



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB - 9 1992

OFFICE OF
AIR AND RADIATION

Mr. John J. Surmeier
Chief, Uranium Recovery Branch
Division of Low-Level Waste Management
and Decommissioning
Office of Nuclear Material Safety
and Safeguards
Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Surmeier:

This is in response to your letter of December 11, 1992, concerning the Nuclear Regulatory Commission's (NRC) proposed final staff Technical Position (TP) on Alternate Concentration Limits (ACLs) for Title II uranium mill sites.

Your letter points out two key new provisions of the proposed TP that NRC considers to be generally consistent with the Environmental Protection Agency's (EPA) "Alternate Concentration Limit Guidance, Part I, ACL Policy and Information Requirements," which EPA published in July 1987 for establishing ACLs at hazardous waste management sites under the Resource Conservation and Recovery Act (RCRA). These provisions are: 1) That a binding predetermination is proposed to be required committing future Federal or State custody of land outside the actual disposal impoundment, in order to qualify a proposed point of exposure (POE) at the edge of such land. 2) That the health basis for ACLs is proposed to be a 10^{-3} lifetime risk (the maximum total risk from all pathways under 40 CFR Part 190), instead of the 10^{-6} to 10^{-4} lifetime risk range specified in the EPA guidance.

The first of these provisions is quite consistent with EPA policy. However, the second is not. There are two fundamental problems. The first is that the EPA policy is quite clear, and the level of acceptable risk for an ACL under the proposed TP simply does not satisfy it. The second is that the proposed application of 40 CFR Part 190 to ACLs for drinking water use is inappropriate, for a number of reasons. First, Part 190 applies to all possible pathways of exposure combined, and the ACLs apply to drinking water use only. Thus, for example, under the Clean Air Act no more than 40% of the Part 190 limits are allowed for all air pathways combined. A second difficulty is that Part 190 specifies separate limits for each organ, and for the drinking water pathway these are considerably more restrictive for most radionuclides than a 10^{-3} lifetime risk. Finally, the Part 190

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standards apply to operating facilities, while they are providing a benefit to society, whereas the ACLs apply to the cleanup of decommissioned sites, with a view to unrestricted use of resources at the POE following the cessation of beneficial uses of the site involving radioactive materials. These are entirely different circumstances, and the same standards would not necessary apply.

Your letter comments that use of such a revised risk objective for ACLs is "in the spirit of risk harmonization activities between the two Agencies." This may not turn out to be the case, not only for the above reasons, but also because "harmonization" is a process just getting underway, and this particular application has not been discussed between the Agencies.

In summary, I do not believe that the proposed revised health basis for ACLs will be found acceptable by EPA. If NRC decides that it still wishes to relax the EPA ACL policy for use by its licensees, please advise us so that this matter can be resolved at an appropriate higher level between our Agencies, prior to publication of the TP.

Thanks for the opportunity to provide comments.

Sincerely yours,



Allan C.B. Richardson
Deputy Director for
Federal Guidance
Criteria & Standards Division
Office of Radiation & Indoor Air

< TRANSACTION REPORT >

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WASHINGTON, D.C. 20460

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OFFICE: NRC

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DATE: 2/9 NO. OF PAGES: 3

FROM: Alber Richardson (including this page)

TELEPHONE NO.: 233-9290

MESSAGE/INSTRUCTIONS: _____



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20556

020 1 1 1992

Mr. Allan C.B. Richardson, Deputy Director
Federal Guidance
Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
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Washington, DC 20460

Dear Mr. Richardson:

The U.S. Nuclear Regulatory Commission staff has completed the final Staff Technical Position (TP) on Alternate Concentration Limits (ACLs) for Title II Uranium Mills, a copy of which is enclosed for your review and comment. This TP provides guidance for preparing and reviewing ACL applications for uranium and thorium mill tailings sites regulated under Title II of the Uranium Mill Tailings Radiation Control Act (UMTRCA). Specifically, the TP describes NRC requirements for instituting ACLs; the standard format and content of ACL applications; and ACL application review criteria and procedures. We would like the Environmental Protection Agency's (EPA) comments or suggestions on this TP before we announce its availability in the Federal Register.

The final TP on ACLs represents a revised and updated version of our draft TP, which was announced in the Federal Register on June 30, 1988 (53 FR 24820). I gave you a draft copy of our proposed final TP during our meeting of August 13, 1992. It should be noted that the proposed final version has been slightly modified based on comments from our Commission.

We consider the final TP on ACLs to be generally consistent with EPA's "Alternate Concentration Limit Guidance, Part 1: ACL Policy and Information Requirements," which EPA published in July 1987 for establishing ACLs at hazardous waste management sites under the Resource Conservation and Recovery Act. Like the EPA Guidance, the NRC final TP requires that ACL applications demonstrate, on a site-specific basis, that a proposed ACL does not represent a substantial present or future hazard to human health when use of ground water for drinking purposes must be considered.

We have modified the proposed final guidance to strengthen the provision relating to a proposed point of exposure (POE) that is beyond the area that the appropriate Federal or State agency is required to accept for perpetual care under the land transfer provisions of UMTRCA. In such instances, our final TP requires that the applicant secure a binding predetermination of whether the State or Federal government will be the eventual site custodian, and an authoritative commitment from that party that it will accept the land prior to termination of the license.

In addition, the final TP requires that ACL applications include a health risk assessment to determine allowable concentrations at the POE for constituents for which ACLs are proposed. We have modified the specific cancer risk factor

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contained in EPA's ACL guidance. Specifically, the total lifetime cancer risk is specified at 10^{-6} - 10^{-2} in the EPA Guidance; in our final TP, the risk standards, contained in 40 CFR Part 190, have been referenced instead as a guide for determining the maximum risk allowed at a particular site. Based on a risk conversion factor of 5×10^{-4} per person-rem for doses to the public that are within the limits of Part 190, a maximum annual individual risk of approximately 1×10^{-5} , or a lifetime risk of 10^{-3} , would, therefore, be allowed under the TP. We believe that adopting the EPA standards in Part 190 in our TP is in the spirit of risk harmonization activities between the two Agencies.

We believe that a timely release of the final TP on ACLs for Title II Uranium Mills is now needed by ACL applicants, as well as the reviewers of ACL applications from NRC. Several ACL applications have already been received by our Uranium Recovery Field Office (URFO), and more application submittals are expected by URFO. We would like to make the TP available to prospective users as soon as possible. I must, therefore, ask that EPA provide us with any comments on the TP by January 19, 1993.

Sincerely,

John J. Surmeier, Chief
 Uranium Recovery Branch
 Division of Low-level Waste Management
 and Decommissioning
 Office of Nuclear Material Safety
 and Safeguards

Enclosure: As stated

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 ON ACLS FOR TITLE II URAN MILLS (FOR FR)

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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

DECEMBER, 1992

U.S. NUCLEAR REGULATORY COMMISSION

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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

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1. REGULATORY POSITION

1.1 Introduction

Pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), the U.S. Environmental Protection Agency (EPA) promulgated Environmental Standards for Uranium and Thorium Mill Tailings at Licensed Commercial Processing Sites (40 CFR Part 192, Subparts D, and E) on October 7, 1983 [48 FR 45946]. These standards incorporated ground-water protection regulations previously developed by EPA under authority of the Solid Waste Disposal Act. The incorporated regulations include provisions for establishing alternate concentration limits (ACLs) as a part of site-specific ground-water protection programs. These provisions have been subsequently incorporated into the U. S. Nuclear Regulatory Commission's regulations governing the disposal of uranium mill tailings (10 CFR Part 40, Appendix A) on November 13, 1987 [52 FR 43562].

The ground-water protection programs consist of four elements: (1) a list of hazardous constituents; (2) ground-water concentration limits for these constituents; (3) a location where compliance with the concentration limits is verified; and (4) a time period during which compliance is required. Concentration limits may be established as concentrations representative of background ground-water quality (background limits), drinking water limits (10 CFR 40, Appendix A, Table 5C), or ACLs. Under 10 CFR 40, Appendix A, Criterion 5B(6), NRC may approve ACLs for contaminants in ground water provided that the concentration limits are as low as is reasonably achievable considering practicable corrective actions, and that the contaminants will not pose a substantial present or potential hazard to human health or the environment, as long as the ACLs are not exceeded at the compliance point.

The NRC published a notice in the Federal Register on June 30, 1988 (53 FR 24820) requesting comments on the draft Technical Position. The NRC received many comments on the draft Technical Position from Federal agencies, State governments, affected Indian tribes, as well as the public. These comments were reviewed and taken into consideration during the final preparation of this Technical Position.

This Technical Position provides the methodology for the licensee to prepare and the NRC staff to review ACL applications. This Technical Position has been tailored for general characteristics of uranium mill tailings sites. It applies only to review of ACL applications for uranium and thorium mill tailings sites regulated under Title II of UMTRCA. It does not apply to similar reviews at sites regulated by EPA or States under Resource

Conservation and Recovery Act (RCRA) or Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This Technical Position is based on, and is generally consistent with, EPA's "Alternate Concentration Limit Guidance, Part 1: ACL Policy and Information Requirements," which EPA published in July 1987 for establishing ACLs at hazardous waste management sites under RCRA. This Technical Position provides a uniform basis for consideration of the 19 criteria listed in 40 CFR Part 264.94(b) as referenced in 40 CFR Part 192.32(a)(2)(iv) and incorporated into NRC's regulations in Criterion 5B(6) of Appendix A to 10 CFR Part 40.

1.2 Purpose of Guidance

The purpose of this Technical Position is to provide: (1) guidance for the NRC staff's interpretation of the requirements for establishing ACLs according to Criterion 5B(6), Appendix A, 10 CFR Part 40; (2) a standard format and content for ACL license applications; and (3) consistent NRC staff review procedures for ACL applications. The Technical Position describes the composition of an ACL application that the NRC staff would find generally acceptable. The guidance provided in this Technical Position will help to ensure the high quality and uniformity of ACL application reviews conducted by the NRC and Agreement States. This document is intended for use by licensees, NRC staff, and possible use by Agreement States for assessing and establishing ACLs at Title II uranium mills.

1.3 Document Organization

This document is organized in three parts to provide the necessary guidance for both the ACL applicant and the NRC reviewer. Section 1 provides the background and regulatory basis for the NRC Technical Position on ACLs for Title II uranium mill sites.

Section 2 presents the format and content expected for an ACL application. The information presented in this section is of a general nature to allow a degree of flexibility when making an application. It is recognized that each application will be developed from site-specific data and that there will likely be a noticeable variability among applications with regard to the types of data needed to make the ACL demonstration.

Section 3 describes the general ACL application review process and presents guidelines for the reviewer to follow during the detailed application review. This section is designed to encompass all of the factors that might be

included in an ACL application, and provide a consistent framework for the NRC review process. This section can also be used by Agreement States for conducting ACL application reviews.

1.4 ACL Implementation

ACLs may be established as part of the site-specific ground-water protection standards, as described above in Section 1.1. In accordance with NRC requirements in Appendix A of 10 CFR Part 40, licensees implement detection monitoring programs to detect releases of hazardous constituents from tailings impoundments. These programs progress into compliance monitoring if it is indicated that constituent concentrations exceed established standards. Compliance monitoring programs contain concentration limits for hazardous constituents, a point of compliance (POC) in the uppermost aquifer and a period of compliance. The concentration limits are either background values, drinking water limits, or ACLs. ACLs may be established, provided that it is demonstrated that: (1) the constituents will not pose a substantial present or potential hazard to human health or the environment, as long as the ACLs are not exceeded; and (2) the ACLs are as low as reasonably achievable considering practicable corrective actions.

ACLs may not be proposed to delay the implementation of corrective action programs. However, revised ACLs may be proposed if new information indicates that the ACLs should be modified. In all cases, ACL applications must demonstrate that hazardous constituent concentrations will not pose substantial present or potential hazards to humans or the environment at the points of exposure (POE), and the ACLs are as low as reasonably achievable considering practicable corrective actions.

The POC and POE are two locations that must be considered in the review of ACL applications. The POC is defined in Appendix A to 10 CFR Part 40 as the site-specific location in the uppermost aquifer where the ground-water protection standard must be met. In contrast, POEs are defined as the locations where humans, wildlife, or other environmental species could reasonably be exposed to hazardous constituents from the ground water. For example, the POE may be represented by one or more domestic wells that could be constructed and could result in withdrawal of contaminated ground water, or the locations where aquatic biota may be exposed to hazardous constituents as a result of contaminated ground-water discharge to a river. Thus, ground-water quality at the POEs must be maintained at levels that are protective of potential receptors.

In practice, the POC will be located within a vertical surface representing the intersection of the downgradient edge of the reclaimed tailings impoundments with the uppermost aquifer. POEs, in most situations, will be located at the downgradient edge of the land that will be transferred to either the United States or a State for long-term institutional control after the license termination. There may be some instances where the property boundary is a significant distance from the uranium mill and tailings impoundments. 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. (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).

The applicant should investigate the consequences of the land transfer provisions of UMTRCA and their effect on 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 byproduct 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 State. (In some rare cases, the surface land ownership transfer requirements may be waived for Title II disposal sites, such as with deep burial of tailings where ongoing site surveillance would not be required.) Section 83.b of the AEA specifically requires that only the land used for disposal of any section 11e.(2) byproduct materials be transferred to the Federal government or State for long-term institutional control.

The applicant is required to secure a binding pre-determination of whether the State or Federal government will be the eventual site custodian, and an authoritative commitment from that party. Unless such a commitment is secured by the licensee/applicant, to the satisfaction of the Commission, ACL applications involving a distant POE will not be approved. In instances where the licensee chooses to keep the mill property under specific NRC license and apply for an ACL as part of a compliance monitoring program, the applicant

¹ Distant refers to any POE that is spatially beyond the area that the appropriate Federal or State agency is required to accept for perpetual care under the land transfer provisions of UMTRCA.

would still be required to secure a binding commitment from the State or Federal government that will accept the transfer of the specific property, including land in excess of that used for disposal of byproduct material after the termination of the specific license.

In cases where the POE will be located at the edge of the lands that will actually be used for byproduct material disposal as defined in Section 11e.(2) of the AEA, including those lands necessary to accommodate the design features of the erosion control system and reasonable extensions necessary for perimeter roadways and extreme site terrain features, the advance commitment by the State or Federal government and corresponding approval by the Commission would not be required.

Furthermore, it should be noted that the licensee must provide financial assurances within the specific license for the restoration of ground water, with the surety scaled to the anticipated cost and time frame for achieving compliance before the land is transferred for long-term care. Additionally, unreasonably long time periods in order to achieve compliance through natural attenuation and flushing are not acceptable for license continuation.

The spatial relationship between the POC and POE is critical to the establishment of ACLs. Natural processes such as dilution, dispersion, decay, and sorption may attenuate hazardous constituents between the POC and POE. Thus, ACLs for hazardous constituents established at the POC may be greater than appropriate health and environmental concentration limits for those constituents at the POE and still be protective of human health and the environment. However, the assumption of a low-concentration projection at the POE may not be valid in cases where the majority of a contaminant plume for a particular constituent may have already passed the POC. The likelihood of this situation should be identified and addressed by the ACL applicant.

Ultimately, ACLs must be protective of human health and the environment at the POE. If there is a case where there is no practicable corrective action involving ACLs which is protective of human health and the environment, then the ACL framework is not appropriate for a licensing action. Instances such as this would have to be addressed by the Commission on a case-by-case basis.

2. APPLICATION CONTENT AND FORMAT

2.1 Application Content

Table 1 provides an outline of a generic ACL application. 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, and that the ACLs are as low as reasonably achievable considering practicable corrective actions. The demonstration should assess the hazards associated with present and potential exposure to hazardous constituents, and evaluate the reasonableness of the concentration limits, considering corrective actions. The demonstration must consider the 19 factors listed in Table 2 (Criterion 5B(6), Appendix A, 10 CFR 40). Hazard assessments should evaluate the: (1) existing distribution of hazardous constituents as well as the potential source(s) for future releases of these constituents; (2) transport of hazardous constituents in ground water and hydraulically-connected surface water; and (3) risks associated with exposure of humans and the environment to hazardous constituents. Corrective action assessments should (1) identify practicable corrective actions; (2) assess their technical feasibility; (3) determine the costs and benefits; and (4) select a practicable corrective action to achieve hazardous constituent concentrations that are as low as reasonably achievable.

ACL applications should be sufficiently detailed to allow the NRC reviewer to independently verify that the ACLs will not pose a significant hazard (present or future) to human health or the environment, and that they are as low as reasonably achievable considering practicable corrective actions. Much of the ACL application material may already be available in licensing documents. Commonly, hydrogeologic information is available in environmental reports, license applications, or detection monitoring submittals. This information can be readily incorporated into the ACL application. ACL application information may also include contaminant transport assessments and effects of human and environmental exposure to hazardous constituents.

Site characteristics, milling processes, disposal operations, and ore composition should be discussed in the ACL applications. Information related to each of the 19 factors listed in Criterion 5B(6), Appendix A, 10 CFR 40 (Table 2) should be addressed, but all factors may not be applicable due to the site-specific nature of an ACL application. If this is the case, the ACL application should provide an explanation of why a particular factor is not

appropriate. Commonly, ground-water discharge to surface waters does not occur near mill tailings sites. Therefore, information such as stream flow characteristics and transport assessments within the surface water may not be necessary. However, the burden of proof resides with the applicant to demonstrate that selected factors do not need to be considered.

2.2 Application Format

A standard format for ACL applications is proposed for the following reasons: (1) helps to assure that applications contain the information required by Criterion 5B(6), Appendix A, 10 CFR 40; (2) assists the applicant and the NRC reviewer in assuring the completeness of the provided information; (3) guides both the reviewer and application reader to pertinent and critical information; and (4) contributes to the time efficiency of the review process. Conformance with this standard format is not required. The NRC staff will accept applications with different formats, if the application adequately demonstrates the suitability of the proposed ACLs. However, reviewing an ACL application with a different format may require considerably more time to achieve the same level of detail than would have been accomplished if the application were submitted in the standard format. But, the NRC staff recognizes that the format and content of individual applications may vary somewhat, due to the site-specific differences of compliance demonstrations which may make stringent observance of this format impractical.

The applicant should present the information contained in the ACL application as clearly as possible. The technical information provided should support the applicant's demonstration that the ACLs meet the requirements in Criterion 5B(6) of Appendix A to 10 CFR Part 40. Applicants should follow the numbering system and headings of the standard format. Applicants are encouraged to use appendices to provide supporting data not specifically included in a particular section. Conventional abbreviations should be used consistently throughout the application. Any abbreviations, symbols, or special terms should be defined where they first appear in the text. Where appropriate, calculated error bands or estimated uncertainties should be included along with numerical values. Some types of information are better presented in a clear and concise graphical manner by using maps, graphs, drawings, or tables in addition to text descriptions. Applicants should ensure that graphical materials are legible and that the physical scales are adequate to clearly show details and notations. Symbols should be clearly defined and referenced.

An outline for a generic ACL application is shown in Table 1. It provides supporting information on the site and its setting, a hazard assessment, a review of practicable corrective actions, and the proposed concentration limits. The goal of standardizing the application format is to reduce review time and organize the applications.

It is strongly suggested that applications be structured to allow ready substitution of pages in response to reviewer's comments and information requests. Pages should be punched for a standard loose-leaf binder. Revisions should be provided on pages that will replace the original pages, with the changes indicated by a "line change" demarkation. The date and revision number should be indicated in the bottom outside margin of each change page, and each package of revisions submitted should include a listing of all page changes in that submittal.

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. This map should become the base map for isoconcentration maps depicting the current and estimated future distributions of hazardous constituents.

Table 1
Standard Format of an ACL Application

EXECUTIVE SUMMARY

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1. General Information
 - 1.1 Introduction
 - 1.2 Facility Description
 - 1.3 Extent of Ground-Water Contamination
 - 1.4 Current Ground-Water Protection Standards
 - 1.5 Proposed Alternate Concentration Limits
2. Hazard Assessment
 - 2.1 Source and Contamination Characterization
 - 2.2 Transport Assessment
 - 2.3 Exposure Assessment
3. Corrective Action Assessment
 - 3.1 Results of Corrective Action Program
 - 3.2 Feasibility of Alternate Corrective Actions
 - 3.3 Corrective Action Costs
 - 3.4 Corrective Action Benefits
 - 3.5 As Low As Reasonably Achievable Demonstration
4. Proposed Alternate Concentration Limits
 - 4.1 Proposed Alternate Concentration Limits
 - 4.2 Proposed Implementation Measures
5. References
6. Appendices and Supporting Information

3. APPLICATION REVIEW PROCEDURES

3.1 Areas of Review

A systematic approach to reviewing ACL applications has been developed, based on regulatory requirements in Criterion 5B(6) of Appendix A to 10 CFR Part 40, and Subparts D and E of 40 CFR 192. This approach considers two major review elements and eight sub-components as shown below. The two major elements and the applicable components include:

1. Hazard Assessment Review

The NRC staff reviews the licensee's assessment of the (1) distribution and extent of hazardous constituents, as well as the potential for future releases of constituents; (2) transport of hazardous constituents in ground water and hydraulically-connected surface water; and (3) risks associated with exposure of humans and the environment to hazardous constituents.

2. Corrective Action Review

The NRC staff reviews the licensee's corrective action assessment relative to (1) identification of alternatives; (2) technical feasibility; (3) estimated costs; (4) estimated benefits; and (5) selection of practicable corrective actions for controlling, reducing, mitigating, or eliminating ground-water contamination.

The information required to perform an acceptable hazard assessment and corrective action review will contain all relevant site-specific data to determine what level of corrective action, if any, may be needed at the site. The proposed ACLs are evaluated, based upon the measured or predicted hazardous constituent concentrations, as are the selected measures that will ensure compliance with the proposed ACLs.

3.2 Acceptance Criteria

3.2.1 Acceptance Review

An ACL application is initially reviewed to determine whether the application provides sufficient information content to allow a Detailed Review, relative to the requirements in Criterion 5B(6), Appendix A, 10 CFR Part 40.

Deficiencies that are identified during the Acceptance Review will be compiled in a list that will itemize the incomplete information. Submittal of additional information from the applicant may be necessary before the Detailed Review can begin. In some cases where the deficiencies are few, the review can proceed while the additional information is pending. Acceptance of the application does not preclude later requests for additional information by the NRC staff through the course of the detailed review.

A tentative schedule for the completion of the Detailed Review may also be established at this time. The schedule is not binding nor mandatory, but will represent the anticipated time-frame of the pending Detailed Review. It is expected that the tentative review schedules will be unique to each application and be heavily dependant on the amount and quality of the supporting information submitted by the applicant. The schedule should be developed with consideration of the current and projected regulatory workload, amount and quality of submitted information, receipt of any additional information from the applicant, and any other anticipated information exchanges between the NRC staff and the applicant.

An ACL application can be rejected if (1) the application is made for the purpose of delaying corrective action when significant human health or environmental hazard(s) exists, or (2) the application is found to lack sufficient content to permit a detailed review and evaluation of the ACL demonstration. The specific findings of the Acceptance Review and the basis for the application rejection will be described and transmitted to the applicant in writing for any ACL application not accepted for a Detailed Review.

3.2.2 Regulatory Basis and General Criteria

EPA issued standards relative to uranium and thorium mill tailings in 40 CFR Part 192. The EPA standards in 40 CFR Part 192.32(a)(2)(iv), as well as Criterion 5B(6) of Appendix A to 10 CFR Part 40, provide for the establishment of site-specific ACLs. These regulatory criteria assume that background concentrations of hazardous constituents pose no incremental risks and the drinking water limits provide acceptable hazards. It is further recognized that these two options may not be practicable or achievable at a specific site. Due to this, alternate concentration limits that present no significant hazard may be proposed provided that it is demonstrated that the limits are as low as reasonably achievable, considering practicable corrective actions. In reviewing this demonstration, the NRC staff will establish

alternate concentration limits for hazardous constituents if the proposed limits are as low as reasonably achievable 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 alternate concentration limit is not exceeded. In making the present and potential hazard finding, the 19 factors listed in Table 2 will be considered.

ACL demonstrations utilize monitoring data and physical characteristics of the site as well as the proposed reclamation plan criteria to demonstrate that hazardous constituents in the ground water will meet the criteria discussed above. 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. The application should provide or reference sufficient information to allow the NRC staff to verify the demonstration used to support the proposed ACLs.

Table 2
Factors for Consideration in Establishing
Alternate Concentration Limits
[10 CFR 40, Appendix A, Criterion 5B(6)]

- A. Potential Adverse Effects on Ground-Water Quality
1. Physical and chemical characteristics of the waste in the licensed site, including its potential for migration.
 2. Hydrogeological characteristics of the facility and surrounding land.
 3. Quantity of ground water and the direction and rate of ground-water flow.
 4. Proximity and withdrawal rates of ground-water users.
 5. Current and potential future uses of ground water in the area.
 6. Existing quality of ground water, including other sources of contamination and their cumulative impact on ground-water quality.
 7. Potential for health risks caused by human exposure to waste constituents.
 8. Potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents.
 9. Persistence and permanence of potential adverse effects.
- B. Potential Adverse Effects on Hydraulically-Connected Surface-Water Quality
1. Volume and physical and chemical characteristics of waste in the licensed site.
 2. Hydrogeological characteristics of the facility and surrounding land.
 3. Quantity and quality of ground water, and the direction and rate of ground-water flow.
 4. Patterns of rainfall in the region.
 5. Proximity of the licensed site to surface waters.

Table 2 (concluded)

6. Current and future uses of surface waters in the area and any water quality standards established for those surface waters.
7. Existing quality of surface water, including other sources of contamination and the cumulative impact on surface water quality.
8. Potential for health risks caused by human exposure to waste constituents.
9. Potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents.
10. Persistence and permanence of potential adverse effects.

3.2.3 Specific Criteria

3.2.3.1 Review Element 1: Hazard Assessment Review

The hazard assessment review includes (1) characterization of the source(s) and extent of ground-water contamination; (2) assessment of hazardous constituent transport in ground water and hydraulically-connected surface water; and (3) assessment of risks associated with exposure of humans and the environment to hazardous constituents.

3.2.3.1.1 Source and Contamination Characterization

Characterization of the contaminant source(s) and their extent provides the source term for contaminant transport assessments. The source characterization should provide reliable estimates of the release rates of hazardous constituents as well as constituent distributions.

In addition to the contaminant source, facility characterization is also necessary and should consist of: (1) the uranium recovery process(es) used at the facility; (2) types and quantities of the reagents used in milling; (3) ore compositions milled at the facility; and (4) historical and current waste management practices. This information should be considered in conjunction with the physical and chemical composition of the waste for estimating the source term of contaminant transport (e.g., location of waste discharges, retaining structures for wastes, and waste constituents). Information from these four elements should be presented in the demonstration that the ACLs will not pose a significant (present or future) hazard to human health or the environment as long as the ACLs are not exceeded.

The waste characterization includes those characteristics that significantly affect the release or transport of the hazardous constituents. Waste characterization should include the identification of hazardous constituents in the waste and in the leachate generated by the waste, including any degradation products of the constituents. 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; (2) presence and effect of complexing ligands and chelating agents, to the extent that constituent mobility may be enhanced; (3) potential for constituents to degrade due to biological, chemical, and physical processes; and (4) attenuation properties of constituents and the

affected hydrogeologic media, considering such processes as ion exchange, adsorption, absorption, precipitation, dissolution, and ultrafiltration.

At sites which have highly developed plumes, the spacial distribution of the various hazardous constituents must be defined. This information is needed to calibrate contaminant transport models and to evaluate whether humans and environmental populations are currently being exposed to elevated concentrations of hazardous constituents. Characterization of the contamination extent should include (1) the distribution of hazardous constituents in the ground water; (2) the distribution of hazardous constituents in contaminated materials other than the uranium tailings; (3) the detection monitoring program, water quality data for radionuclides, trace metals, as well as ions; and (4) documentation of sampling, analysis, and quality control / quality assurance programs.

3.2.3.1.2 Transport Assessment

The transport assessment is used to estimate the projected distribution and exposure potential of hazardous constituents. The transport assessment generally includes the following (1) hydrogeologic characteristics; (2) ground-water flow direction and quantity; (3) background water quality; and (4) estimated transport rates, geochemical attenuation, and concentrations of hazardous constituents in the ground water and hydraulically-connected surface water.

The hydrogeologic characterization must describe the ground-water environment in sufficient detail to define the hazardous constituent transport mechanisms. 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. Applicants may develop estimates that conservatively bound the magnitude of the processes affecting hazardous constituent transport for some aspects of the transport assessment.

Characterizations of site hydrogeology generally include (1) identification of hydrogeologic units that have been or may be affected by transport of hazardous constituents; (2) characteristics of the hydrogeologic units (both aquifers and aquitards) such as geometry, stratigraphy, structural inconsistencies, lithology/mineralogy, hydraulic conductivity, effective porosity, potentiometric data, recharge/discharge locations and rates, and dispersivity; (3) representative conceptual models of the ground-water flow

system; (4) surface water characteristics used in assessing the surface water transport of hazardous constituents; (5) climatic characteristics such as distributions and amounts of precipitation, evapotranspiration rate, estimated infiltration rates into contaminated materials, and the effects of variable recharge on ground water and surface water flow characteristics; (6) representative lateral and vertical ground-water flow rates and directions, including information such as estimated discharge and recharge rates, temporal variations in flow rates and directions; and (7) descriptions of the monitoring practices, procedures, and quality assurance / data validation programs used to characterize site hydrogeology.

Where possible, the hydrogeologic characterization should be based upon actual aquifer monitoring data and hydraulic measurements. This information will be utilized to assess the constituent concentrations that will likely exist in the future. Critical monitoring locations include the points of compliance and points of exposure.

Background water quality is defined as the quality of water that would be expected if milling contamination had not occurred at the facility. Background ground-water quality characterization should include (1) a map showing the locations of background monitoring sites; (2) a description of the monitoring wells, springs, surface-water samplers, suction lysimeters, and other devices; (3) descriptions of the distribution of wastes at the site; (4) information on historical changes in hydraulic heads, flow directions, flow rates, and ground-water quality; (5) analytical background water quality data; (6) descriptions and analysis of potential sources of off-site contamination; and (7) descriptions of the sampling, analysis, preservation, and quality assurance protocols.

Contaminant transport estimates are based on the hydrogeologic characteristics, transport rates, attenuation factors, background water quality, extent of contamination, and sources of contamination. The objective of the hazardous constituent transport assessment is to develop defensible and realistic exposure estimates based on reasonable projections of contaminant concentrations in ground water and surface water. This assessment should consider anticipated future events that may alter exposure and transport rates and pathways as well as the transfer of hazardous constituents from aqueous media to other environmental media, as necessary. Transport assessments should include (1) reasonably conservative estimates of the hazardous constituents transport rate in ground water and hydraulically-connected surface water; (2) estimates of the duration of constituent migration,

(3) projected temporal and variability distribution of hazardous constituents; (4) waste composition and water quality monitoring data used to validate projections of constituent transport; (5) assessments of the long-term potential for desorption and remobilization of contaminants into ground water or hydraulically-connected surface water; (6) characterization of the source term for hazardous constituents for ground water and surface water transport; and (7) assessment of uncertainties associated with the projected concentrations and distributions of hazardous constituents and the site hydrogeologic conditions.

3.2.3.1.3 Exposure Assessment

The exposure assessment determines the risks associated with human and environmental exposure to hazardous constituents; evaluates whether projected concentrations of hazardous constituents pose substantial present or potential hazards to human health or the environment; and identifies the maximum permissible levels below which such hazards do not occur. The assessment is conducted at the POE defined in the application. The maximum allowable concentrations at the POE provide the basis for the proposed ACLs. The exposure assessment also considers the ground-water resource classification and water uses, as well as an evaluation of human health and environmental hazards.

The human exposure analysis partially depends on the extent to which people are likely to use the water resources that may be affected by contamination from the site. Therefore, the current and projected future uses of ground water and surface water are assessed by determining existing and anticipated water uses, classification of water resources, institutional controls on water users, relevant water use standards, as well as the availability and characteristics of alternative water supplies. Assessments of existing and future water uses should include (1) location, type and rate of water use, as well as statutory or legal use issues; (2) water quality criteria, standards and guidelines; (3) Federal, State, or other ground-water classification; and (4) availability and characteristics of alternative water supplies. Where applicable, agricultural, industrial, domestic/municipal, environmental, and recreational water uses should be discussed.

Health and environmental hazard assessments discuss the exposure pathway identification, hazard identification, dose-response assessment, and risk characterization. The hazard assessment should project the response of human and environmental populations to the hazardous constituent exposure, based on

the projected constituent concentrations, anticipated exposure pathways, as well as available toxicological and epidemiological information. Hazard assessments commonly consider two potential human exposure pathways; (1) ingestion of contaminated water, and (2) ingestion of contaminated foods. Other pathways, such as inhalation and dermal exposure are also considered in the assessment when these exposures could result in significant hazards to people or the environment. The assessments distinguish between health impacts associated with threshold and non-threshold constituents. Mutagenic, teratogenic, and synergistic effects are considered in the analysis, if applicable, based on toxicological testing, structure-activity relationships, or epidemiological studies. The hazard assessment should also identify the assumptions and uncertainties associated with the projected health and environmental impacts.

Potential responses of environmental or non-human populations to the various hazardous constituents are assessed if such populations may realistically be exposed to contaminated ground water or hydraulically-connected surface water. Terrestrial and aquatic wildlife, plants, livestock, and crops are included in the assessment. The assessment should provide (1) inventories of potentially-exposed environmental populations; (2) recommended tolerance or exposure limits; (3) contaminant interactions and their cumulative effects on exposed populations; (4) projected responses of environmental populations from exposure to hazardous constituents; and (5) anticipated changes in populations independent of the hazardous constituents exposure. Alternatively, an applicant may demonstrate that environmental hazards are not anticipated, because the exposure will not occur.

The hazard assessment also evaluates potential damage to physical structures (such as corrosivity), that may result from exposure to the hazardous constituents in ground water and hydraulically-connected surface water. Alternatively, an applicant may demonstrate that damage to physical structures is not anticipated, because the exposure will not occur.

The hazard assessment concludes with a brief statement of the concentration limits below which the hazardous constituents no longer pose a substantial present or potential hazards to human health or the environment; along with a summary of the narrative basis for each proposed concentration limit.

3.2.3.2 Review Element 2: Corrective Action Review

Corrective actions assessments consider (1) practicable remediation

alternatives; (2) technical feasibility; (3) costs and benefits; (4) selection of appropriate corrective actions; and (5) demonstrate that the proposed concentration limits are as low as reasonably achievable, considering practicable corrective actions. The assessment should provide supporting calculations and assumptions used in estimating the costs and benefits of each of the alternatives.

The corrective action assessments are linked with the proposed concentration limits resulting from the hazards assessment section. Acceptable assessments are those that demonstrate that ACLs will be no higher than the maximum allowable concentration limits identified in the hazards assessment. If practicable corrective actions lead to constituent concentrations below those identified in the hazard assessment, then it may not be necessary to achieve the most stringent alternative. 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 hazard assessment and that can reasonably be attained by practicable corrective actions. The assessment also evaluates the costs and benefits associated with each set of target concentrations. Evaluating the costs and benefits associated with corrective action to attain the target concentrations assures that the proposed ACLs are as low as reasonably achievable, considering practicable corrective actions.

3.3 Review Procedures

3.3.1 General

In conducting reviews of ACL applications, the NRC staff verifies that the proposed ACLs would not pose a substantial present or potential hazard to human health or the environment, and that the ACLs are as low as reasonably achievable, considering practicable corrective actions. Open issues or requests for additional information are generally transmitted to the applicant in the form of written comments. The comments document the issues; discuss the significance of the comment in terms of the proposed ACLs; and suggest, if appropriate, a technical approach that may resolve each of the issues. The NRC staff may conduct literature surveys, data assessments, and perform evaluations as needed to confirm the basis for the proposed ACLs, and to verify that the proposed ACLs satisfy the general criteria listed in Section 3.2.2.

3.3.2 Review Element 1: Hazard Assessment Review

The hazard assessment used to support ACL demonstrations should ensure that the following are satisfied:

1. The hazardous constituent source term must be adequately characterized with respect to the transport assessments.
2. The rates and directions of hazardous constituent migration must be adequately determined with respect to exposure assessments.
3. The routes, amounts, and effects of human and environmental exposure to hazardous constituents must be adequately assessed.
4. The proposed concentration limits for hazardous constituents must ensure the prevention of substantial present or potential hazards to humans and the environment.

3.3.2.1 Source Term Characterization

The reviewer evaluates the characterization of the hazardous constituents source term considering the transport assessment. Generally, the source term will include existing contaminated ground water and tailings, if applicable; contaminated soils; and other wastes that may cause future releases of hazardous constituents should be considered contributing to the source term. The reviewer determines whether the characterization is sufficient to provide a defensible estimate of the types, characteristics, and release rates of hazardous constituents that have been or are anticipated to be released from the source term.

The reviewer will ensure that the demonstration (1) identifies appropriate hazardous constituents in the waste or leachate derived from the waste; (2) identifies the extent and characteristics of contaminated ground water and soils; (3) characterizes the properties of the hazardous constituents that affect their transport; and (4) estimates release rates of hazardous constituents as a function of time and space.

The reviewer generally assesses information on the uranium recovery process; the amounts and types of reagents that were used; the composition of ores as well as transport characteristics and leachability of the hazardous constituents. These factors are combined with the current distribution of

contaminated ground water to evaluate potential transport of hazardous constituents. Other relevant information may include the volume of waste, as well as volatility, octanol-water partitioning coefficient, viscosity, degradation rate constants, and density, if these properties may significantly affect transport or toxicity of hazardous constituents. 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.

3.3.2.2 Rate and Direction of Transport

The adequacy of the rate and direction of hazardous constituent transport considers (1) hydrogeology characteristics including attenuation factors; (2) hydraulic heads and water level data; and (3) rainfall patterns that may affect transport. Additionally, the characterization of background water quality is reviewed to verify existing and potential future uses of water resources.

The review of the rate and direction of hazardous constituent transport examines the hydrogeologic characterization of the site to determine if the hydrogeologic characterization of the site is adequate to support the projected extent and distribution of hazardous constituents. 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. Additionally, the reviewer evaluates potential changes in transport rates and directions related to mine dewatering and facility operation as well as rainfall distribution. Commonly, rainfall distribution is not a variable; however, construction practices could cause changes in recharge into waste materials which, consequently, could modify the releases of hazardous constituents.

Attenuation considerations for establishing ACLs should be reviewed, based on (1) extent of existing ground-water contamination, (2) projected extent of future contamination, (3) duration and spatial distribution of attenuation, (4) uncertainties associated with attenuation mechanisms, and (5) other factors.

The review of hazardous constituents transport includes an evaluation of constituent mobility in ground water and also surface water, if the ground-water discharge contributes to surface water. The reviewer determines whether

estimated hazardous constituent concentrations and projected distribution are either best estimates or reasonably conservative representations of the rate, extent, and direction of constituent transport. This determination is made considering the existing distribution of hazardous constituents in ground water and their characteristics, as well as the effects of such factors as chelation, degradation, and attenuation mechanisms. The reviewer confirms that all likely and significant pathways of hazardous transport in ground water and surface water have been identified and assessed, considering conservative or realistic effects to humans or the environment and that the assessments used to estimate constituent transport are appropriate to support regulatory decisions. Additionally, the reviewer confirms that the projections have been sufficiently validated and calibrated based on site-specific information.

The reviewer also evaluates the adequacy of the existing detection monitoring program, water quality data, modeling approach and results, facility characteristics, and the procedures used to measure the background concentrations. The reviewer determines whether the transport assessment reasonably characterizes facility impacts on the quality of ground water and surface water. Background concentrations may be complicated in areas where there are several affected aquifers, or where existing contamination from activities unrelated to uranium milling has altered ambient water quality. The reviewer should verify that appropriate characterizations of background water quality are established for each affected aquifer and for hydraulically connected surface-water bodies that are downgradient from the facility.

At sites where entire aquifers are contaminated by seepage, the reviewer evaluates the applicant's justification for not characterizing background water quality and the applicant's estimate of the unaffected water quality. The reviewer evaluates site and facility information and either confirms the determination of background water quality or determines that the estimates are not reasonably conservative. Facility information is reviewed to ensure that estimates of background water quality are sufficient to support analyses of potential use and effects associated with human and environmental exposure to hazardous constituents.

3.3.2.3 Exposure Assessment

The reviewer verifies that the POE proposed in the application meets the Point of Exposure definition presented in Section 1.4 ACL Implementation. In most cases, the POE for pathways assuming well-water use will be proposed at the

downgradient limit of the perpetual care boundary. The reviewer must verify that the application contains properly documented assurance that the appropriate Federal or State agency will accept the transfer of the specific property, including land in excess of that needed for tailings disposal. The reviewer also evaluates the assessment of the risks associated with human and environmental exposure to hazardous constituents, considering the source term rates and directions of constituent transport, and the location of the POE. The assessment includes characterization of existing and potential uses of water resources that may be affected by the facility, evaluation of human and environmental exposure to hazardous constituents, and assessment of the permanence and persistence of any adverse effects associated with exposure.

The reviewer determines whether the characterization of exposure pathways is adequate, considering human and environmental exposure to hazardous constituents. Physical and biological pathways of constituent transport by ground water and surface water are primary considerations. The reviewer confirms the applicant's identification and characterization of sensitive human and environmental populations, and that the sensitive populations have been adequately considered in the exposure assessment. The assessment must consider human exposure due to ingestion of drinking water and contaminated food products. If other exposure pathways are likely, these should also be identified and considered.

The applicant's assessment of adverse effects associated with present and potential human exposure to hazardous constituents should be confirmed, based on the exposure pathways characterization. The human exposure assessment includes: (1) classification of affected water resources; (2) assessment of existing and potential water uses; (3) evaluation of the likelihood that people will be exposed to hazardous constituents; and (4) evaluation of adverse effects associated with exposure to hazardous constituents, including assessment of the permanence and persistence of adverse effects.

When ground-water flow contributes to surface water, the reviewer also ensures that the ACLs prevent (1) hazardous constituent concentrations 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).

3.3.2.3.1 Resource Classification and Water Use

A review of resources classification, as well as existing and potential water uses, confirms that the applicant considers domestic and municipal drinking water, fish and wildlife propagation including special ecological communities, industrial, agricultural and recreational water uses. Additionally, assurance must be provided that the applicant's assessment of water yields, costs for development of alternate water supplies, and assessment of legal, statutory or other administrative constraints on the use and development of the water resources are verified. The applicant's assessment of existing and potential uses of water at the facility should be consistent with Federal, State, and local water use inventories, thereby providing an adequate basis on which to assess existing and potential human and environmental exposure to hazardous constituents.

The reviewer ensures that the assessment conservatively estimates the probability of human exposure to contaminated water. Such estimates are often difficult to establish quantitatively. Consequently, defensible qualitative estimates are often necessary. Qualitative determinations include either of the following:

1. Reasonably likely - exposure has or could have occurred in the past, or available information indicates that exposure may reasonably occur during the duration of the contamination; or
2. Reasonably unlikely - exposure could have occurred in the past, but will probably not occur in the future, because initial incentives for water use have been removed, or available information indicates that no incentives for water use are currently identifiable, based on foreseeable technological developments.

Qualitative exposure determinations consider existing and potential water uses relative to background water quality. In general, the reviewer considers existing and potential uses of water that may be affected by the facility. Existing use may include past uses, even though water resources are not presently being used. Potential uses include anticipated and possible uses. Anticipated water use includes only those uses that are reasonably sure to occur. Possible uses are those that are compatible with background water quality without water treatment before use.

The review of long-term water use considers aquifer classifications consistent with EPA's "Groundwater Protection Strategy". The reviewer assumes that exposure is likely to occur for Class I ground waters, unless the applicant demonstrates that exposure to people using the Class I ground water is effectively impossible. The reviewer considers potential uses of Class II ground water, but such uses are not considered for Class III ground waters, unless they are currently utilized for beneficial purposes.

The reviewer confirms the assessment of existing and anticipated uses of water by comparing background water quality with Federal, State, and local water quality standards. Background water quality is compared with the water quality standards, considering legal constraints, to determine existing and potential water uses. When standards are inconsistent among several intended water uses, the more stringent criteria prevail unless the applicant demonstrates that lesser standards apply. Additionally, the reviewer considers water use estimates based on demographic projections, zoning patterns, and projected population growth estimates. The reviewer may also utilize information on water use from local organizations, water supply companies and State and Federal agencies, along with considering wellhead protection areas as defined by the Safe Drinking Water Act.

The most significant pathway for human exposure to waterborne contaminants is through consumption of contaminated drinking water. Other pathways include dermal contact, inhalation, and food ingestion. These pathways should be considered, but need not always be assessed by the applicant. Class II ground water is further clarified as a Class A resource - having a mean annual total dissolved solids (TDS) concentration less than 3000 mg/l or a Class B resource - with a mean annual TDS concentration equaling or exceeding 3000 mg/l in water. The reviewer may determine whether the water representative of background quality is Class A or B, on a site-specific basis, by considering concentrations of other constituents that affect human exposure to hazardous constituents.

For Class A resources, the reviewer assumes that humans will withdraw water from affected aquifers and/or surface water bodies at any hydraulically downgradient point beyond the site boundary (either current or perpetual use). This assumption applies to Class A resources regardless of whether or not water resources are currently being used. For Class B resources, the reviewer evaluates adverse effects on human health considering the location and purpose of the nearest, downgradient, existing or potential water use. Generally, human health effects, due to exposure from using Class III ground-

water resources, are not evaluated unless the water is currently utilized or future use is anticipated.

3.3.2.3.2 Evaluation of Health Hazards

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. This determination is based on comparisons of existing and projected constituent concentrations with appropriate exposure limits and dose-response relationships from available literature. The reviewer confirms that the applicant considers Maximum Contaminant Levels (MCLs) for drinking water, reference doses (RfDs), or risk specific doses (RSDs) in assessing potential health hazards for each constituent for which an ACL is proposed. In the absence of applicable MCLs, RfDs, or RSDs, the reviewer confirms that the applicant has assessed dose-response relationships based on literature searches or toxicological research. The reviewer verifies that the exposure analysis distinguishes between threshold (toxic) and non-threshold (carcinogenic) effects associated with human exposure as well as teratogenic, fetotoxic, mutagenic, and synergistic effects.

The RfDs are the amounts of toxic constituents to which humans can be daily exposed without suffering any adverse effect. RSDs are the amounts of proven or suspected carcinogenic constituents to which humans can be daily exposed without increasing their risk of contracting cancer above a specified risk level. RSDs and RfDs for most hazardous constituents in uranium tailings can be obtained from EPA. The RfD and RSD assessment assume a human mass of 70 kg and consumption of 2 liters of water per day. More stringent criteria may apply if sensitive populations are exposed to hazardous constituents.

In making a required finding that a proposed ACL does not represent a substantial present or future hazard to human health when use of ground water for drinking purposes must be considered, as well as in making as low as reasonably achievable determinations, such findings must necessarily be made on a case-by-case basis due to the absence of limits in the regulations. The reviewer confirms that the applicant has used the appropriate risk level in the RSD calculations. The standards in 40 CFR Part 190 can be used as a guide to make this determination. Based on a risk conversion factor of 5×10^{-6} per person-rem for doses to the public that are within the limits of 40 CFR Part 190, the maximum annual individual risk would be approximately 1×10^{-5} . For the purposes of the ACL guidance, it should be understood that this value

(10^{-5}) represents the combined total risk from radiological and nonradiological hazardous constituents.

The applicant should consider the cumulative effects of human exposure to hazardous constituents for which ACLs are proposed and other constituents present in contaminated ground water. The reviewer confirms that an additive approach is utilized in assessing adverse effects associated with exposure to hazardous constituents.

The reviewer also confirms that the applicant identifies and justifies a maximum allowable human exposure level for each ACL constituent. The reviewer verifies that the applicant has considered uncertainties in estimating risks and the persistence and permanence of adverse effects. The reviewer determines whether the proposed human exposure levels are reasonably conservative, defensible, and sufficiently protective of human health to avoid a substantial present or potential hazard to people for the estimated duration of the contamination.

3.3.2.3.3 Evaluation of Environmental Hazards

Similar to the review of human health effects, the reviewer verifies the assessment of risks associated with hazardous constituent exposure to environmental populations. The review includes consideration of adverse effects to aquatic and terrestrial wildlife, plants, agricultural crops, animals, and physical structures. The reviewer confirms that the assessment adequately identifies and evaluates the adverse effects such as: (1) contamination-induced biotic changes, (2) loss or reduction of unique or critical habitats, and (3) jeopardizing endangered species. If adverse effects on endangered species and critical habitats are predicted, they are included in the assessment. Consultation with the U.S. Fish and Wildlife Service is required under the Endangered Species Act if an endangered or threatened species is found on the site or thought to inhabit the site.

For each potential exposure pathway, the reviewer compares existing and predicted constituent concentrations with chronic toxicity levels for plants and animals. Acute and subchronic effects may be considered based on estimated constituent concentrations and limits for acute and subchronic environmental exposure. For physical structures, such as foundations, underground pipes, and roads; the reviewer ensures that estimated constituent concentrations will not result in any significant degradation or loss of function as a result of contamination exposure. 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.

Bioaccumulation and food web interactions are also considered, in reviewing adverse effects. Aquatic wildlife effects are evaluated by comparing estimated constituent concentrations with Federal and State water quality criteria. The reviewer ensures that the applicant considers terrestrial wildlife exposure to constituents through direct exposure and food web interactions. The assessment should identify and assess terrestrial habitats at sites where terrestrial wildlife may potentially be exposed to hazardous constituents.

Agricultural effects consider both direct and indirect exposure pathways, crop impacts, reduced productivity, and bioaccumulation of constituents. Reasonably conservative estimates of constituent concentrations are compared with Federal and State water quality criteria to estimate agricultural effects associated with constituent exposure. Additionally, crop exposures through contaminated soil, shallow ground-water uptake, and irrigation; along with livestock exposure through direct ingestion of contaminated water and indirect exposure through grazing should be assessed. The reviewer ensures that the agricultural assessment is consistent with any assessment of human exposure to hazardous constituents through ingestion of contaminated food products.

3.3.3 Review Element 2: Corrective Action Review

The applicant's assessment of the need for and selection of corrective actions is reviewed, in conjunction with the hazard assessment. Previous, current, and proposed practicable corrective actions are reviewed to determine if the applicant has demonstrated that the proposed ACLs are as low as reasonably achievable. The demonstration includes identification of alternative corrective actions, assessment of their technical feasibility, implementation, costs and benefits, and selection of practicable corrective actions.

The corrective action assessment should ensure that the following are satisfied:

1. A complete range of reasonable alternative corrective actions has been identified.

2. The identified corrective actions are feasible and appropriate to reduce constituent concentrations at the site.
3. The corrective actions have been designed to optimize their effectiveness.
4. An objective comparison of the costs and benefits associated with the corrective actions is complete.
5. The proposed ACLs are as low as reasonably achievable.

The reviewer verifies that the applicant's assessment identifies and evaluates an adequate range of reasonable corrective action measures. The assessment should provide sufficient descriptive detail for each of the identified measures, so that the reviewer can independently verify reasonableness of the corrective action. Numerous corrective actions are currently in operation at Title II uranium mill sites. These corrective actions, their results, and their application at other sites can serve as the basis for an applicant's selection of a corrective action program. Sufficient analytical data exist to accurately predict the hazardous constituent concentrations that would likely result from implementation.

Following the review of the identified corrective actions, the reviewer verifies the applicant's assessment of the technical feasibility for each of the identified actions. The technical feasibility review considers site-specific hydrogeologic characteristics that may affect the performance of the corrective measure. In addition, the contamination extent and the potential for human and environmental exposure are also considered. The applicant's feasibility assessment should be based on proven applications of corrective action techniques at other contaminated sites; however, this does not limit the applicant from proposing new and promising corrective action techniques for approval, given there is adequate documentation of the likelihood for success. Additionally, the reviewer confirms that the identified corrective action is followed by a suitable monitoring period to verify that the remediated water quality is stable.

The reviewer should then determine whether the feasible corrective actions have been designed to optimize the effectiveness in reducing hazardous constituent concentrations. Optimization calculations should provide approximations of the effects on the hydrogeologic system.

The direct and indirect benefits of implementing each of the identified corrective actions should be compared with the costs of performing (or not performing) such measures. The cost estimates include consideration of capital costs for design, implementation, and decommissioning, along with operation and maintenance costs. The reviewer verifies estimates of the current and projected value of pre-contaminated water resources based on water rights, availability of alternative water supplies, and projected water use demands. The reviewer generally considers the value of potentially contaminated water resources as equal to either the cost of domestic or municipal drinking water supplies, or the cost of supplied water to replace the contaminated resources. The absence of alternative water supplies increases the relative value of potentially contaminated water resources. The adequacy of the benefits assessment is similarly evaluated considering the avoidance of adverse health effects, value of pre-contaminated ground-water resources, prevention of land value depreciation, and benefits accrued from performing the corrective action.

Finally, the adequacy of the applicant's consideration of practicable corrective actions and the demonstration that proposed ACLs are as low as reasonably achievable are evaluated. The reviewer considers relevant guidance such as the as low as reasonably achievable philosophy in Appendix I to 10 CFR Part 50, National Council on Radiation Protection and Measurements Report Number 39, and International Commission on Radiological Protection Publication 22. The reviewer verifies that the applicant's assessment has demonstrated that the proposed ACLs are as low as reasonably achievable, considering practicable corrective action.

3.4 Review Findings

The findings from the detailed application review will likely support one of the following recommendations: (1) approval of the entire application proposal, (2) approval of selected ACLs, or (3) non-approval of the application in its entirety. The reviewer develops a separate written report which fully documents the recommendations, including a detailed description of the technical basis that supports each recommendation. The report should address the general and specific criteria presented in Sections 3.3.2 and 3.3.3; along with any other criteria that may be relevant, because of site-specific conditions presented in the application. The documentation report must be prepared before formal approval of the proposed ACLs, so that it can be used for reference in the licensing action.

If the applicant's ACL submittal satisfies the acceptance review criteria and the detailed review confirms the basis for the proposed ACLs, then it can be concluded that regulatory compliance has been achieved. The reviewer may then recommend approval of the site-specific alternate concentration limits for the constituents requested by the applicant and provide the documentation to support the approval.

The reviewer may also recommend establishing ACLs for only those constituents for which the applicant's demonstration is sufficient to satisfy regulatory requirements. In this case, the reviewer would document and describe which ACLs proposed by the applicant were not recommended for implementation along with those approved. These descriptions should cite specific inadequacies that caused the demonstration to fail for the selected constituents, describe the technical basis for the review conclusions, and identify an alternative technical approach that might resolve the inadequacies. The reviewer will also develop documentation for the approved ACLs.

If the applicant's ACL submittal fails to demonstrate compliance with Criterion 5B(6) of Appendix A to 10 CFR Part 40, then the reviewer documents the basis for the failure, cites specific inadequacies, and describes the technical basis for the review conclusions. These review findings are then transmitted to the applicant for resolution.