disposal facilities that we have, and will arbitrarily cause disposal facilities to function sub-optimally. The arbitrariness is palpable. For example, this would cause sites in less populated areas to be evaluated the same as sites in more populated areas, since the probability of intrusion is assumed to be 1 for either case in the IA. This approach subverts the idea that site-specific analyses should drive decisions. Forcing the probability of intrusion to be unity removes the site-specific nature of the probability of intrusion, which can be a significant discriminator of between sites. WAC should be based on site-specific PA, not on IA.

The IA should be folded into the PA, and intruders should be addressed as potential receptors just like any other MOP, with probability of occurrence included in the analysis. All animals are equal, and some should not be more equal than others. Our approach in developing models has been to develop appropriate probabilities of exposure for all receptors, without labeling them as MOP or IHI, which is an artificial and sometimes misleading distinction. Models can provide for a special case in forcing the probability of an even (e.g. drilling through waste) in order to examine the consequences of that event in detail, but those consequences should not enter in decision making out of context, which is what the IA does. We expect that this approach will fit into the proposed requirement of having both a PA and an IA by using the very same model, with the only difference being forcing of a particular (and otherwise potentially unlikely) event. That special case of the PA modeling would be an IA, but the resulting IA should not be considered out of context of its probability of occurrence.

It is therefore curious that the last statement in Section 1.1.4.2 is that “An intruder assessment shall... Account for uncertainties and variability” when the largest uncertainty may be whether an intrusion event would occur at all.

On a positive note, it is encouraging to see the language that an inadvertent intruder is in fact a member of the public (§2.2.4.2, p. 2-14, lines 39-41.)

§ 1.1.4.3 and 5.0 Site Stability Analysis

The point of the stability analysis is not clear. How will it be evaluated? It needs metrics. We strongly suggest that risk (dose) be used to evaluate stability, along with cost. That is, this should be folded into the PA, with potential options for stability evaluated. Stability for the sake of stability, removed from the context of risk, is not useful except for appearances.

§ 1.1.4.4 and 6.0 Protective Assurance Period Analyses

This statement is most welcome: "The primary purpose of the protective assurance period analyses is to provide information that demonstrates that releases of radioactive from a LLW disposal facility are minimized during the protective assurance period..." What is refreshing here is the use of the term "releases", which makes the analyses reminiscent of the Containment Requirements for transuranic waste, in EPA's 40 CFR 191. Given the long time frame of these analyses, it is good to be rid of the term "dose", since this is burdened with the unfathomable uncertainties of human behaviors past 10,000 years.

Later discussions of the protective assurance period analyses sometimes revert to the use of the term "dose" as a performance metric, and we encourage that such references be modified to make reference to "releases" instead.

§ 1.1.5 and 9.0 Waste Acceptance Criteria

As mentioned above, a site-specific WAC should be based on a site-specific PA, and not on an IA, or even on the classification tables.

At the end of section 1.1.5 is a bulleted list of requirements for a certification program. Missing from this list is the characterization of uncertainty in waste documentation. In our experience, having developed PA models for over half a dozen radioactive waste disposal sites, the uncertainty in inventory is the most significant and most irreducible variable in the model. Unless positive steps are taken to require generators to characterize uncertainty in their wastes, this will continue to be the case. Without this uncertainty characterization, decisions about waste acceptance and disposal site operations will continue to be clouded, leading to inefficiencies in the *de facto* national radioactive waste disposal program and a squandering of the precious resources that are waste disposal facilities.

§ 1.4 Risk-Informed Approach

The term "risk-informed" is promising, but there is little of substance here. How should a risk-informed decision be made? This guidance sets up an approach based on *ad hoc* decision making—some people get together and make a decision. We have the technology to do better than that. "Risk-informed" would have meat if it were framed in a decision analysis context. This is the paradigm shift that is needed to support effective decision making, and remove the confusions that stigmatize this industry.

§ 2.2.1 Data Adequacy

It is unclear what is meant by "some amount of incompleteness in the data may be overcome by appropriately accounting for parameter uncertainty." This indicates a confusion of ideas.

Incompleteness of data leads to greater uncertainty in the sense that there is less data than there might have been otherwise. Parameter uncertainty is based on the amount of data available. Hence, this sentence makes no sense. We suggest it be deleted.

Note also that there are other ways to obtain data to support a specific parameter. These include model abstraction and meta analysis. It's not clear what is meant by "last resort" for expert elicitation. There is nothing inherently problematic with expert elicitation. If "last resort" is meant to imply cost-effectiveness, then this should be stated, but it is incorrect to imply that expert elicitation is not a reasonable approach, which seems to be the intent here.

Upscaling is not needed only to achieve representativeness. It is critical to the whole approach of modeling fate and transport of the radionuclides. A probabilistic PA must be built around averaging over large spatial and temporal scales, which is the essence of upscaling (though the analyst needs to be careful about what is being averaged, per the precipitation example). This is how a contaminant fate and transport model ultimately characterizes and addresses uncertainty. Then receptors are exposed to average concentrations and the uncertainty associated with that average.

§ 2.2.2 Uncertainty

The final sentences of Section 2.2.2 state, "For example, an uncertainty analysis could provide information about where a licensee should focus model support activities, which in turn could reduce uncertainty. Parameter uncertainty is uncertainty in the parameters used in the technical analyses." This is not the role of uncertainty analysis—this is the role of *sensitivity analysis*, which is not discussed much in this document. Uncertainty analysis (UA) addresses uncertainty in the decision. Sensitivity analysis (SA) addresses what drives the outcome and how to reduce uncertainty. There should be a separate and distinct discussion of sensitivity analysis to clarify the different roles of UA and SA.

§ 2.2.2.1 General Structure of Uncertainty

It is not clear that uncertainties are greater for long-lived waste. In fact some things become certain for long-lived waste even if the exact time frame is uncertain (the exact time frame is not very relevant in deep time). For example, in the Clive DU PA Model, it is relatively clear (not uncertain) that in 2 million years (My) all waste disposed below grade will be part of an organically developed geologic repository (i.e., under about 300 m of sediment). Whereas, for short lived waste disposed above grade, for example, the waste will be dispersed at some point well before 2 My. DU does not actually reach secular equilibrium until about 2.1 My—there is a lot of certainty then, even if the exact time is not known. The sentence needs to be qualified.

§ 2.2.2.1.1 Scenario Uncertainty

A challenge here is that probabilistic modeling essentially considers a continuum of scenarios. For example, climate variation spans a continuum of possibilities, which can be handled through probabilistic modeling (i.e., through probabilistic specification of input parameters). Scenarios are best left for truly discrete distinctions that cause the system to move in a different direction, and not for changes that are unknown but possible across a continuum.

§ 2.2.2.1.2 Model Uncertainty

In this case, different distinct models could be proposed. So, model uncertainty should involve evaluation of distinct models (for example, there are several models of tortuosity in the literature—which one is best for a specific PA and site?) For this type of model uncertainty, some model averaging could be brought in to support the PA effort.

Conceptual model uncertainty, on the other hand, can probably be handled for the most part through uncertainty characterization of the parameters. Simulation uncertainty is different yet again, and should be separated into its own section. Model uncertainty, conceptual model uncertainty, and simulation uncertainty are really all different enough that they need separate sections.

§ 2.2.2.1.3 Parameter Uncertainty

Parameter uncertainty is not reducible or irreducible. Parameter uncertainty is simply reducible by collecting more data/information. It could be argued that variability is irreducible, but variability should not be applied to the fate and transport model (except to support development of uncertainty estimates—more or less standard deviation (variability measure) divided by n). This is always a difficult discussion because of the number of literature articles on the subject, most of which cause greater confusion. It would be better to define terms here, and, since these are statistical/probabilistic issues, that should be the basis for the definitions.

Note that the approach to parameter uncertainty depends on how the simulations are performed. Most models involve drawing random numbers at the beginning of time, and then using those as deterministic values through the model's propagation in time. If, instead, random numbers are pulled at each time step, then some further thought needs to be put into how parameters are probabilistically specified.

Note also that in a probabilistic risk assessment (which is essentially what a probabilistic PA is), the exposure parameters need to cover the potentially exposed population, in which case they are based on variability rather than uncertainty. If the terms uncertainty and variability are not palatable here, then at least it should be recognized that some parameters (fate and transport leading to concentration assessment) are addressed through upscaling (distributions of means, essentially, which implies characterizing uncertainty), whereas, some are addressed without upscaling (because PRA is about addressing all members of the population, not the average member).

§ 2.2.2.1.4 Uncertainty Example—Transfer Factors

Applying conservative values *does not address uncertainty*. It addresses misplaced value judgments. It obfuscates effective decision analysis and decision making.

This document would benefit from further sections that specifically address upscaling and correlation. Why do large variances only require careful treatment in an intruder analysis—this makes no sense. Since transfer factors are applied to fate and transport components, they address uncertainty and upscaling. The degree of skew in the supporting data (or expert opinion) is mitigated to some extent through upscaling. It is important that the fate and transport parameters (those that are used to lead towards estimation of concentrations in various media, locations, etc.) are established as upscaled (averaged) quantities. The care that needs to be taken in upscaling must address the dilution effect mentioned. The role of inter- and intra-site values is not made clear. This is an issue of ability to generalize data from one site to another. In general, we probably do not assign sufficient uncertainty to that generalization, but a combination of data from another site and expert opinion can be used to at least address some of the missing uncertainty. Note again that this must be in terms of uncertainty in the upscaled values.

Conservative values should not be used. One is reminded of the question asked Charles Babbage: “Mr. Babbage, if I provide you the wrong inputs, can your machine produce the right output?” His answer was, “I fail to understand the confusion of ideas that led to such a question.” And yet, that is what is proposed here. If there are no data, then use expert elicitation. If there are no experts, then put a wide distribution in, and let the sensitivity analysis determine if it matters. If it matters, then put more effort into it (at greater cost.) If it doesn’t matter, then leave it alone and move on.

Page 2-10, line 24: Replace “uncertainty” with “sensitivity”. This is an example of the confusion between the UA and SA concepts that exists in this document.

If this section is to remain, it should be re-cast as a section on data generalization issues, instead of being presented as an uncertainty example.

Also, the NRC Regulatory Guide 1.109 (NRC 1977) should not be cited as an example, as it is quite dated and has values in it with no support.

§ 2.2.3.1 Peer Review, Expert Judgment, and Expert Elicitation

Peer review does not belong in a section with expert judgment and elicitation. Peer review is a form of model support (which could be described in Section 2.2.3), whereas expert judgment and elicitation are methods to specifying a model (akin to data collection). These are different concepts that do not belong in the same section.

§ 2.2.4.1 Human Activity - Scenarios

Receptor scenarios should be based on site-specific knowledge, and projected into the future based on that knowledge (i.e., conditioning on current knowledge). The point is made more effectively on page 2-16, line 11, but should be reinforced in this section. This is also an example of how use of the term “FEPS” works better than merely “FEP” (see editorial comments below.)

§ 2.3.1 Context of the Performance Assessment

Although the data quality objectives (DQO) process has some problems in its implementation, philosophically it is a sound rendition of the scientific method. It basically starts with the question, “What decision needs to be made?” The same should be true here. The decisions include compliance, but much more importantly, should include optimization of waste disposal: the best cover design, best placement of waste, best institutional controls, etc. Rather than DQOs, it would be better if this were all framed in a decision analysis construct. More specifically, it should be framed as a stakeholder-engaged structured decision making process—this is the paradigm shift that is needed so that the public is protected rationally and defensibly, while allowing for the disposal of waste in responsible ways.

§ 2.3.2 Approach to Different Time Frames

Evaluation against these time periods is unfortunate. It is not clear why radionuclides are treated so differently technically than wastes that will never change and might pose greater hazards (lead, arsenic, asbestos), and other wastes that have effective decay sequences that lead to more hazardous waste (PCE to TCE to VC, for example). There are several reasons why 1,000 years is too long—these include reasonableness of evaluating dose beyond 200 to 300 years, change that is inevitable, vastly increased uncertainty with time, and economic considerations (e.g., discounting, which is a natural phenomenon) coupled with the need for long term financial planning. There is a great confusion of regulations and guidance across different radioactive waste issues, let alone expanding further to include hazardous waste regulations. There are occasional opportunities to make real effective change. This is one of them, but this is not being achieved.

§ 2.3.2.3 Performance Period

The reference to "releases" (p. 2-23, line 24) is appropriate, but that positive is quickly negated with mention of the metric "peak annual doses that are projected to occur after 10,000 years" (p. 2-23, line 30, and again on p. 2-24, line 15). We recommend sticking to the "releases" or "activity concentrations or fluxes" concept, as invoked again at the top of p. 2-24.

§ 2.3.2.4 Site Characteristics

The term "C" in the equations on p. 2-25 (lines 26 – 28) requires a careful definition in order for it to be implemented consistently. Is this the activity (or mass) concentration in disposed wastes at the time of closure? At 1000 years after closure, accounting or decay and ingrowth? Some other time? IS it radionuclides that are in the original waste volume, or would it account for radionuclides that have been transported elsewhere in the environment? These questions must be answered, or an analyst will be forced to guess what the intent is.

§ 2.5 Scenario Development

The use of stylized scenarios is potentially problematic. Their use implies conservatism, which is essentially misplaced value judgments. It is perfectly fine to make conservative decisions, but it is not fine to make important decisions based on conservative models. Conservatism should be addressed through value judgments, so that it is properly characterized.

FEPS screening should take place, and should be based on an understanding of probability and consequence. Refer to *The Foundations of Statistics* (Savage, 1954). This reference lays out exactly how models should be built, what considerations should be given, etc. It addresses both marginalization (ignoring distinctions between events), and conditioning (ignoring events), and offers useful insight for how a FEPS screening process could be implemented.

§ 2.5.3.1.2.2 Probability

Page 2-42, last bullet, lines 3-4: It's interesting that FEPSs that do not have information or data, and nothing is known about the process, are included automatically here. There are many processes that are never included in a PA because we don't know how to include them. For example: microbiological degradation of containers, colloid transport. However, NRC implies here that they should be included.

Uncertainty associated with probability: Possibly most FEPSs evaluations would have to be evaluated based on expert elicitation. It is difficult to see how the FEPSs can be evaluated probabilistically otherwise. At the very least, expert elicitation is likely to play an important role. Perhaps this can be noted and referenced to the section on expert elicitation. Some more explanation is needed here. The Yucca Mountain Project evaluated the probability of volcanic hazard as part of the FEPSs process (at very large cost). This was done by building a complex model that led to (uncertain) estimates of this probability.

§ 2.7.4 Analysis and Evaluation of Results

This section discusses, among other things, the concept of SA, but subtly mischaracterizes it in saying that "...the purpose of sensitivity analysis is to evaluate uncertainty and variability in the assessment. (p. 2-61, lines 16-17.) The purpose of an SA is to identify which model input parameters contribute most to that uncertainty. Further discussion on this page revolves around the flawed approach of on-at-a-time (OAT) SA, which will not allow one to thoroughly evaluate the contributions of input parameters to uncertainty in the model results. The text on p. 2-62, while a bit garbled, attempts to put OAT-SA in its appropriate context, identifying its limitations, but this OAT-SA approach needs to be more forcefully deprecated.

§ 3.2.7 Direct Release

It is interesting to see the reference to "Anthropogenic direct releases..." (p. 3-16, line 41.) This would suggest that releases of radionuclides that might occur from intrusion into wastes should be considered as part of the contaminant transport in a model. For example, drill cuttings brought to the surface should be incorporated into the larger contaminant transport calculations, as they could result in exposures to not only the drilling crew but to other receptors as well, perhaps much later in time. We agree with this approach.

§ 4.0 Inadvertent Intrusion

See our comments above about why the IA is not useful for making decisions about radioactive waste disposal.

§ 4.3.1.1 Generic Intruder Receptor Scenarios

A generic IA is of even less use than a site-specific one.

At lines 12-13 on p. 4-13, the statement is made that "Loss of intuitional control is not expected..." Quite the opposite is true. Loss of IC is certain—it is only a matter of when control is lost.

§ 4.3.1.1.2 Intruder-Drilling Receptor Scenario

The drilling referred to in this scenario is for water wells. It should be made more generic to include drilling for petroleum resources (gas and oil) as well.

§ 4.3.2.2 Source Term

Included in an exposure source term should be not only radionuclides in the original waste layers, but those that have migrated upwards into the column above the waste, towards the ground surface. These, especially the decay products of ^{222}Rn which may have diffused upward, can add significantly to the receptor dose.

§ 4.3.2.2.1 Inventory

The last paragraph on p. 4-31 has problems. It says that licensees "may conservatively assume no decay." This is at odds with the very next sentences, which recognizes the "impacts of significant progeny", and that "radioactive decay can result in significant ingrowth of progeny at future times." ("at future times" should be deleted, as it is redundant.) As we know, using depleted uranium as an example, assuming no decay is in some cases definitely not conservative. The following sentence attempts to make this clear, but should be changed from "For example, doses from depleted uranium may increase for more than one million years due to ingrowth of shorter-lived and more highly mobile decay products." to "For example, activities from depleted uranium will increase for more than two million years due to ingrowth of shorter-lived and more highly mobile decay products."

§ 5.0 Site Stability Analyses

As stated above, we do not see the need for a special site stability analysis. Site stability and its consequences should simply be modeled as part of the PA. If an unstable site produces no added risk, then why should we care? We agree that all the processes that contribute to loss of stability, as discussed in the subsections of 5.0, should be included in the FEPS analysis, and if they survive screening, in the PA modeling. The consequences to receptor dose will then naturally fall out of the PA.

Lines 17-19 contain an adequate definition of "stability" that should be used as a definition in 10 CFR 61.2. The current definition in 61.2 is self-referential and wholly inadequate.

§ 6.2.1.1 Alternatives Analysis

An alternative analysis as described is a decision (options) analysis. It should be described this way, and should describe how such an analysis is performed. It seems that this is simply a comparison of doses, but, if so, that is inadequate. Doses can be reduced to zero if money is no object (put a titanium box around the whole facility), but in reality the costs can be prohibitive, and still might not satisfy all stakeholders (because in that simple example, the waste is still there). Based on this approach, the titanium box is the best alternative, because cost doesn't come into it. This discussion should be deleted, or merged with the next section while maintaining the title of this section (that is, alternatives analysis should include costs).

This section also references "peak of the mean". This is a very poor decision metric for sites that have no receptors for long periods of time. This is why PA decisions should be based on population risk instead of individual risk (which was part of the original basis for the selection of many of the disposal sites in the country anyway).

We applaud the consideration of alternative sites for disposal. The final paragraph of this section hints at a larger scope of decision making with respect to radioactive waste disposal for the nation. IT is appropriate to consider that one site may be more suitable than another for disposal so specific wastes, and yet this has received very little discussion in the waste disposal community. We are happy to see the issue raised here.

§ 6.2.1.2 Minimization Analysis

Discounting is difficult to deal with, but perhaps because of how little research has been done to date. A reframing of the decision problem to address both discounting and a long-term financial plan. With discounting, including discounting of receptor doses (contrary to bullet 2 on p. 6-8), compliance periods become unnecessary. Recall Neptune's presentation at the Spring 2013 meeting of the LLW Forum in Charleston, SC.

While we understand NRC's position, some further research on discounting coupled with financial planning seems warranted. At the moment the effective discount function on dose is zero discounting until the end of the compliance period, and then complete discounting (zero value) thereafter. (NRC has inserted one more step in there potentially with the second period having a different dose limit). This is not a reasonable discount function, so some research is needed.

A better approach would be to shorten compliance periods, and have financial planning that implies discounting. The net effect of the revolving time window that this approach would engender would be longer term management of the disposal facility. Under current regulations, at the end of institutional control the Government can simply walk away—does it make sense to make decisions under that paradigm? A paradigm shift is needed.

Also, decision analysis for radioactive waste disposal should depend on population dose rather than individual dose. Or, better, it should depend on risk. Even better, it should depend on mortality and morbidity, as is done in risk assessment within the medical community. Dose is used as a proxy for these, but it is not a good proxy.

§ 6.2.1.3 Other Decision Analyses

It is not clear how this would differ from what is presented in Section 6.2.1.2. Please clarify.

§ 7.0 Performance Period Analyses

p. 7-1, line 26 contains the statement, "The level of detail in the assessment should be risk-informed". It is not clear at all what that means. The term risk-informed has been used for several years now, but without definition. Metrics are needed to make decisions. What are the risk-informed metrics in this case?

The footnote to Table 7-1 says "Any isotope [sic] that is to be disposed of in sufficient quanitites should be considered as part of the LLW PA inventory." Please define "sufficient quantities".

Top of p. 7-4: It is not clear why more expert judgment is needed in this case. This seems to be a continued "knock" on expert elicitation as a "poor man's data analysis". This is not the case. Expert elicitation should be used when it is most cost-effective to do so. Since these long-term models essentially project today's conditions into the future, it is not clear why longer term modeling requires more expert elicitation. Most of the input distributions will not change from the 1,000-year model.

Further, why would simple conservative analyses be used? The model is already set up for 1,000 yr (unless there are new events)—it is trivial to project out the same model for 10,000 yr or longer. This section should be re-written. As former Commissioner Magwood once said a problem we face in waste management is “conservatism on top of conservatism on top of conservatism”. Conservatism has no place in modeling for important decisions. Its place is in specification of value judgments in a complete decision analysis, based on realistic—not conservative—analysis.

Otherwise this section seems to ramble some, and might benefit from some reorganization and deletion of material.

p. 7-4, line 28: Change “is variability in hydrogeology” to “may be variability in hydrogeology”. There are sites where hydrogeology is simply unimportant.

Editorial Comments

“FEPS”, not “FEP”

This is not merely an editorial comment. We strongly recommend that the traditional term “FEP”, for features events, and processes, be replaced with the term “FEPS”, which includes receptor scenarios. Receptor scenarios are not merely the result of the assessment of other FEPs—they are fundamental to the scoping of analyses, and deserve “top billing”, in the principal acronym. The development of modeling scenarios indeed is the product of the analysis of FEPs, as the document discusses, but such scenarios are also dependent on the receptor scenarios that are identified as being fundamental to the scoping of a PA. As an example, section 2.6, Conceptual Model Development, should include receptor scenario development as a foundation leading to CSM development.

This guidance is a great opportunity to start making this point more clear to the PA community. Please consider replacing all instances of “FEP” with “FEPS”.

“radionuclide”, not “isotope”

The word “isotope” is used throughout the document, in most cases incorrectly. There are a few cases where it is used appropriately to mean various isotopes of a single chemical element (e.g. p. 2-25 line 32, in reference to “uranium isotopes”), but in most cases, “isotope” should be replaced with “radionuclide”, or even simply “nuclide”. This is something NRC should strive to correct in general. Isotopes have the same number of protons, and hence the same atomic number. Isotones are chemical elements having the same number of neutrons. Isobars have the same atomic mass, meaning the same sum of protons + neutrons. All are nuclides, and radioactive ones are radionuclides. The difference in usage is perhaps best illustrated by example. These are isotopes: ^{234}U, ^{235}U, and ^{238}U (same number of protons, therefore same atomic number. These are not isotopes, though they are isobars: ^{238}Pu, and ^{238}U (same atomic mass, P+N). These are also *not* isotopes, but are isotones: ^{29}K and ^{37}Cl (same number of neutrons). These are none of the above, but are radionuclides: ^{3}H, ^{36}Cl, ^{99}Tc, ^{222}Rn. All of the above examples are radionuclides, and that is the best term to use, unless there is a specific reason to use “isotopes”, as in, “All isotopes of uranium share the same geochemical characteristics."

"naturalization"

In the context of the degradation, deterioration, and alteration of engineered features of a disposal facility, such as the cover, we would promote use of the term "naturalization," first introduced at the NRC Workshop on Covers. "Naturalization" includes all these processes, and more, and suggests the idea that these processes are natural and inevitable, and that engineers should work with nature in developing designs that will age well.

"disposed" not "disposed of"

Inclusion of the word "of" in essentially all occurrences is superfluous.

minor edits

p. 2-4, line 38: Remove "large quantities of", since depleted uranium "may pose a long-term risk to the public" in even small quantities. Don't let previous disposals of DU hide behind the "large quantities" terminology.

p. 2-5, line 2: Change "predominately" to "predominantly".

p. 2-24, line 2: Remove "rate". A flux is already a rate, as in mass per time. A "flux rate" is nonsensical, and would mean mass per time per time . See: Stauffer, P.H. (2006). "Flux Flummoxed: A Proposal for Consistent Usage". Ground Water 44 (2): 125–128.

p. 2-28, line 42: Change "which to "that". There are other instances of this grammatical error throughout the document. Fortunately, you got most of them (though introduced some new instances) in the proposed 10 CFR 61 rule changes.

p. 2-30, line 24: Change "Sandia National Laboratory" to "Sandia National Laboratories".

p. 2-42, line 20: Change "phenomena" to "phenomenon".

p. 2-42, line 32, and p. 2-55, line 43: Change "are" to "be".

p. 2-47, line 41: Replace "less" with "fewer".

p. 2-49, line 13: Remove "a"

p. 3-22, line 17 and p. 12-7, second reference: The last name of Ghislain de Marsily is "Marsily, not "de Marsily", and certainly not "deMarsily". He told me this personally. He should be referenced as "Marsily, G. de"

p. 7-8 *et seq.*, Examples 7.2 and 7.3: Use SI units: Bq (or MBq) instead of Ci.

This concludes comments from Neptune and Company, Inc. on the proposed *Guidance for Conducting Technical Analyses for 10 CFR Part 61* (NUREG-2175).