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

Subject: **Comments on Low-Level Radioactive Waste Regulatory Management Issues, 77 FR 40817, July 11, 2012**

Reference: **Docket ID NRC–2011–0012**

Dear Ms. Vietti-Cook:

Neptune and Company, Inc. (Neptune) is submitting the attached comments in response to the subject notice. We appreciate the opportunity to comment on the planned changes to 10 CFR 61 regarding disposal of low-level radioactive waste. These comments primarily address the four items included in Commission direction to the NRC staff as described in SRM–COMWDM-11-0002/COMGEA-11-0002.

We believe that the proposed 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. In our comments, we have addressed the four items referred to above, and a range of related items that we think are equally important to achieve a revision to 10 CFR 61 that will help optimize the potential of our Nation's waste disposal facilities.

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to Dr. Paul Black at (720) 746-1803 ext 1 (pblack@neptuneinc.org), or Dr. John Tauxe at (505) 662-0707 ext 15 (jtauxe@neptuneinc.org).

Sincerely,

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

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Comments on the U.S. Nuclear Regulatory Commission's Preliminary Proposed Rule, "Site Specific Analyses for Demonstrating Compliance with Subpart C Performance Objectives," to Revise 10 CFR Part 61

Neptune and Company, Inc. (Neptune) appreciates the opportunity to provide comments on the U.S. Nuclear Regulatory Commission (NRC) preliminary language for *Code of Federal Regulations Title 10 Part 61: Site Specific Analyses for Demonstrating Compliance with Subpart C Performance Objectives, Preliminary Proposed Rule Language.* We believe the NRC efforts are timely, and that the proposed revisions to 10 CFR 61 are sorely needed. We believe that all four items listed in SRM–COMWDM-11-0002/COMGEA-11-0002 should be included in revisions to Part 61, and that some other related changes are also needed.

In general, we believe that the performance assessment (PA) process should embrace probabilistic modeling and probabilistic risk assessment. Our understanding is that this is consistent with NRC's preference. We further believe that PA decisions should be based on human health risk consequences in the relatively short term and the consequences of major perturbations in the system in the long term. This can be regarded as a two-tiered system, but we also recommend addressing the two tiers in a decision analysis framework that includes an economic analysis component, which should address issues such as intra- and inter-generational equity. In effect we believe that risk-informed decision-making should encompass these aspects of a proper decision analysis, and that, in doing so, radioactive waste disposal decisions would be optimized. Given our experience with other Federal regulatory programs, we also find that this approach is consistent with the latest direction in which other Federal agencies are moving for solving complex environmental problems in the context of risk management. Our specific comments provided below follow this general approach to decision making.

Our general approach is consistent with the Scientific Method. The idea is to build appropriate decision analysis models, including the science-based probabilistic PA models that are formed based on our best understanding of the problem and our uncertainties in that understanding, and economic components that, among other things, address the critical issues of intra- and inter-generational equity. The traditional approach to PA, as envisioned in the current 10 CFR 61, is extremely conservative, which only makes sense if there is some desire to make disposal of radioactive waste very difficult. If, as a society, we believe that nuclear industries are necessary, and that legacy waste needs to be disposed rather than stored indefinitely above ground, then we need a regulation that better supports maximizing societal benefits for current and future generations. This does not imply opening the door to disposing of radioactive waste in any unsafe manner. It implies instead that optimal decisions can be made for disposal, that insights can be gained into why certain decisions might be made, and that the decision model more appropriately reflects what is known and what is not known in a typical PA dose model, and what preferences the stakeholders have in a decision model, which can be invoked through ALARA. This process should be stakeholder driven to ensure that various preference structures

are addressed. In this way, conservatism can be applied to the decision options, but not to the model assumptions and inputs, and hence, a more thoughtful risk-informed decision process can be followed.

Our view is that the conservatism that is not only inherent but suffocating in the current regulation and guidance, must be removed to effect useful decision making and maximize the benefits of waste disposal for current and future generations. As a society we need to be able to dispose of relatively benign radioactive waste so that our nuclear industries can function effectively. In effect, the disposal decisions that we make, offer insight into the larger issues of the viability of our nuclear industries. If our current regulation reflects our socio-political stance on our nuclear industries, then so be it, but this can be brought out in the open with a proper decision analysis approach to PA. However, we suspect that this is not the case, and that we are limited by a regulation that has been passed by in time, and is overdue for revision.

Our comments are organized initially around the four items that the Commission directed the staff to consider should be included in revisions to Part 61. Other specific technical comments are also provided. Some more generic, non-technical comments are provided first:

1. 10 CFR 61 was written approximately 40 years ago. There were many good reasons for its content and approach to PA at the time. Computer technology was not readily available to perform complex site-specific PA, so an approach was taken that promoted generic default exposure/receptor scenarios in order to establish conservatively protective concentration limits. However, with modern computer technology, site-specific probabilistic PA models can be built within a decision analysis framework. There is no longer a need for concentration tables and default scenarios. Various agencies, including the NRC, have advocated the use of probabilistic risk assessment—a crucial component of proper PA modeling. The National Academies have also recommended such an approach. In addition, the ALARA process can be invoked for performing decision analysis, if this is necessary (we should be doing decision analysis to make optimal decisions anyway, but ALARA might make that easier from a regulatory perspective).

   Since there has been 40 years since 10 CFR 61 was written, it seems likely that the next revision, even a partial revision such as the one planned here, will occur some decades again into the future. It is important that this revision open the door to engaging modern technology in the PA process. It is also important that this revision not inadvertently constrain further innovation in PA, as the current regulation and guidance has arguably done. The current regulation suggests or requires evaluation of stylized exposure/receptor scenarios that are not applicable at some sites. This inconsistency adds further conservatism to an already conservative process, and limits our disposal capability unnecessarily. Although we believe the current regulation forces "conservatism on top of conservatism on top of conservatism...", we also note that treatment of depleted uranium (DU) as a Class A waste is not conservative. Our preference is to address all types of

waste in an objective PA process in which conservatism in understanding of the problem is removed, but conservatism in the final decision can be accommodated if desired. This would provide a much more transparent approach to radioactive waste disposal decisions.

We recommend that a revised regulation address simpler and more focused goals and requirements for waste disposal decisions. We also recommend that any subsequent guidance is process oriented, so that future innovations in how PA should be performed can be accommodated without the need for further changes in regulation or guidance. We recognize the challenge here, but believe that if this can be achieved, then any further revision beyond what is planned now to 10 CFR 61 might not be necessary.

We also note that given the longevity of the current regulation, the NRC should not be in a hurry to complete its revision. It is far more important that the NRC take the time necessary to "get it right". Waiting a few more months in this context should not be a concern.

We realize that any changes could affect decisions that have been made previously, or could require revisions of PAs, etc. Although some grandfathering could be possible, the need for these types of changes should not affect any decisions the NRC makes on the revision to the regulation. It is far more important to move the PA process into the 21st century, so that better radioactive waste disposal decisions can be made in the future.

2. Although we acknowledge that most stakeholders involved in 10 CFR 61 do not want to address the implications of regulatory changes for previous disposals because of the difficulties that could be created, we note that waste classification is generally unhelpful and confusing. Addressing waste classification is beyond the current scope of the revised rule-making, but it would be helpful if the NRC could find a way of addressing this issue in the future, without also upsetting licensing decisions that have already been made. The work-around for this at the moment might be to allow site-specific PA, but this might not be adequate to address the current regulatory requirement that the 10 CFR 61 waste concentration tables be used to support PA decision-making.

3. The most critical feature of any revised rule is to move away from generic concentration tables and default receptor scenarios, in favor of site-specific analysis. The generic approach that is inherent in the current 10 CFR 61 should be replaced with an approach that promotes site-specific analyses, following the general technical approach outlined above (probabilistic modeling and ALARA to support decision analysis).

4. NRC has recently been using the term "risk-informed decisions". We believe it would be helpful if NRC would clearly define the meaning of this term. It is vague as stated. Our

understanding is that the NRC's intent is that probabilistic risk assessment be used for PA, and that this is a large component of the underlying meaning of the term "risk-informed decisions". If this is the case, then it would be helpful if NRC would make that explicit in some guidance and in their general presentation and use of the term.

5. It would be beneficial for the NRC to support Agreement States and other local regulators by providing the appropriate technical resources so that effective reviews can be performed. It might be unreasonable to expect individual Agreement States to maintain a staff capable of reviewing PAs. However, we believe that high quality reviews are of paramount importance for PA models. This is too often overlooked, but it leads to far more defensible products. NRC should be willing to support Agreement States and other regulators in their PA reviews to ensure high quality in the review process.

6. To further assist regulators, the NRC should provide guidance on how to perform decision analysis in order to optimize waste disposal decisions. This should include guidance on how to perform an economic analysis including, aspects such as discount rates and intra- and inter-generational equity. Such guidance would help fully operationalize probabilistic risk assessment for radioactive waste disposal decisions.

We now address the four items that the Commission directed the staff to consider for revisions to Part 61.

1. Allowing licensees the flexibility to use International Commission on Radiological Protection dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste.

Neptune supports allowing licensees to use the most current dose methodologies in conducting PAs. PAs should always use the latest available information and data for each component submodel of the PA to support the most effective decision making. This should be no different for radiation dosimetry than for contaminant transport. The reference to a particular dosimetry model in regulation should be limited only by necessity when specifying dose units associated with a threshold, such as equivalent dose.

We have one other observation. Information exists to quantify uncertainty in some aspects of the radiation dosimetry component of PAs. With the move towards site-specific PA, including PRA, inclusion of uncertainty in this aspect of the modeling would help improve understanding of the sources of uncertainty in a PA. This would better inform sensitivity analysis, and subsequent decision-making.

However, we believe that a requirement to use a specific version of the ICRP DCFs should not be included in the revised regulation or in accompanying guidance. Instead, the NRC should recommend use of the latest dose methodologies and DCF values in a PA. This will not limit the ability to use future revisions to these factors. As PAs undergo regular revisions under PA

maintenance, they should be expected to update dose calculation methodologies to be consistent with the current ICRP recommendations.

2. A two-tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not a priori and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geohydrology) and the peak dose to a designated receptor.

Our recommendations presented below assume that the Time of Compliance, or Compliance Period, that could be specified in a revised 10 CFR 61 will be used to define the period of time for which quantitative risk/dose assessment should be performed and the results should be compared to performance objectives. PA modeling should include fate and transport modeling and dose/risk assessment throughout the Compliance Period. It can be performed for longer to gain insights, but this would not directly affect quantitative interpretation of results in support of risk-informed decision making. Modeling beyond the Compliance Period may continue to project current conditions and knowledge, but for exploratory purposes only. To the extent that current knowledge can predict future developments in society or technologies, such as in the realm of current developments of laser drilling, these could be accounted for as well. However, no performance objectives should be imposed on dose, risk, or other possible endpoints beyond the Compliance Period. Given that understanding, we see three options:

1. Continue with the current policy of not specifying a Compliance Period. This would allow local regulators and stakeholders to continue to specify site-specific compliance periods. However, we believe this should be accompanied by NRC guidance that helps regulators establish site-specific compliance periods.
2. Specify a Compliance Period in the revised regulation, but allow site-specific deviations with sufficient justification. If this option is chosen, then our recommendation is to specify a value of no greater than 1,000 years. Again, guidance should accompany this approach.
3. Specify a Compliance Period that must be used. If this option is chosen, then our recommendation is to specify a value of no greater than 1,000 years.

Ideally, we would prefer the adoption of Option 1, but there are potential downsides if the local regulators and stakeholders do not have sufficient understanding of how to specify a compliance period. Specification should depend on understanding of the "reasonably foreseeable future", and economic considerations that address intra- and inter-generational equity. The process is not necessarily straightforward, and we would expect the NRC to provide guidance. Because of the difficulties involved, it might be preferable for the NRC to specify a value, and possibly to allow site-specific adjustments. The problem with NRC specification of a Compliance Period is, once in the regulation, it is difficult to change. However, Option 2 could address that by making a

recommendation but allowing site-specific deviations. If the NRC chooses to specify a value, we recommend that the value should be no greater than 1,000 (one thousand) years.

In general, we believe there is good justification for specifying a Compliance Period considerably shorter than 1,000 years. The justification is based on three primary supporting concepts:

1. Dose/risk assessment is only meaningful for the "reasonably foreseeable future". In PA modeling we typically project current knowledge and conditions into the future. In particular this includes projecting knowledge of current society and technology. Considering the rapid changes that society and technology have undergone in the past several hundreds of years, we believe the "reasonably foreseeable future" is limited to, at most, a few hundred years, and, more likely, a much shorter time frame.
2. Economic factors should be included in an assessment of the optimal path to disposal of radioactive waste. Such economic factors should address intra- and inter-generational equity, and include an evaluation of discount factors in support of risk-informed decision making for radioactive waste disposal. There are many aspects that should be considered when specifying discount factors. However, we believe that discounting factors will suggest a diminished utility for risk-informed decision making in using results from continued PA dose/risk modeling after at most 1,000 years, and likely considerably less.
3. Other environmental regulations should be considered when establishing a Compliance Period for a revised 10 CFR 61. Other regulations related to disposal of non-radioactive waste, such as RCRA, disposal of uranium mill tailings, and disposal of low-level radioactive waste require Compliance Periods of 1,000 years or much less.

Note that Items 1 and 2 do not pertain to specific types of radioactive waste or of any forms of chemical waste, although the intent of 10 CFR 61 is to address low-level radioactive waste. In which case that is the intended context here. The point is simply that risk/dose assessment is not meaningful or useful into the long distant future. Regarding Item 3, we presume that similar considerations were made when these other environmental regulations were developed. As a consequence we recommend that NRC specify a Compliance Period in a revised 10 CFR 61 of 1,000 years or less.

In a decision-making context there are other related factors that should be considered in a risk-informed decision-making process; that is, decision factors other than the whether some specific waste can be disposed safely. Part of the reason for applying an economic analysis is to acknowledge future changes in society or technology that would mean that future generations should be given the chance to make better decisions than we can make today. Today's radioactive waste managers decry some past decisions already. Some parties regard DU as a resource, research into recycling cobalt-60 from resins is seeing success, and we are arguably approaching a cure for cancer. Societal and technological change is a matter of both intra- and inter-generational equity.

We make a recommendation of specifying a Compliance Period in the regulation even though the period we suggest of 1,000 years is longer than we think is necessary. We are concerned that if a Compliance Period is not specified, then regulators and stakeholders will require site-specific periods of evaluation that are far longer than 1,000 years, despite the reasons we offer for a shorter Compliance Period. NRC could provide guidance on how to specify a site-specific Compliance Period, but we are concerned that until such guidance is proven, vetted and used for waste disposal decisions, longer time frames will be established in the interest of conservatism. In general, we agree entirely that protection of human health and the environment are critically important objectives for addressing potential contamination, however, conservatism in risk-informed decision making leads to sub-optimal decisions that can have other serious deleterious effects on society. Consequently, we are comfortable with recommending that the NRC specify a Compliance Period of 1,000 years to be applied to PA dose/risk modeling, but that NRC should provide guidance on how and why local regulators and stakeholders can alter that value when appropriate. We note, for example, that various places in the US have already demonstrated different preference judgments for acceptance of radioactive waste. Providing some flexibility will allow site-specific preferences to be made, and will allow sufficient flexibility in the regulation that a future change will not be necessary.

If the NRC chooses to allow specification of site-specific compliance periods, then the accompanying guidance should describe the full range of consideration that should be given to contributing factors such as projection of current societal and technological conditions into the foreseeable future, economic factors to include policy and social implications of those factors, and other regulatory precedent that has been established. Of course, if the NRC decides to follow Option 3, then the NRC will need to provide similar justification. Some further explanation is provided below:

- Regarding the reasonably foreseeable future, ICRP 81 indicates that dose and risk as measures of health detriment should not be measured beyond a few hundred years; that they lose meaning in that sort of time frame. Other cited work would suggest projecting current knowledge into the future should be performed only for even shorter time frames. Counter-arguments often focus on using stylized scenarios to evaluate potential performance. However, we believe this is not an appropriate way to consider risks. Contrived stylized scenarios are difficult to justify, and do not support effective decision analysis or decision-making, which should be the primary objective of performance assessment. Protection of human health and the environment is the required endpoint, but the disposal and engineered methods by which that is achieved should be evaluated in a probabilistic risk assessment that is performed as realistically as possible so that optimal decisions are chosen that maximize benefits to society now and into the future. This does not require or even fit with the idea of specifying long compliance periods and using stylized scenarios that do not take into account site-specific knowledge or conditions.

- A time frame of a few hundred years based on the concept of "the reasonably foreseeable future" also aligns with time frames that might be suggested by considering economic arguments that address issues of intra- and inter-generational equity. Although we recognize that economic factors can be challenging, continued research in this area is providing more insight on how best to develop economic arguments into important long-term issues. Discount factors play a large role in this type of economic analysis, but discounting should not be misconstrued as lack of concern about the long term future. Discounting in a complete economic analysis is a tool that can be used effectively to relate economic considerations to policy decisions.

  Very small discount factors imply paying now for future events, which, in the extreme, can mean using all current financial resources to address future problems so that future generations do not have to suffer at all. Large discount factors instead imply postponing decisions to the future. This can be accompanied by investing the money now to address the problem in the future. A discount rate might be specified by local regulators and stakeholders, but the policy implications should be clearly understood. For these reasons, we recommend that NRC issue guidance on bringing economic analysis into the waste disposal decision-making process, which can be tied in a regulatory context to the principles of ALARA (keeping risks as low as reasonably achievable). We note also that NRC has previously implemented some relatively simple decision analyses using discount factors, so the precedent exists.

We are not opposed, however, to site-specific modeling into the long distant future. We are concerned that the concept of "peak dose" is being misused, since we do not believe it is reasonable to evaluate dose into the long distant future. However, if insights can be gained into long-term fate and transport of long-lived radionuclides, it might be reasonable to evaluate concentration in various media. Dose could be used as a surrogate or concentration because of presumed familiarity, but this is really unnecessary.

We recommend, and agree with the NRC, that probabilistic risk (dose) assessment (PRA) should be used during the compliance period, so that model evaluation and sensitivity analysis can reveal the parameters (variables) that are most important for describing the dose endpoints of interest. The same basic principles can be applied to continued fate and transport modeling into the long-distant future, although we recommend the endpoints should be concentration rather than dose. These longer-term analyses should be performed not for compliance, but for insight into the future fate of the disposal system under long-term projections of current knowledge and conditions.

However, a problem that we see with this approach to the long-term is that it does not allow for consideration of long-term consequences in the final decision analysis or decision-making. The results are, instead, interpreted qualitatively. We recommend a different approach to addressing

long-term concerns. In this context we agree that a two-tier approach is reasonable. Such an approach would focus on a 1,000-year time of compliance (or shorter) for a probabilistic risk (dose) assessment. For longer times, rather than testing compliance with a conservative dose limit that has purposely currently been established well below typical public exposure levels, there should be no absolute limits or performance objectives. Instead, evaluation should involve analysis of major perturbations in the natural and engineered systems. This can be performed using decision analysis methods, invoked through ALARA if necessary, rather than compliance with a conservative performance objective. Major perturbations in the natural or engineered system can be evaluated in terms of the preference or desire to address the consequences or impacts now. For example, erosion and exposure of waste in Los Alamos in the long distant future can be evaluated in the context of willingness to find alternative solutions that avoid such exposure. This is irrespective of human presence or dose. Instead, this involves stakeholder driven value judgments on the consequences and impacts to determine if society is willing to address the problem now. The same basic principles apply to other major perturbations that could occur in our Nation's disposal systems. For example, this might include volcanism at Yucca Mountain, post-glacial flooding and scouring at Hanford, and, return of a deep glacial lake in the Bonneville basin.

Along these lines, some have suggested that disposal of DU in shallow land systems is *de facto* inappropriate. We contend, instead, that full evaluation of system performance through objective performance assessment is critical, and that disposal decisions should be based on risk-informed PRA, and subsequent decision analysis invoked through ALARA. This should be a stakeholder driven approach, so that different sub-populations in the US can express and base decisions on their different values and preferences.

All of the relevant site-specific factors should be included in a comprehensive decision analysis aimed at optimizing the use of a disposal facility. All sites should be evaluated with the same process of using PRA and ALARA in a decision analysis context that includes stakeholder values and judgments to optimize radioactive waste disposal decisions. This is not intended at all to pre-suppose any decisions. This approach instead forces a structure on the risk-informed decision process. Depending on the dose results, the long-term consequences of major perturbations to the system, and preferences, costs and value judgments of the stakeholders, optimal decisions can be better supported through this approach. This approach is far more transparent and defensible for decision-making, and provides a framework for gaining insights into the important factors. The current approach hides behind supposed conservatism, and results in negotiation of endpoints instead of understanding of assumptions, inputs and model structure.

3. Flexibility for disposal facilities to establish site-specific waste acceptance criteria based on the results of the site's performance assessment and intruder assessment.

This follows naturally from performing site-specific PA. It is our opinion that this should be a requirement. As described above, with modern technology there is no need to limit PAs to some generic constructs, concentration limits and stylized receptor scenarios.

We note that with modern PA, there is no specific need for waste concentration limits, which seems to be what is intended here. It is helpful for waste generators and site operators to have a target to aim for, and not to have to get specific waste acceptance on each waste item, but from a PA perspective estimation of WAC is not necessary. That is, modern PA programs can be (and some have been) developed based on current inventory, with the capability to evaluate additional waste. If disposal of the addition waste leads to the PA objectives being rejected then the waste cannot be disposed. If, instead the revised PA including the new waste passes performance objectives, then the new waste can be disposed and the PA is update accordingly. At that point, WAC could also be revised. The role of WAC in such a system is to provide target concentration that a new waste stream should remain below. Such a screening target, however, should not rule out the possibility of taking waste that exceeds a current WAC. Such waste would need to enter the PA to determine compliance and optimal strategies for disposal.

This describes the system that we set up for the NNSS low-level waste disposal sites that has been implemented so successfully for the past six years. The same approach can work just as well at any waste disposal facility that continues to receive waste.

4. A compatibility category for the elements of the revised rule that establish the requirements for site-specific performance assessments and the development of the site-specific waste acceptance criteria that ensures alignment between the States and Federal government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements.

We recommend a very high degree of compatibility for Agreement States with NRC regulations regarding disposal of LLW. Even this level of compatibility, however, is not sufficient to ensure that regulations are properly applied. In our experience, we have found that Agreement States have not been able to execute sufficient review of PAs that have been presented to them, nor have they asked for assistance from NRC in reviewing them. Poorly executed review could result in both overly restrictive and overly permissive approvals for waste disposal. Overly restrictive state oversight would result in disposal site underutilization, with no benefit to the public. Overly permissive oversight could result in radioactive waste disposal that does not comply with the performance objectives of 10 CFR 61, possibly putting the public at risk.

The issues of the quality of PAs submitted for review, and the quality of the reviews themselves, are not addressed by compatibility, unfortunately. The quality of PAs is enforced only by consistent and thorough review, and the quality of review is nowhere addressed in the regulations. In practice, individual Agreement States can vary widely in their acceptance of PAs,

creating a problem of inconsistency between disposal sites in different states. If Agreement States, or NRC for that matter, cannot execute a sufficiently thorough review of a PA, and if reviews (and therefore PAs) are inconsistent, then no amount of regulatory language matters.

One approach to this problem would be for NRC to rescind authority from Agreement States in matters regarding the disposal of LLW. This would put the burden of review on the NRC, resulting in perhaps more consistent reviews, but also perhaps reducing flexibility.

Alternatively, NRC could develop a review plan for PAs, much like the Standard Review Plans that exist in other regulatory contexts. It is not clear if the NRC would have the ability to require Agreement States to abide by an NRC review plan, and the development of such a plan would be made all the more challenging by allowing site-specific analyses and flexibility.

5. Other Issues

A number of other issues are important to keep in mind while considering the changes that might be made to 10 CFR 61. These are addressed below.

The Problem of the Intruder vs the Member of the Public

We recommend that the NRC revisit the concept of the inadvertent human intruder (IHI) as distinct from the member of the public (MOP) in assessing acceptable doses to individuals. If one considers risk to any future receptors, the distinction between IHI and MOP becomes artificial, and should be dispensed with. As part of the analysis of features, events, and processes (FEPs) for a site (discussed below), consideration must be given to identifying what persons would be most likely to come into contact with contaminants in the disposed radioactive waste, be it through inadvertent exposure to waste directly or via some intermediate exposure medium, such as soil or water. There are several scenarios where the distinction is blurred, even at current disposal sites. Consider, for example, a scenario where some future person inadvertently exposes waste through his or her normal activities, aside from those proposed in the stylized intruder scenarios that have been relied on in the past, such as drilling or excavation of a basement. This person may be simply traversing the site, and by doing so could disturb it in a subtle way that results in waste exposure, perhaps after some time. This person did not "occupy" the site, so he or she would not be considered an intruder. But if, later, the waste were to be exposed due to his or her actions, this would be a problem for others who would visit the site. This scenario is not captured by the current regulatory constructs of IHI and MOP, and yet it could result in significant human exposures in the future.

NRC should abandon the approach of requiring analysis of specific intruders, such as drillers or constructors of dwellings. Instead, a site-specific analysis should be done to identify what sorts of activities would be expected to occur at a given site, and these scenarios should be evaluated. There are sites where drilling will almost certainly not take place, and there are those where it is easily within the realm of possibility. There are also intrusive activities that could result in much

greater exposures than drilling or basement excavation at some sites, and these are currently not addressed. Receptor scenarios are as site-specific as is hydrogeology, and they should be defined as part of site-specific PA.

The intruder analysis is an anachronism that played a possibly important role 40 years ago, prior to the advent of modern computer technology. Without the technological advances that are now available, it is understandable that relatively simple screening approaches were needed to address protection of human health and the environment. However, modern technology allows us to perform more realistic PA modeling and subsequent risk-informed decision analysis. Relying on the concept that the intruder analyses provide "defense in depth" is not only unnecessary, it is futile and it results in making very conservative decisions for our Nation's radioactive waste disposal facilities. Within the environmental industry we have been performing exposure assessment as part of human health risk assessment for many years. The approach is well understood and should be part and parcel of PA. We recommend that all language about intruder analysis be removed from the regulation, and that it be replaced with some recognition that risk assessment is the appropriate technical approach to performing PA.

Protection of Any Member of the Public

Section 61.41 protects "any member of the public". 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 as well. 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. NRC should clarify exactly what is meant in the regulation. If we are to protect only an average adult male, which is current practice, then it should be made clear that this is the case, and justification should be provided as to why other more vulnerable members of the public are not likewise protected. PA models can readily be constructed to consider a variety of ages of the public, just as they can consider a variety of receptor behaviors that might be expected at a given site. For example, while a residence at the site may well include children who grow into adults if they stay long enough, but the population of well drillers would not include children. These differences can be accounted for in modern PA models.

Organ Dose vs Total Effective Dose Equivalent

The current language in §61.41 requires that doses to individual organs be calculated, though current practice is to adopt the concept of total effective dose equivalent, or TEDE. It has been argued that TEDE is sufficient to supplant organ-specific dose assessments, but in practice there is no reason to favor one over the other. PA models can easily be built to evaluate both TEDE and organ-specific doses, and the results of both approaches can be compared to see if there are significant differences. This sort of flexibility, as with the age ranges and general types of receptors, can be easily accounted for in modern PA models.

Dose vs Risk

Both NRC and DOE regulations and guidance for PA limit the endpoints to radioactive dose. Dose is not a very good surrogate for risk. We would prefer to see a move towards risk assessment in the context of risk-informed decision making.

Site Stability and Future Risk

Section 61.44 addresses site stability in its own right. This is currently a criterion for PA completely separate from future risk. One might wonder if that is appropriate. Are we not concerned primarily about risk? It must be acknowledged that an unstable site may pose greater risks to the future public, but that is already considered in PA in assessment of risk. Why is stability a criterion in its own right? As long as the consequences of site instability are considered in the context of risk assessment, what more need we be concerned about? Consider the hypothetical case where a site may be unstable at some point in the distant future, when there are no identified receptors. If the instability of the site does not increase risk, then why does it matter?

This is more a philosophical and logical argument than a practical one, but the point is that there may be no need to require site stability *per se*. We recommend that this requirement be dropped, but that the characterization of long term site stability should be explicitly identified as a concern in the estimate of future risk to the public.

FEPs Analysis

A site-specific PA should be founded on an exhaustive analysis of what is likely to happen at the site that would contribute to future risk to humans. This includes the environmental milieu as well as the possibilities for future receptor activities. This analysis of features, events, and processes (FEPs) and scenarios (FEPS, perhaps) helps to define and constrain the universe of what should be included in the PA and in the model supporting the PA. Included in the FEPs should be all the site-specific phenomena discussed above, such as things affecting site stability, fate and transport of contaminants from wastes to exposure media, and physiological responses to radiation. Constructing FEPs frames the site-specific PA analysis, and to the extent that it is thorough, assures that no significant issue is omitted. Since the universe of FEPs in general can be quite large, and since each site will have its own subset of applicable FEPs, no generic regulation or guidance can address each possible case. The current 10 CFR 61 attempts to do just that, by requiring particular intruder scenarios, for example. It requires these of all sites, and yet they are not appropriate for all sites, and appropriate scenarios may not be addressed or required at all (see above). There is no one-size-fits-all approach that works, if a regulator insists on specifying most any aspect of the analysis. The regulation should not identify particular scenarios, nor should it identify particular waste classes. A true site-specific analysis would have a different classification table, of the style of the Part 61 tables, for each site. What is "Class A-like" at one site may be quite different from what it would be at another site. The only consistent

metric to be applied is one of risk, be it TEDE, or organ dose, or whatever metrics are chosen, to a population of hypothetical future receptors. That population, of course, also varies with each site. That risk should be evaluated through time, and should be allowed to naturally decay in significance into the future, just as all social constructs do, as opposed to having some arbitrary limit of 100, or 300, or 500, or 1000, or 10,000 years. Let the site speak for itself.

To that end, a revised 10 CFR 61 should not specify any particular numbers besides the maximum allowable risk to persons, naturally discounted into the future. There is an opportunity to align allowable risk with, for example, the Environmental Protection Agency's values of 1e-4 or 1e-6 excess cancer risks, which would be a more sensible metric than dose. It would be more sensible because it is what we are really interested in, and because it could incorporate more than simply radiological risk. Many heavy metals associated with radiological wastes, such as uranium and lead, have toxicity risks that can be more significant than the radiological risks. But whether the final metric is dose or risk, it should be the only numeric value in the regulation.

The rest of the regulation and guidance should be about process. How do we evaluate site performance with respect to the allowable risk? ("Allowable" is subtly different from "acceptable", since it means that ownership of the value is by NRC, who allows it, rather than deems it acceptable. What is acceptable varies widely in our society. What is allowable is determined by regulation, acceptable or not.) The beginning of the process is the identification and vetting of FEPs for a site. Once a collection of FEPs has been identified that is acceptable to stakeholders, the rest of the PA follows. The remainder should step through the process of performing a PRA and using ALARA for decision analysis.