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Dear Mr. Meyer:

The Department has reviewed the draft "Branch Technical Position on a Performance Assessment Methodology for Low-Level Radioactive Waste [LLW] Disposal Facilities," which the Nuclear Regulatory Commission (NRC) made available for public comment in a May 29, 1997, **Federal Register** Notice (62 FR 29164). We are assembling a Department-wide consolidated set of comments which we will provide in the near future as a supplement to the enclosure.

There are aspects of the draft technical position (TP) that are good and others that are not. The endorsement of the uses of probabilistic analysis as a decision tool is generally positive. Compared with deterministic analyses, probabilistic analyses can provide additional, quantified information to decisionmakers and thus facilitate a judgement regarding "reasonable assurance." The Department also supports many of the specific performance assessment recommendations such as the assumption of undisturbed (by humans) performance, use of current technologies, and the critical group.

However, the TP contains serious flaws that would make an adjudicatory licensing process far more difficult without any substantive improvement in health and safety or site performance. Certain recommendations in the TP may cause a proliferation of many small waste sites (due to the TP effectively limiting site inventories) where fewer larger sites may possibly be more (or at least as) protective of the public welfare. Other recommendations act to effectively punish the use of superior disposal sites. A fundamental problem is the uncertain role of active and passive institutional controls in assuring long-term safety and compliance with regulatory requirements.

Given these issues and the enclosed comments, the TP should be reconsidered. NRC needs to precisely articulate its fundamental tenets and assumptions regarding institutional controls in light of current law and regulation, and then develop its recommendations based on this foundation.

We believe that assurance of protection of the public and the environment requires the continuation of active and passive institutional controls at waste disposal sites until such time as they can be safely released (applying appropriate decommissioning criteria to the disposed waste in addition to ancillary surface facilities).

Thank you for the opportunity to review the draft TP on low-level radioactive waste performance assessments.

Sincerely,

/S/

Raymond F. Pelletier
Director
Office of Environmental Policy
and Assistance

Enclosure

Summary Comments on Draft Branch Technical Position on a Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities

Although the draft technical position (TP) makes some good points, it is seriously flawed. The fundamental problem is the uncertain role of active and passive institutional controls in assuring long-term compliance with regulatory requirements. The Part 61 rulemaking record is contradictory with respect to this critical issue.

Part 61 requires a regulatory prediction that doses to members of the public will not exceed specified dose limits. On what basis, ultimately, will NRC justify this prediction? If active institutional controls end in the future, then NRC must rely very heavily on performance assessments (PAs) to provide the required prediction of compliance with specified dose limits. But if active institutional controls form an essential component of assurance of long-term safety, then the prediction about long-term compliance with dose limits depends more significantly on a site-specific assessment of the adequacy of the long-term institutional control provisions, including funding mechanisms. PAs serve a planning rather than a predictive role. (Although for planning purposes one may calculate hypothetical public doses assuming that the future site custodial agency does not act to preclude the doses from occurring, such inaction is actually not intended and may be inconsistent with legal or regulatory requirements.)

Because the long-term role of institutional controls is not clearly established, the role of PAs in making decisions, and the interpretation of PA results and limitations, is also not clear. The TP reflects this lack of clarity, and reads as if the authors simultaneously believe, and do not believe, that PA calculations represent real doses to real people.

Among other concerns we note:

- The TP lacks, but needs, a clear process that would enable NRC to arrive at a licensing decision on a timely basis, considering and accounting for uncertainties. NRC seems to be hoping that all decisions could be made at the time of license issuance, and is compensating for expected data limitations and analytical uncertainties by calling for either a highly conservative bounding analysis or compliance with an abstract numerical formula. We believe, however, that as the TP is written, it discourages a timely licensing process, particularly if adjudicatory hearings are contemplated. Assuming that new disposal facilities are ultimately approved, the TP recommendations could result in decisionmaking based on grossly conservative and misleading performance assessments, a situation that promotes large numbers of disposal facilities, each containing only small quantities of waste.

NRC needs to develop and set forth a decision process that clearly and honestly confronts the need for a licensing decision based largely on judgement, considering a site-specific data record that covers only a few years.[1] For this, the general principles of the Data Quality Objectives process may be helpful. The decision process should be established so that initial regulatory decisions are reviewed at appropriate followup intervals for as long as the waste presents a sufficient hazard to be of concern, consistent with a long-term "responsible control" approach to LLW management.

- NRC provides insufficient justification for recommendations about PA assumptions for undisturbed performance, current technologies, land use practices, and biological trends. Also, NRC provides no justification regarding its recommendation to avoid "unnecessary speculation" in performance assessments, nor guidance (e.g., examples) in interpreting the recommendation. Uncertainty about these matters can be detrimental to achieving a timely licensing process, particularly if adjudicatory hearings are contemplated. The rule requires reasonable assurance about protection of a member of the public, and is silent about conditions on that protection. On what basis would NRC justify not considering an unlikely or speculative scenario (e.g., disturbed performance) in a PA? A "calculational inconvenience" argument may not be compelling, even though one can argue that anthropogenic processes and biological trends are difficult to project beyond a very short period of time. (We believe the needed justification for these concerns must be largely based on institutional control considerations. Some issues may be appropriate for expert elicitation with recommendations reviewed on a periodic basis (such as every 25 years) as part of a long-term responsible control approach to waste management.)

- TP recommendations on time of compliance are contradictory and reflect an ambivalence about the role and limitations of performance assessments in making licensing decisions. NRC seems to be trying to compensate for analytical uncertainty by increasing the level of uncertainty. The TP acknowledges the large uncertainties associated with performance

[1]As part of preparing and reviewing PAs for its own LLW disposal facilities, DOE frequently identifies sources of significant technical uncertainty, even though DOE has been operating some of its sites, and collecting data, for over 50 years. Assuming that DOE authorizes a LLW disposal facility, significant technical uncertainties must be addressed as part of required PA maintenance programs, in recognition of the need for continuous long-term management of LLW disposal facilities.

assessments, and notes that uncertainties can increase with time (e.g., the TP notes the uncertainties associated with projecting a "site's biological environment..beyond...a few hundred years.", and also with other factors such as human technology changes, glaciation, and climate change.) Yet the TP recommends analyses to 10,000 years and beyond, and even suggests that applicants consider restricting inventories based on such analyses. NRC is therefore asserting that such calculations far in the future have predictive validity. This assertion is highly questionable.

NRC also states that shorter time periods, such as 1000 years, would be generally inappropriate for assessments of LLW disposal facilities. But a requirement to extend compliance times beyond 1000 years requires analyses that have such large uncertainties that they are just as likely to lead to wrong decisions as right ones. Furthermore, such extended analyses effectively punish "good" sites. It would be easier under the TP to license a site based on a PA that projected a dose of 10 mrem per year over 300 of the first 500 years, than it would to license a site based on a PA that projected zero release over 1000 years but a spike of 40 mrem in year 5600. This is intuitively wrong. It would be highly unreasonable to treat highly suspect dose projections thousands of years in the future with the same level of concern as projections over the first few hundreds of years.

NRC should therefore incorporate the concept of information quality into the TP. One approach would be for an applicant to provide an assessment of his or her confidence in the analytical projections as a function of time. Those aspects of a confidence estimate pertaining to physical, measurable parameters (e.g., the geological and hydrological data record) should be considered separately from those pertaining to anthropogenic processes or biologic trends, recognizing that the one influences the other.[2]

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[2]One may have a high confidence that given an assumption of current conditions, and an assumption for calculational purposes that a custodial agency takes no corrective actions, one can project (bound) the release and transport of radionuclides to the environment. However, one may have a low confidence that current conditions (reflecting current anthropogenic and biologic processes) can be projected over a few hundred years. The result can be that one may have a high confidence that he or she understands the current physical processes affecting a disposal facility, and the likely release and transport pathways based on these current processes, but a low confidence in the future public "dose" implied by the analysis beyond a time that "current conditions" can be reasonably projected.

- NRC seems undecided about the purpose(s) of performance assessments. Although the TP makes statements (p. xii) such as "the goal of the analysis is not to accurately predict the future," it makes other statements that contradict this premise. For example, in Section 1.3 the TP states that "Low-level waste performance assessment is a type of systematic (risk) analysis that addresses what can happen, how likely it is to happen, and what are the resulting impacts." Another example is the discussion about the goal of performance assessment being to "defensibly and transparently address uncertainty." But although presenting defensible analysis in a clear manner is necessary, the process is intended to address more than uncertainties.

- The TP often gives the impression that one must evaluate uncertainty in the model outcome and investigate the parameters and assumptions that affect this uncertainty for their own sake. However, uncertainties in the results of performance assessment are important only to the extent that they affect a decision about regulatory outcome. The TP lacks, and should provide, guidance about "rolling up" the uncertainty analysis into an overall assessment of the quality of the information used in and provided by the analysis.

- The TP is confusing and contradictory in its treatment of deterministic analyses. On the one hand, it appears to say that an applicant need not be concerned about uncertainties, such as human activities, that are difficult to project over time. On the other hand, the TP appears to say that if an analytical parameter value is based on a measurable physical process, then a bounding analysis must be "clearly demonstrated" (i.e., conservative at all costs). We have several concerns.

  First, how can one truly provide a bounding analysis if one does not consider **all** uncertainties, including those associated with anthropogenic influences? These influences can have a large effect on disposal facility performance, but are difficult to predict or to model. There seems to be no justification for excluding uncertainties associated with anthropogenic influences without institutional controls sufficient to forestall or mitigate them.

  Second, the TP admonishes the reader to **demonstrate** that models, parameters, and calculated doses are bounding. But although in some cases a bounding assumption can be demonstrated (e.g., one could ignore decay for long-lived fission or activation products), in many cases a "demonstration" of a bounding assumption is really an **argument** based on the judgement of the analyst considering available data. One cannot "demonstrate" the future in a manner consistent with a dictionary definition of the word.

Third, if one is depending on a bounding analysis to help reach a licensing decision, then the question should be whether the **overall** analysis is likely to be bounding (subject to initial assumptions and predictive limitations). It does no good to assume a high degree of conservatism for each parameter in a model, so that conservatisms are propagated through the analysis, leading to grossly misleading results. With enough conservative assumptions, perhaps no site could meet the requirements of the performance objectives. Realism, not conservatism, must be encouraged in LLW performance assessments.[3]

Finally, the TP provides no useful guidance about the level of protection required to be identified as acceptably conservative. There can be an extremely wide range in definitions of what is conservative depending on the person or organization conducting the assessment.[4]

- NRC recommends that "...where a formal uncertainty analysis is performed and a distribution of potential outcomes for system performance is provided, the mean of the distribution ... [should] be less than the performance objective, and the 95th percentile of the distribution be less than 1 mSv (100 mrem), to consider a facility in compliance."

  Although we appreciate that NRC is attempting to provide a numerical measure of "reasonable assurance" as an aid in making a licensing decision, we must point out that use of such a formula would not relieve NRC from the need to exercise judgement in this decision. Although a probabilistic approach may help to organize and present information in a way that hopefully leads to better-informed judgements, it cannot be used to create data. There is often not a black and white distinction between the deterministic approach and the probabilistic approach. When a performance assessment is performed probabilistically, some parameters are still either fixed or based on arguably bounding assumptions. Also, the recommendation appears to be limited to the uncertainties associated with those aspects of a PA pertaining to natural conditions, processes,

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[3]NRC implies the need for analytical realism by suggesting that applicants avoid unnecessary speculation, but contradicts this suggestion by recommending highly conservative analyses.

[4]If parameters are viewed probabilistically, one can quantify a definition of conservatism (e.g., a specified confidence level). There is often not a large difference in the data needed to identify a conservative or bounding parameter and the data needed to identify a probability distribution for the parameter. The difference is that the amount of conservatism applied to the bounding parameter is unspecified.

and events. As noted, NRC's has not provided a justification for its recommendations pertaining to future anthropogenic, climatological, and biological processes. Although there are techniques for estimating probabilities or bounds for these processes, the estimates must be based on current knowledge and therefore require periodic reassessment.

- o NRC's blanket recommendation to not perform probabilistic evaluations of scenarios is inconsistent with its endorsement of a probabilistic approach to PAs. It would be reasonable to consider scenarios, or at least to identify the critical group for performance assessment, that are appropriate for the site under consideration. One cannot do so without at least a qualitative assessment of probabilities. Remote sites in the desert southwest are very different from sites in more populated areas (such as the west coast or east of the Mississippi River), and exposure scenarios that may be most appropriate for one site may be inappropriate for another.

- o There is no justification for NRC's guidance about the 500-year limit on the performance of engineered barriers.[5] Why not merely require that all assumptions be justified, and that projections of performance be consistent with existing data, designs, and material parameters? There is nothing unique about engineered barriers as compared to natural site conditions that should cause engineered barriers to be considered separately. Alternatively, NRC could consider an option, through institutional control mechanisms, to ensure maintenance or repair of engineered barriers for as long as may be needed. One could estimate a bounding time for barrier performance, estimate costs for assumed major repairs at prescribed intervals, and establish sufficient funds in an interest-bearing account to make the repairs. Such an approach would be allowable under Part 20 requirements for restricted release; we see no reason why a similar provision could not be considered for LLW disposal facilities.

- o NRC's recommendations on intruder dose analyses have not been given the level of regulatory analysis that is required. Several issues must be addressed and resolved, such as the costs and benefits of implementing the recommendation, appropriate scenarios and dose or risk

[5]The 500-year criterion in Part 61 was placed in the rule to be consistent with the 500-year assumption for the Part 61 classification system. This 500-year assumption was arbitrary, and was used to specify **generic** concentration limits for radioactive material allowable for near-surface disposal, not for any purpose associated with Section 61.41.

criteria, the disposition of wastes determined to be unacceptable for near-surface disposal, whether larger concentration limits could be determined for some radionuclides (e.g., Ni-59, Ni-63), and whether a probabilistic or deterministic analysis should be used. Considering that the Part 61 rulemaking record indicates that NRC consciously discounted ingrowth of uranium progeny when it established the classification system, an amendment to the rule may be needed to implement the recommendation.

- Although the critical group concept is worthwhile for performance assessments, the TP lacks justification for the recommendation. Section 61.41 refers to "any member of the public," not to an average member of a critical group. (NRC may consider that if institutional controls continue, PAs are clearly planning documents; PA results do not constitute actual doses to any member of the public, adult or child.)

- The TP should address uncertainties in estimates about the radiological, physical, and chemical inventories in waste. If NRC is assuming that LLW shipment manifests can be used for these estimates, NRC should evaluate the accuracy these manifests in that many manifest citations have been questionable in the past.

- The TP is repetitive and scattered, as if it was two or three documents at once, and the language is imprecise. This condition reflects a root uncertainty about the basic principles driving the recommendations.

- The TP lacks, and should provide, guidance on compliance with the ALARA requirement in Section 61.41.

- Although it would be desirable to use effective dose equivalent for compliance with Section 61.41, it would not be consistent with the rule as it is stated.

Recommendation

NRC should reconsider the TP. NRC should precisely articulate its fundamental tenets and assumptions for active and passive institutional controls, and then develop its recommendations based on this foundation and in terms of a long-viewed, "responsible control" approach to LLW management. Such an approach would be consistent with the recommendations of a 1994 workshop held by the National Academy of Public Administration on Intergenerational Equity issues. An initial licensing decision can be based on a limited but acceptable amount of site-specific data. Technical uncertainties in assessments of disposal system performance can be addressed using performance monitoring and research programs conducted over the life of the disposal facility. Difficult questions involving anthropogenic processes could be addressed and periodically reassessed through techniques such as formal expert elicitation.

The elements of a "responsible control" approach could be as follows:

- A site selection process directed toward sites expected to result in minimal costs for long-term maintenance, or for correction if needed (e.g., the site suitability requirements of 10 CFR 61.50).

- Design of disposal facilities[6] directed toward passive disposal systems requiring minimal maintenance over time (and avoiding water accumulation and management problems).

- An initial licensing decision subject to followup review for as long as the waste presents a sufficient hazard to be of concern.[7]

- An initial assessment (basis for licensing) that would be updated and amended as needed. The assessment could address adherence to generic design requirements or to adherence to a performance standard such as a dose limitation assessed using a PA.

- A system of physical, legal, and administrative controls to ensure operational and long-term protection of the public and the environment. Controls would include limitations on public access and use, performance monitoring (including vadose monitoring) and environmental surveillance, periodic assessments of real-time public dose, markers and public records, contingency plans, periodic reassessments of the licensing basis, assured funding mechanisms, and so forth.

- Identification of parties legally responsible for inspections, oversight, corrective action, if necessary, etc.

Under this approach, primary assurance of public and environmental protection is derived from the continuation of passive and active institutional controls, including access controls, environmental monitoring and surveillance, and periodic

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[6]"Design" is used generally, to include considerations (as appropriate) such as engineered barriers, waste form, size of buffer zone, or waste concentration or inventory.

[7]Depending on the situation (e.g., short-lived radionuclides disposed in an arid environmental setting), one might determine that it would be safe in the future to reduce the levels of oversight and control, and possibly to release the site on either a restricted or unrestricted basis applying appropriate decommissioning criteria to the disposed waste in addition to ancillary surface facilities.

assessments (and reporting) of public dose. Because an entity will be present or responsible for ensuring that actual doses to the public are within requirements, the consequences of a "bad" licensing decision are essentially economic. Should there be unanticipated or unallowed radionuclide release from the disposal facility, the realistic impacts are the costs (above a baseline of custodial costs) required to remedy the problem.

Therefore, one would design disposal facilities to be sufficiently robust (given current knowledge) to tolerate a reasonable envelope of variations from expected conditions without requiring human intervention. Those variations occurring outside this envelope would be left to the custodial agency to address. The possibility that a future society would be burdened with a large expense could be reduced by (1) expanding the envelope of variations to be considered, and modifying the design accordingly, or by (2) augmented financial assurance and oversight mechanisms.[8] The proper balance of these and related tradeoffs (e.g., the design life) is not easy to decide. Some could be decided on a generic basis and others on a site-specific basis. Decision tools will need to be applied.

A PA is therefore seen in the context of a tool used to assist in design of disposal facilities, to characterize radionuclide release and transport pathways, to identify and characterize significant assessment uncertainties, to develop monitoring programs (including "performance" monitoring), and to plan for contingencies.[9] A PA represents a best estimate <u>at a point in time</u> of disposal system performance, given a technically defensible conceptual model, site-specific characterization data, surface and subsurface process definitions, exposure scenarios, and a host of assumptions about factors in the future. It is

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[8]If one postulates that a potentially disruptive event might occur within -- say -- 500 years, one could estimate the costs required to remediate the site in current dollars, and establish sufficient funds (assuming long-term interest and inflation levels) in an interest-bearing account to address the problem if and when it occurs.

[9]PAs would be used to provide decisionmakers with a reasonable expectation that corrective action would not be needed, over a specified design time horizon and consistent with "current conditions" assumptions, to assure compliance with applicable dose limits and constraints. To do this, the PA could be conducted based on the design assumption that, should releases from a disposal facility hypothetically occur, the custodial agency would take no action to prevent public dose. This approach is similar to, but not the same as, one that would prohibit "any considerations from active institutional controls..." in the manner stated in 40 CFR Part 191.

through definition of the assumptions, quantification of the data, uncertainty and sensitivity analysis, and a realistic assessment of the collective error of the PA results that PA useability and reliability are determined. Decisions and actions based on PA results are data- and site-specific and should be evaluated in a graded approach.

PAs have limitations as decision tools. Factors that contribute to variable PA results include input data quantity and quality, period of record of the data, data trends and interpretations, robustness of the conceptual model, steady-state versus transient modeling assumptions, numerical versus analytical modeling, the period of projection for the model runs, and so on. Changes in the steady-state groundwater gradient due to regional or local groundwater withdrawals can invalidate model projections. Likewise, a 20-year input data record can propagate very large uncertainties in steady-state or transient calculations over 10,000 years.

For these reasons, the reliability of the PA calculations should be assessed and documented. A value of information analysis should be included in a PA "results and interpretations section" to inform the reader of deficiencies or limitations in the PA projections, and to describe how these concerns affect PA useability. (In this regard, deterministic PA methods do not provide the analyst with as detailed or sensitive a set of tools to describe and quantify uncertainty as do probabilistic methods.) PAs are based on a set of steady-state assumptions that represent a snapshot in time that is carried forward for many years. Because data estimate reliability erodes over time, depending largely on the period of record of the input data, it may be inappropriate to assume that the analyses can provide reasonable assurance of system performance for more than several tens of years. Hence, iterative update through a formal PA maintenance program is needed. Significant limitations or uncertainties in PA assessments (e.g., data limitations) should be identified during the licensing process, prioritized, and addressed during the disposal facility life.