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Mr. Joseph J. Holonich, Chief
High-Level Waste and Uranium Recovery
Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
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Mail Stop 5E-4 OWFN
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

The U.S. Department of Energy (DOE) Uranium Mill Tailings Remedial Action (UMTRA) Project Office reviewed the *Draft Final Technical Position, Alternate Concentration Limits for Title II Uranium Mills, Standard Format and Content Guide, and Standard Review Plan for Alternate Concentration Limit Applications, February 1994, prepared by the U.S. Nuclear Regulatory Commission* as a document that would be applied to Title II sites. Our principal concern is its potential applicability to Title I sites. We are very interested in learning if the U.S. Nuclear Regulatory Commission (NRC) plans to prepare a separate guidance document for Title I sites or if appropriate modifications for Title I sites will be made to this document. The UMTRA Ground Water Project is moving forward and we fully anticipate applying alternate concentration limits (ACL) at sites where ACLs are technically justified. The best interests of both the NRC and DOE will be served if DOE's technical approach to ground water restoration is considered in the NRC guidance for Title I sites.

At a minimum, the guidance document would need to address the following comments to be applicable to Title I sites.

1. The technical position of the guidance document on Title I ACLs needs to address Subparts A and B of the Environmental Protection Agency (EPA's) proposed ground water standards that apply to ACLs for ground water compliance and to ground water protection following disposal. The guidance document refers only to ground water *protection* strategies, and not to ground water *compliance* strategies. Many Title I processing sites have off-site disposal cells.

Remedial action plans for Title I off-site disposal cells included strategies to protect the ground water below the disposal cells. The associated Title I processing sites, which are the source of the contaminated plumes below the processing site, may also be subject to ACL application. Unlike the off-site

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disposal cells, these processing sites are not licensed, will not be owned by the federal or state government, and do not have points of compliance (POC).

2. The requirements of the ACL application process may not be practical or feasible, depending on how rigorously and how extensively they are enforced. In some cases, the quality of proof needed for the ACL demonstration is unattainable, extremely costly, burdensome, and scientifically difficult. For example, meeting the requirements of the ecological assessment may be very difficult because data may not be available for all classes of organisms for all chemicals of concern. Meeting the requirement for reliable estimates of the release rates of hazardous constituents and constituent distributions (see page 15) could also be difficult. If demonstrations are unattainable, this may effectively preclude ACLs as a regulatory option.
3. The drinking water limits (10 CFR Part 40, Appendix A, Table 5C) should be updated to include the following hazardous constituents and their associated MCLs: combined uranium-234 and uranium-238, nitrate (as N), and molybdenum.
4. NRC needs to clarify whether it intends to consider as low as reasonably achievable (ALARA) *and* the elimination of a substantial present or potential hazard to human health or the environment, or if the NRC would consider ALARA *or* the elimination of a substantial present or potential hazard to human health and the environment.

The May 1991 draft of the EPA ground water standards (40 CFR Part 192, May 1991) deleted reference to the term ALARA. In verbal communication between Alan Richardson, EPA Office of Radiation Programs, and Don Metzler of this office, Mr. Richardson stated that the EPA believed that the ALARA concept was being misinterpreted/misapplied. The guidance document should consider EPA's deletion of the reference to ALARA.

In addition, ACLs could be used for alternate application other than "ALARA considering practical corrective action." For example, ACLs for constituents of concern that do not have MCLs could be determined by proposing a concentration limit based on statistical background. However, this may be unnecessarily restrictive when an ACL could be set at a level that is protective of human health, but above background.

5. POC must be comprehensive and include any point where contaminated ground water has an exposure pathway to a potential receptor, or point of exposure (POE).

This is especially valid under 40 CFR Part 192, Subpart B, when the defined contaminant plume has migrated outside the site boundary. The DOE is authorized under the Uranium Mill Tailings Radiation Control Act (UMTRCA)

to accept title to the land "which is used for the disposal of by-product material." If that land within a POE is determined by the NRC to be used for the disposal of any by-product material, then the DOE will be able to accept title to the land. However, the DOE has no authority to acquire, either through purchase or condemnation, any such land.

Section 3.2.3.1.3, page 18, states, "The maximum allowable concentrations at the POE provide the basis for the ACLs." When residual ground water contamination migrates off the site, the POE equals the POC; the POE is considered anyplace that the plume can be accessed.

Section 3.3.2.3, page 24, states, "When ground water flow contributes to surface water, the reviewer also ensures that the ACLs prevent . . . (2) the exposure of human and environmental receptors to contaminated ground water between the POC and the location where the ground water discharges into the surface-water body (point of exposure)." When contaminated ground water is below an MCL but above background, the ACL would not necessarily prevent exposure to the contaminated ground water (assuming the ACL application is at a level that is protective of human health).

6. Section 1.4, page 4, states that "A POE could be established at the distant site boundary and justified, on the basis that land ownership by the licensee or the long-term care custodian would ensure that no public water resource use would exist on the property." A public wellhead protection evaluation would be more effective in ensuring no public water resource use would exist rather than relying on property boundaries. Ground water capture is independent of property boundaries.
7. Section 1.4, page 4, states, "It should be noted that in some instances, a distant POE may be established without invoking land ownership issues; for example, when the possibility of human exposure is effectively impossible because the ground water is Class III." Limited beneficial use under Class III, such as livestock and irrigation use, must be considered. The distant POE must be protective of limited use under the Class III provision.

Also, classifying of ground water as consistent with EPA's Groundwater Protection Strategy is no longer recognized as a viable nationwide scheme. The EPA is supporting the states in developing and implementing ground water protection strategies. The ACL guidance should not use Classes I, II, and III ground water as a criterion for water use.

8. Section 1.4, page 5, states, "Additionally, unreasonably long time periods in order to achieve compliance through natural attenuation and flushing are not acceptable for license continuation." Periods of 100 years to achieve

compliance through natural attenuation and flushing are acceptable at Title I sites.

9. Section 3.2.2, page 11, references 40 CFR 192.32, which in turn references 40 CFR 264.92, (MCLs for ground water protection). The Safe Drinking Water Act regulations, 40 CFR Parts 141, 142, lists MCLs for common inorganic constituents of concern that (for a few hazardous constituents) have associated MCLs different from 40 CFR 264.92, including barium, cadmium, chromium, and selenium. In addition, there seem to be three EPA published concentration levels for soluble uranium. The guidance should clarify which table in which CFR is applicable for referencing a drinking water limit that provides acceptable hazards.
10. Definitions are noticeably absent. Terms including "practicable," "substantial threat," "significant hazard," and "reasonably conservative" may be interpreted widely and require various degrees of defense. What constitutes a significant distance between the property boundary and the uranium mill and tailings impoundments is unclear. Also, a definition of "waste" would clarify Table 2, Factors for Consideration in Establishing Alternate Concentration Limits. The standard range for the maximum annual individual risk for a carcinogen should be included in Section 3.3.2.3.2. Section 3.2.2, page 12 states, "In the absence of this type of information, modeling based upon an adequate amount of monitoring data and site characterization work, is an acceptable alternative." A general explanation is needed to define "an adequate amount."
11. Section 3.2.3.1.1, page 16 states, "At sites which have highly developed plumes, the spatial distribution of the various hazardous constituents must be defined. This information is needed to calibrate transport models and to evaluate whether humans and environmental populations are currently being exposed to elevated concentrations of hazardous constituents." This may be appropriate when contaminants have not migrated off-site. However, at most Title I sites the contaminants of concern are documented in highly defined off-site plumes. Calibrating a computer code is not needed to evaluate the risk to potential receptors when a residual plume is documented off the site.
12. For Title I sites where tailings and soil contamination have been removed, and relocated to an off-site disposal cell, it may not be necessary to discuss in detail the milling process, disposal operations, and ore composition because the standards for removal of processing wastes have eliminated the source material.
13. The DOE is authorized under UMTRCA to accept title to the land "which is used for the disposal of by-product material." If the land within a POE is determined by the NRC to be used for the disposal of any by-product material, then the DOE will be able to accept title to the land. However, the DOE has no authority to acquire, either through purchase or condemnation, any such land.

Mr. Joseph J. Holonich

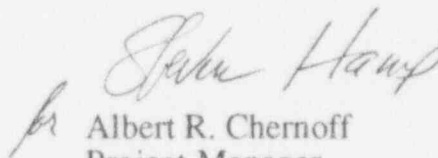
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14. The ACL guidance addresses conflicts between the NRC's requirements and more- or less-stringent state or local water quality standards (see page 26). Title I cooperative agreements between the DOE and the states and Indian tribes may include negotiated language that specifies the requirements the DOE must follow; the cooperative agreement may not agree with the NRC ACL guidance.

The enclosed presents the comments provided in this cover letter, general comments on ACL guidance recommendations for consideration, and then a page-by-page review of the ACL guidance. All comments in this cover letter are included in the enclosures.

We appreciate the opportunity to review this document. If you have any questions, we will be happy to meet with you to discuss our concerns. We also look forward to your response to the question of NRC's plans to prepare a Title I ACL guidance document.

Sincerely,



Albert R. Chernoff
Project Manager
Uranium Mill Tailings Remedial Action
Project Office

Enclosure

cc w/enclosure:

S. Hamp, UMTRA
C. Smythe, UMTRA
D. Metzler, UMTRA
D. Bierley, TAC

cc w/o enclosure:

P. Beam, EM-451, HQ

The U.S. Department of Energy UMTRA Project Review of
Draft Final Staff Technical Position
Alternate Concentration Limits for Title II Uranium Mills
Standard Format and Content Guide and
Standard Review Plan for Alternate Concentration Limit Applications
February 1994, U.S. Nuclear Regulatory Commission

The *Draft Final Technical Position, Alternate Concentration Limits for Title II Uranium Mills, Standard Format and Content Guide, and Standard Review Plan for Alternate Concentration Limit Applications, February 1994, prepared by the U.S. Nuclear Regulatory Commission* (hereafter referred to as the ACL guidance) was reviewed by the U.S. DOE UMTRA Project office.

This review presents the comments provided in the accompanying cover letter, general comments on ACL guidance recommendations for consideration, and a page-by-page review of the ACL guidance.

Comments Applicable to Title I sites

1. The technical position of the guidance document on Title I ACLs needs to address Subparts A and B of the EPA's proposed ground water standards that apply to ACLs for ground water compliance and to ground water protection following disposal. The guidance document refers only to ground water *protection* strategies, and not to ground water *compliance* strategies. Many Title I processing sites have off-site disposal cells.

Remedial action plans for Title I off-site disposal cells included strategies to protect the ground water below the disposal cells. The associated Title I processing sites, which are the source of the contaminated plumes below the processing site, may also be subject to ACL application. Unlike the off-site disposal cells, these processing sites are not licensed, will not be owned by the federal or state government, and do not have points of compliance (POC).

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Also, classifying of ground water as consistent with EPA's Groundwater Protection Strategy is no longer recognized as a viable nationwide scheme. The EPA is supporting the states in developing and implementing ground water protection strategies. The ACL guidance should not use Class I, II, and III ground water as a criterion for water use.

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information is needed to calibrate transport models and to evaluate whether humans and environmental populations are currently being exposed to elevated concentrations of hazardous constituents." This may be appropriate when contaminants have not migrated off-site. However, at most Title I sites the contaminants of concern are documented in highly defined off-site plumes. Calibrating a computer code is not needed to evaluate the risk to potential receptors when a residual plume is documented off the site.

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13. The DOE is authorized under UMTRCA to accept title to the land "which is used for the disposal of by-product material." If the land within a POE is determined by the NRC to be used for the disposal of any by-product material, then the DOE will be able to accept title to the land. However, the DOE has no authority to acquire, either through purchase or condemnation, any such land.
14. The ACL guidance addresses conflicts between the NRC's requirements and more- or less-stringent state or local water quality standards (see page 26). Title I cooperative agreements between the DOE and the states and Indian tribes may include negotiated language that specifies the requirements the DOE must follow; the cooperative agreement may not agree with the NRC ACL guidance.

General Comments and Recommendations

1. The scope of the ACL guidance assumes that all Title II sites will be stabilized on site. This assumption should be stated early in the document and address the applicability of the guidance to Title II sites with relocated tailings.
2. A summary of the applicable regulations [40 CFR 192.32(a)(2)(iv) and Criterion 5B(6) of 10 CFR 40 Appendix A] for ACLs under Title II sites should be included rather than merely cited. The NRC should also state how the NRC has expanded on existing requirements and show how the ACL guidance works within the context of the regulations.
3. The quality of proof needed as part of the ACL demonstration is unattainable in some cases (for example, the ecological information required on page 19). Demonstrations that are unattainable effectively preclude ACLs as a regulatory option.
4. Definitions are noticeably absent. Terms including "substantial threat," "significant hazard," and "reasonably conservative" may be interpreted widely and require various degrees of defense. Imprecise language in the ACL guidance can allow a regulator to dismiss an ACL application without solid foundation.

For threshold effects, the definition is presumably a Hazard Index not larger than one, but this is not discussed or explained anywhere. For non-threshold effects (cancer), the definition is presumably some incremental lifetime cancer risk. It appears that the NRC plans to provide guidance on this, if that is what is meant by "(reserved)" on the bottom of page 27. This referenced guidance will be essential for applicants to evaluate whether the ACLs they are proposing comply with the "no substantial hazard" requirement.

5. A definition of "waste" would clarify Table 2, Factors for Consideration in Establishing Alternate Concentration Limits. It is not clear if the Table's reference to "waste" refers to tailings and soil or to contamination in ground water.
6. The definition of "practicable" should be defined as it relates to Title II sites. The preamble to the 40 CFR Part 192, Standards for Remedial Actions at Inactive Uranium Processing Sites Proposed Rule, published in the Federal Register September 24, 1987, (applicable to Title I sites) states, "It should be noted that the word "practicable" is not identical in meaning to the word "practical." As used here, the former means "able to be put into practice" and the latter means "cost-effective." "
7. The ACL guidance states that the hazard assessment must consider separately threshold and non-threshold effects. Although this is appropriate, the text also calls for an evaluation of mutagenic, teratogenic and fetotoxic effects (as if they were neither threshold nor non-threshold effects). Typically, fetotoxicity and teratogenicity are evaluated as threshold effects, and RfD values are low enough to protect against any recognized potential for these effects. Mutagenicity may be

either threshold or non-threshold, but there is general acceptance of the view that mutagenicity is not a particularly useful indicator of adverse effect, and should only be taken as part of the weight of evidence evaluation on the carcinogenicity of a chemical. If the NRC requires only a summary of the data on these effects, then it is not clear how those ACLs should be derived.

8. The requirements of the application process for ACLs may or may not be practical and feasible, depending on how rigorously and how extensively some of the requirements are enforced. Specifically, it may be difficult to comply with the following requirements:
 - a. The text states that in the absence of applicable MCLs, RfDs, or RSDs, the applicant shall assess dose-response relationships based on literature searches or toxicological research. Depending on the number of chemicals which fall into this category, this may be a tremendous burden. Typically, literature searching, review of the data, and development of appropriate quantitative indices of cancer and noncancer effects can take upwards of several hundred hours per chemical. Even when done, there will always be room for debate on the appropriateness of the evaluation. This requirement, if rigorously applied, could create insurmountable obstacles.
 - b. The requirements for the human health evaluation focus on water ingestion and exposure via the food chain. The former is easy, but the latter can be difficult. The most likely food-chain pathways from the ground water to human are 1) irrigation of home gardens, 2) irrigation of agricultural crops for direct human consumption, 3) irrigation of pastures and agricultural crops for feeding livestock subsequently consumed by humans, and 4) direct watering of livestock consumed by humans. The text also mentions uptake from contaminated soils and uptake from shallow ground water. Setting up a good quantitative exposure assessment for all these pathways is labor intensive. On the other hand, once it is done, the basic scheme can probably be used repeatedly with only minor modification at multiples sites. Ideally, NRC would develop a "default" approach to evaluation of these pathways, and applicants would use the defaults or substitute site-specific data as they saw fit.
 - c. The requirements of the ecological assessment may also be very difficult to meet. Specifically the text calls for comparison of ACLs to recommend chronic tolerance or exposure limits for all exposed plants, wildlife (both aquatic and terrestrial) and livestock and crops. In some cases, comparison to subchronic tolerance values may also be appropriate. The problem is that data may not be available for all these classes of organisms for all of the chemicals of concern. If the applicant is expected to derive recommended values to fill all data gaps, this is subject to all of the same problems as outlined above for humans.
 - d. In addition, the ecological assessment calls for an evaluation of anticipated changes in environmental populations, independent of any site-related

exposures. This is a potentially valuable opportunity for applicants where an environmental population at risk from site contaminants is likely to be eliminated due to other factors, but it certainly puts a burden on applicants who do not wish to make such an argument.

- e. Both the human and the ecological assessments call for consideration of interactions and synergy. If the NRC recognizes that there will usually be little or no data on interactions, and an assumption of simple additivity is all that is required, this is not a problem. If the NRC expects something else, especially if this involves a non-additive risk model, then the level of effort could increase dramatically.
 - f. The text specifies that the hazard assessment should conclude with a "brief statement" of the maximum concentration limits below which the hazardous contaminants no longer pose a substantial hazard, and this should be accompanied by a "summary narrative" of the basis for each. This is an essential part of the application process but it is probably not reasonable to think this can be done in a "brief statement" or a "summary narrative." Derivation of the appropriate upper bound concentration values is simple if only one chemical is of concern, but becomes quite complex if there are multiple chemicals. This is because the ACLs set must account for the combined risk across all chemicals, and risk must be "apportioned" among the chemicals.
 - g. The ACL guidance states in several places that interactions and synergy need to be considered when developing ACLs, but the text on page 28 (first paragraph, second sentence) states that the reviewer should check to see that an additive approach was used. If an additive approach is to be followed, it is not clear why effort should be invested in seeking to evaluate evidence (often there is none) on synergistic interactions. Is the "additive approach" to human exposure appropriate and feasible?
9. Clarification is requested as to whether the NRC intends to consider ALARA and the elimination of a substantial present or potential hazard to human health or the environment, or if the NRC would consider ALARA or the elimination of a substantial present or potential hazard to human health and the environment.

Two criteria for acceptability of an ACL are presented in the ACL guidance: 1) exposure at the ACL must not pose a "substantial present or potential hazard to human health or the environment," and 2) the ACL must be ALARA.

The requirement for ALARA is found in 40 CFR 192.32(a)(2)(iv) "The regulatory agency may establish alternate concentration limits (to be satisfied at the point of compliance specified under §264.95) under the criteria of §264.94(b), provided that, after considering practicable corrective actions, these limits are as low as reasonably achievable, and that, in any case, the standards of §264.94(a) are satisfied at all points at a greater distance than 500 meters from the edge of the disposal area and/or outside the site boundary, and (v) . . ."

NRC's regulation 10 CFR 40 Criterion 5B(6) states, "The Commission will establish a site specific alternate concentration limit for a hazardous constituent as provided in paragraph 5B(5) of this criterion if it finds that the proposed limits is as low as reasonably achievable, after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternative concentration limit is not exceeded."

The conceptual problem is that these two criteria are independent, and it is possible that one may be satisfied while the other is not. It would be very helpful to the applicant charged with responsibility for developing ACLs to know which of these two criteria is most important, and what to do when one criterion is satisfied but the other is not.

Three examples of this follow.

- a. In a case where there is little or no exposure to ground water contaminants, the ACL needed to protect human health and the environment is very high, higher than could be achieved by ALARA.
 - b. In the case where the concentrations are ALARA, the risk to human or the environment may still be "substantial."
 - c. In a hypothetical situation, vanadium in background is 1/20th of a safe, health-based level. There is no MCL. The highest concentration in ground water downgradient from the processing site is 1/5th of the health-based level. (Assume that levels of concern to the environment are much higher, and, therefore, not relevant to this example.) A technology is available to lower the vanadium concentration to 1/10th of the health-based level. No additional health benefit results from installing the treatment system to lower the concentration from 1/5th to 1/10th of the health-based level. The concept of ALARA is so pervasive through the guidance that the regulator may still require the treatment system.
10. The text of page 20 indicates that at least three different target concentration limits must be considered which are 1) below the level identified in the hazard assessment and 2) which can be attained by practical corrective actions. It is not obvious why an applicant would propose an ACL that is lower than is necessary to protect human health and the environment.
 11. The guidance calls for evaluation of uncertainty in estimated concentration values, exposure estimates and risk calculations. This is appropriate, but it is not clear that the NRC is properly distinguishing between uncertainty and variability. That is, there will be a range of exposures and risks to a population of humans exposed at a site (variability), and there will also be uncertainty about the true level of risk to various sectors of the exposed population (uncertainty). It would be helpful to know the NRC philosophy regarding what percent of the exposed population must be protected, and with what degree of confidence.

12. The classification of ground water consistent with EPA's "Groundwater Protection Strategy" is no longer recognized as a viable nationwide scheme. The EPA is supporting states in developing and implementing ground water protection strategies. The ACL guidance should not use Class I, II, and III ground water as a criteria for water use.
13. Section 3.2, Acceptance Criteria and Section 3.3, Review Procedures are so similar that they could be combined as one. The acceptance criteria could conclude with a summation consisting of a listing of the review criteria.
14. It is not clear if the NRC would accept the observational approach and the Streamlined Approach for Environmental Restoration (SAFER), the UMTRA Ground Water Project's basis for the site observational work plan, as sufficient detail for the definition of hazardous constituent transport mechanisms.

Specific Comments

1. Page 4, first paragraph, third sentence, "There may be some instances where the property boundary is a significant distance from the uranium mill and tailings impoundments."

What is the definition of a significant distance?

2. Page 4, first paragraph, fourth sentence, "A POE could be established at the *distant*¹ site boundary and justified, on the basis that land ownership by the licensee or the long-term care custodian would ensure that no public water resource use would exist on the property."

Does this mean that as long as ground water is not to be consumed by humans, a "distant" POE is acceptable? What is the definition of "public water resource?"

3. Page 4, second paragraph, "The applicant should investigate the consequences of the land transfer provision of UMTRCA and their effect of the POE with the appropriate government agency, before proposing an ACL based on a distant POE. Under Title II of UMTRCA, at the time the NRC or an Agreement State terminates a license, the title to the land which is used for the disposal of any by-product materials (tailings); as defined by section 11 e.(2) of the Atomic Energy Act of 1954, as amended (AEA); shall be transferred to the United States or to the State in which such land is located, at the option of such States. . . . Section 83.B of the AEA specifically requires that only the land used for disposal of any section 11e.(2) by-product materials be transferred to the Federal government or State for long-term institutional control."

The DOE is authorized under UMTRCA to accept title to the land "which is used for the disposal of by-product material." If the land within a point of exposure is determined by the NRC to be used for the disposal of any by-product material, then the DOE will be able to accept title to the land. However, the DOE has no authority to acquire, either through purchase or condemnation, any such land.

4. Page 5, second paragraph, last sentence, "Additionally, unreasonably long time periods in order to achieve compliance though natural attenuation and flushing are not acceptable for license continuation."

How long is an "unreasonably long time period" for natural attenuation and flushing?

5. Page 6, first paragraph, second sentence. "The application should contain sufficient information to demonstrate that hazardous constituent concentrations will not pose a substantial present or potential hazard to human health or the environment as long as the ACLs are not exceeded . . ."

How would this be determined?

6. Page 6, second paragraph, 2, 3, 4 sentences, "Much of the ACL application materials may already be available in licensing documents . . . hydrogeologic information is available in environmental reports, license applications, or detection monitoring submittals [and can] be readily incorporated into the ACL application."

NRC's encouragement to use existing materials is appreciated.

7. Page 8, third paragraph, first sentence, "Essential to all applications is a map showing the tailings disposal area, the location of the reclaimed outcrops, the POC, the POE, other monitoring wells, and the boundary of the land to be utilized for long-term control."

The map should also include the approximate location of the contaminated plume.

8. Page 10, third paragraph, Corrective Action Review.

What level of detail is required for the corrective action assessment?

9. Page 11, second paragraph, second sentence. "The schedule is not binding nor mandatory, but will represent the anticipated time-frame of the pending Detailed Review."

No commitment for a maximum NRC review time for an ACL application is provided in the guidance. Such a commitment is important for effective implementation of an ACL program. If the time limit does not appear in this guidance, it should appear somewhere else.

10. Page 11, fourth paragraph, third sentence. "These regulatory criteria assume that background concentrations of hazardous constituents pose no incremental risks and the drinking water limits provide acceptable hazards."

The wording of the sentence is not clear and should be reworded.

11. Page 12, top of page, last sentence, "In making the present and potential hazard finding, the 19 factors listed in Table 2 will be considered."

Will the 19 factors be considered equally, or do some have more weight?

12. Page 13, Table 2, Factors for Consideration in Establishing Alternate Concentration Limits

It is not clear if the waste constituents of A.7, A.8, and B.9 refer to constituents in ground water.

13. Page 15, second paragraph, second sentence. "The source characterization should provide reliable estimates of the release rates of hazardous constituents as well as constituent distributions."

The generation of reliable estimates of the release rates of hazardous constituents would be an extremely costly, burdensome, and scientifically difficult activity. Clarification is requested on what is meant by or how to report "reliable estimates of the release rates of hazardous constituents."

14. Page 15, third paragraph. This paragraph discusses information needed to characterize the source term and then concludes that this information "should be presented in the demonstration that the ACLs will not pose a significant...hazard to human health or the environment." Certainly, the nature of the source term will have a bearing on the likelihood that an ACL may be exceeded, but the ACL itself is toxicologically set, and is protective regardless of the nature of the source term. This incongruity should be addressed.

15. Page 15, fourth paragraph, third sentence. "Depending upon the hazardous constituents present, additional waste-characterization information may be necessary, such as: (1) the hazardous constituent characteristics of density, solubility, valence state, vapor pressure, viscosity, and octanol-water partitioning coefficient; . . ."

The emphasis on organic contamination as the guidance uses such terms as octanol-water partitioning coefficient, complexing agents, and biological degradation may not be appropriate for uranium mill tailings sites.

16. Page 16, first paragraph, first sentence, "At sites which have highly developed plumes, the spacial distribution of the various hazardous constituents must be defined."

Is highly developed plumes intended, or does the NRC mean "well-defined" plumes?

17. Page 16, third paragraph, second sentence, "The scope of the hydrogeologic characterization should be equivalent to the anticipated proportions of the potential hazards associated with ground water contamination, along with the relative distance to the affected human and environmental populations at risk."

This sentence is unclear. Also, with regard to "relative distance", time of travel is the key variable, not relative distance.

18. Page 16 and 17. "Characterization of site hydrogeology generally include (1) identification of hydrogeologic units that have been or may be affected by transport of hazardous constituents;"

Is the hydrogeologic characterization needed if it is known that the prevailing contaminant levels and resulting ACL are low compared to safe health and environmental levels? Also, "affected by" should be replaced by "involved in".

19. Page 17, last paragraph. Different types of estimates are requested. The second sentence says "develop defensible and realistic exposure estimates" and the fourth sentence says, "reasonably conservative estimates." This should be clarified.

20. Page 19, first paragraph, number (3), "contaminant interactions and their cumulative effects of exposed populations."

It is very difficult to assess cumulative effects. Only a limited amount of information is present in the peer-reviewed literature that concerns itself with contaminant interactions.

21. Page 19, first paragraph, number (4), "Projected responses of environmental populations from exposure to hazardous constituents."

Projected responses to environmental populations from exposure to hazardous constituents is a very complex, long-term, and costly exercise. It is recommended that population projections be limited to sensitive species. This is, in effect, ecological modeling. We do not know if the NRC is proposing simple or complex models.

22. Page 19, first paragraph, number (5) "Anticipated changes in populations independent of the hazardous constituents exposure."

It is difficult to determine changes due to exposure to one contaminant. When assessing changes due to exposure to multiple contaminants, the task becomes monumental. Determining changes not due to hazardous contaminants is also difficult. It requires that a good database exist of baseline conditions for the population(s) of concern. This information is rarely available.

23. Page 19, Section 3.2.3.2 Review Element 2: Corrective Action Review

It is unclear what corrective action means. It could refer to the stabilization of the tailings piles, or to the ground water compliance program that may include clean-up activities. This sentence should be clarified.

24. Page 20, top of page, last sentence, "The assessment should provide supporting calculations and assumptions used in estimating the costs and benefits of each of the alternatives."

Additional guidance is needed on what expenditures the NRC feels would be acceptable for what level of risk reduction.

25. Page 20, first paragraph, fourth sentence, "The corrective action assessment considers at least three different target concentration limits proposed by the licensee that are at or below the level identified in the hazards assessment and that can reasonably be attained by practicable corrective actions."

The significance of at least three different target concentration limits is unclear. A definition of target concentration limits is needed. Why are at least three target levels at or below the safe level needed? Unless there is a regulatory basis for this request, it is recommended that it be eliminated from the guidance. A safe level is a safe level, and the multilevel analysis is expensive and pointless.

26. Page 22, top of page, "based on this assessment, the reviewer either confirms the licensee's characterization of the source term or determines that the source term has not been conservatively or realistically characterized."

The terms conservative and realistic are not the same and should be clarified. "Source terms" may not apply to Title I sites.

27. Page 22, first paragraph, second sentence, "Additionally, the characterization of background water quality is reviewed to verify existing and potential future uses of water resources."

The characterization of background water quality does not belong in Section 3.3.2.2 ("Rate and Direction of Transport").

28. Page 22, second paragraph, second sentence, "The review considers site-specific and regional information on the physical and hydrogeologic characteristics of ground water and surface water systems as well as an assessment of the defensibility of the technique and approach utilized to determine transport rate and direction."

If the NRC knows of techniques and approaches that it finds acceptable, they should be included here. If an applicant uses a technique or approach already acceptable to the NRC, then the defense of the technique can be eliminated.

29. Page 22, third paragraph, "Attenuation considerations for establishing ACLs should be reviewed, based on . . . (5) other factors."

What is meant by "other factors"?

30. Page 22, last paragraph, first sentence, "The review of hazardous constituents transport includes an evaluation of constituent mobility in ground water and also surface water, if the ground water discharge contributed to surface water."

Mobility of contaminants in surface water is an odd concept. Stream velocities are easily measured, and dilution is an important process, in contrast to ground water, where the transport evaluation is more complicated.

31. Page 24, last paragraph, first sentence "When ground-water flow contributes to surface water, the review also ensures that the ACLs prevent (1) hazardous constituent concentration in surface water from exceeding health or environmental levels or background concentrations, and (2) the exposure of human and environmental receptors to contaminated ground water between the POC and the location where the ground water discharges into the surface water body (point of exposure)."

This implies that ACLs must prevent "the exposure of human and environmental receptors to contaminated ground water..." Literally interpreted, this means that one atom is too many. This sentence needs to be clarified.

32. Page 25, first paragraph, second sentence, "Additionally, assurance must be provided that the applicant's assessment of water yields, costs for development of alternative water supplies, and assessment of legal, statutory or other administrative constraints on the use and development of the water resources are verified."

It is recommended that examples of verification measure acceptable to the NRC are included.

33. Page 26, top of page, second sentence, "The reviewer assumes that exposure is likely to occur for Class I ground waters, unless the applicant demonstrates that exposure to people using Class I ground water is effectively impossible."

The classification of ground water is not a national standard; many states are developing their own schemes for ground water classification. The term "Class I" should be replaced with qualitative terms to describe uses of ground water that can be recognized regardless of how the ground water is labeled.

The term "effectively impossible" is an extraordinarily high standard of demonstration.

34. Page 26, second paragraph, third sentence, "When standards are inconsistent among several intended water uses, the more stringent criteria prevail unless the applicant demonstrates that lesser standards apply."

It is not clear what standards are being discussed, water use standards or ACL application standards.

35. Page 27, second paragraph, third sentence, "The RfD and RSD assessment assume a human mass of 70 kg and consumption of 2 liters of water per day."

Would a probabilistic approach to estimating some of the exposure parameters based on distributions be more realistic when calculating the exposure dose?

36. Page 27, first paragraph, first sentence, "The applicant's assessment is reviewed to determine if it provides reasonably conservative or best estimates of potential health effects caused by human exposure to hazardous constituents."

If the reviewer will determine if the risk assessment provides "reasonably conservative or best estimates" of potential health risks, this could result in the NRC wanting one, the other, or both.

37. Page 28, last sentence, "The reviewer verifies that the applicant's assessment adequately evaluates the potential adverse effect to environmental species and physical structures that may be exposed to contaminated ground water and hydraulically-connected surface water."

Examples of physical structures would clarify this sentence.

38. Page 29, Section 3.3.3 Review Element 2: Corrective Action Review

It is unclear what corrective action means. It could refer to the stabilization of the tailings piles, or to the ground water compliance program, that may include clean-up activities.

39. Page 30, Corrective action discussion.

Can we know the likelihood for success for a new corrective action? Is this a "catch 22" that effectively precludes new methods?

40. Page 31, Section 3.4, Review Findings

How long will it take the NRC to prepare a documentation report?

41. Page 32, last sentence, "These review findings are then transmitted to the applicant for resolution."

The process, time frame, and resubmittal process for resolution of NRC comments by the applicant should be included.