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APPLICATION OF 40 CFR 191 TO OPERABLE UNIT 4

05/05/94

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DOE-FN EPA
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LETTER



Department of Energy
Fernald Environmental Management Project
P.O. Box 398705
Cincinnati, Ohio 45239-8705

MAY 05 1994
DOE-1630-94

Mr. James A. Saric, Remedial Project Manager
U. S. Environmental Protection Agency
Region V - 5HRE-8J
77 W. Jackson Boulevard
Chicago, Illinois 60604-3590

Mr. Tom Schneider, Project Manager
Ohio Environmental Protection Agency
40 South Main Street
Dayton, Ohio 45402-2086

Dear Mr. Saric and Mr. Schneider:

APPLICATION OF 40 CFR 191 TO OPERABLE UNIT 4

Reference: Jim Saric to Jack Craig, "Application of 40 CFR 191 to Operable Unit 4," dated April 25, 1994

The Department of Energy, Fernald Field Office (DOE-FN) acknowledges the receipt of the attached referenced letter from the United States Environmental Protection Agency (USEPA). As you are aware, DOE-FN does not agree with the application of 40 CFR 191 to the K-65 residues. Enclosed is the DOE-FN position on the application of 40 CFR 191 to Operable Unit 4 on a citation-by-citation basis. However, because Applicable or Relevant and Appropriate Requirements (ARARs) are not subject to dispute as stated in Section XII.F.1 of the Consent Agreement, as Amended, DOE-FN will revise the ARARs in the Draft Record of Decision (DROD) to reflect the direction as provided in the referenced April 25, 1994, letter.

A Statement of Significant Difference Section will be provided in Section 11 of the DROD to address this change. Also, the on-property disposal alternatives for the residues (2A/Vit and 2A/Cem) will be removed from consideration in the DROD since these alternatives will no longer meet the threshold criteria for ARAR compliance. The comparative analysis summary will also be modified accordingly to reflect this change.

If you have additional concerns, please contact Randi Allen at (513) 648-3102.

Sincerely,


Jack R. Craig
Fernald Remedial Action
Project Manager

FN:Allen

Enclosure: As Stated

cc w/enc:

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IMPLEMENTATION OF 40 CFR PART 191 REVISED REGULATIONS AS APPLICABLE OR
RELEVANT AND APPROPRIATE REQUIREMENTS IN THE OPERABLE UNIT 4
FEASIBILITY STUDY/PROPOSED PLAN AND RECORD OF DECISION

BACKGROUND

DOE-FN received conditional approval of the Draft Final Feasibility Study/Proposed Plan - Draft Environmental Impact Statement (FS/PP-DEIS) for Operable Unit 4 (OU4) from USEPA on February 9, 1994. The Amended Consent Agreement with USEPA requires review (and concurrence) on applicable or relevant and appropriate requirements (ARARs) contained in all primary documents 30 days prior to document submittal. This requirement was satisfied during the ARAR presentation conducted with the USEPA and OEPA on August 18, 1993 prior to the first submittal of the draft Feasibility Study. Although no subsequent meetings have been held to discuss revisions to the ARARs, both agencies have had the opportunity to review and comment on the ARARs included in the various drafts of the referenced documents.

Included in the FS/PP-DEIS ARARs is a reference to 40 CFR Part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level, and Transuranic Wastes". Following the last round of comments received on the Draft OU4 FS/PP-DEIS submitted in December 1993, this reference in the OU4 FS/PP-DEIS to 40 CFR §191 was modified in the Draft Final OU4 FS/PP-DEIS, submitted in February 1994, to reflect the changes that occurred upon repromulgation of the rule on December 20, 1993. 40 CFR §191 was originally promulgated by USEPA on September 19, 1985 (50 FR 38084) under the Nuclear Waste Policy Act, et al. On July 17, 1987, following a legal challenge, the U. S. First Circuit Court of Appeals remanded Subpart B of §191 (NRDC v. EPA, 824 F.2d 1258). The Waste Isolation Pilot Plant Land Withdrawal Act of October 1992 reinstated the remanded standards except for the parts of §191.15 and 191.16 that were the subject of the remand. A Proposed Rule to amend 40 CFR §191 was published in the Federal Register on February 10, 1993. Final agency action in the form of the December 20, 1993 rulemaking incorporates comments received on the Proposed Rule, and satisfies the issues which were the subject of the original remand. This Final Rule became effective on January 19, 1994, during final revision of the OU4 FS/PP/EIS.

This paper presents the DOE position regarding the inclusion of the revised requirements of 40 CFR §191 as ARARs in the OU4 FS/PP-DEIS. Included in the paper are an analysis of the definition of applicable or relevant and appropriate requirements as they pertain to 40 CFR §191 and the FEMP, an examination of each requirement of the repromulgated 40 CFR §191, and a discussion of the proposed approach for adoption of the new 40 CFR §191 requirements as ARARs to supplement the FS/PP-DEIS ARAR tables for remediation of OU4.

40 CFR §191 cannot be considered a legally "applicable" class of ARAR for this CERCLA remediation. The OU4 wastes do not include any spent nuclear fuel, high level, or transuranic (TRU) wastes, as defined in 40 CFR §191 and other regulations governing radiation. Since 40 CFR §191 regulates only high level, TRU, or spent nuclear fuel, §191 is not applicable to any OU4 waste streams. Since only applicable requirements pertain to off-site disposal

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under CERCLA, these requirements will not impact the proposed off-site alternative for disposition of the K-65 material. Therefore, the promulgation of the revised regulations does not affect the path forward for the preferred alternatives described in the OU4 FS/PP-DEIS which specify off-site disposal for the K-65 material, or otherwise impact the remediation of OU4, as currently proposed.

DOE previously included 40 CFR Part 191 Subpart A as relevant and appropriate, and Subpart B as to be considered (TBC) criteria for management of K-65 material in accordance with guidance received from the USEPA. Subpart A of §191, entitled "Environmental Standards for Management and Storage" includes public dose rate standards for protection of the public from radiation hazards posed by spent nuclear fuel, high-level, or transuranic waste material. The repromulgation of the Final Rule did not materially affect the sections of Subpart A referenced in the OU4 FS/PP-DEIS; the Subpart A requirement referenced in the OU4 FS/PP-DEIS remains unchanged in the table of ARARs as a relevant and appropriate requirement as directed by the USEPA. Subpart B of §191, entitled "Environmental Standards for Disposal", includes long term (10,000 years) requirements for containment, and protection of individual members of the public from disposed spent nuclear fuel, high-level, or transuranic waste material. A significant change was made to Subpart B during the repromulgation. The Final Rule removed the original section §191.16 containing groundwater monitoring requirements from Subpart B. Groundwater monitoring requirements were modified to require assurance for 10,000 years, and are now found in a new Subpart C of §191. In response to this change, DOE accordingly removed section §191.16 from the requirements of Subpart B referenced as a TBC in the revised OU4 FS ARAR tables. However, the designation of Subpart B as TBC in the document was not revised to "relevant and appropriate", but remains classified as originally directed by the USEPA.

The former 40 CFR §191.16 was the requirement for long term groundwater monitoring of the disposal site for selected radionuclides. However, since ARARs for groundwater monitoring, and protection of an underground source of drinking water from radionuclides are already included in the FS/PP-DEIS, the requirements of the newly created Subpart C were not included in the revised lists of ARARs as either relevant and appropriate requirements, or TBCs.

DISCUSSION OF "APPLICABLE", "RELEVANT AND APPROPRIATE", AND "TO BE CONSIDERED" UNDER CERCLA:

APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS

In order to be considered *either* APPLICABLE *or* RELEVANT AND APPROPRIATE, a requirement must be enforceable by law. Only those requirements that are substantive in nature, rather than administrative, are required to be considered as potential ARARs. Substantive requirements are those that "pertain directly to actions or conditions in the environment... Administrative requirements are those mechanisms that facilitate the implementation of the statute or regulation" (CERCLA Compliance with Other Laws Manual, Draft Guidance, USEPA, OSWER Directive 9234.1-01, 8/8/88). Also, compliance is required to be demonstrated for only those applicable requirements which are identified for off-site alternatives; on-site alternatives must comply with both applicable and relevant and appropriate requirements.

APPLICABLE requirements are cleanup standards or other environmental protection requirements that SPECIFICALLY APPLY to the substances or activities at the Superfund site, and for which compliance with the requirements is mandated. According to the NCP, the basic considerations as to whether the potential ARARs are applicable are "whether the requirement specifically addresses a hazardous substance, pollutant, contaminant, remedial action, location or other circumstances found at a CERCLA site" [40 CFR 300.400(g)(1)].

The basic considerations as to whether a requirement is RELEVANT AND APPROPRIATE are "whether the requirement addresses problems or situations that are sufficiently similar to the circumstances of the release or remedial action contemplated [i.e., relevant] and [emphasis added] whether the requirement is well-suited [i.e., appropriate] to the site, and therefore both relevant and appropriate" [40 CFR 300.400(g)(2)]. To be a relevant and appropriate requirement, the requirement must be both relevant and appropriate.

TO BE CONSIDEREDs (TBCs)

TO BE CONSIDEREDs (TBCs) are broadly defined as unpromulgated criteria, advisories, guidance, and proposed standards that are not legally binding upon the proposed activity, but are considered necessary to protect human health and the environment. TBCs are intended to consist of guidance, or similar non-promulgated advisories, that assist in evaluating health effects or in implementing a regulation.

ANALYSIS OF 40 CFR §191 REQUIREMENTS AS POTENTIAL ARARs FOR OU4 REMEDIATION UNDER CERCLA:

40 CFR 191 Subpart A -
Environmental Standards for Management and Storage

40 CFR §191.01 Applicability.

Requirement: This section describes the applicability of Subpart A to NRC, Agreement State, and DOE facilities.

Discussion: The description of a requirement's applicability is generally considered an administrative, rather than a substantive requirement.

Conclusion: This requirement should not be referenced in the FS/PP-DEIS potential ARARs for OU4.

40 CFR §191.02 Definitions.

Requirement: This section defines various terms used in Subpart A.

Discussion: Definitions are generally considered an administrative, rather than a substantive requirement. These definitions are useful for interpretation of the intent of the regulations.

Although not specifically defined in 40 CFR § 190, §192, or either promulgation of §191, "transuranic" radioactive waste, as used in this part, means

- o waste containing more than 100 nanocuries [per gram of waste]
- o of alpha-emitting
- o transuranic isotopes
- o with half-lives greater than twenty years..." [40 CFR 191.02(i)]

- o The preamble to the previous 40 CFR §191 [50 FR 38066, September 19, 1985] refers to "man-made radionuclides HEAVIER than uranium [emphasis added]" (i.e., atomic number greater than 92) when discussing transuranics.

- o DOE Order 5820.2A also supports this definition, defining a transuranic radionuclide as "any radionuclide having an atomic number GREATER than 92 [emphasis added]."

- o This interpretation by atomic number is further reinforced in the preamble of the newly Final Rule 40 CFR §191 [58 FR 66398, No. 242, published December 20, 1993, effective January 19, 1994], which clarifies the definition of transuranic waste as "materials containing elements having atomic numbers GREATER than 92 [emphasis added] in concentrations greater than 100 nanocuries [per gram of waste] of alpha-emitting isotopes, with half-lives greater than twenty years ..." [58 FR 7924, No. 26, February 10, 1993].

The K-65 material is byproduct from the processing of natural ores rich in uranium and radium. Most of the activity in the K-65 material is due to radionuclides having atomic numbers LESS than 92, predominantly radium and its daughters. This activity exceeds 100 nanocuries per gram. A small fraction of the total activity is attributed to natural uranium isotopes (which have an

atomic number of 92) present in the waste. Since all TRU radionuclides are man-made and not naturally occurring, and since the K-65 material is generated from the processing of natural ores, there are expected to be no transuranic radionuclides (atomic numbers greater than 92) present in the K-65 waste material.

Conclusion: Since this requirement contains only definitions, it is administrative and should not be referenced in the FS/PP-DEIS potential ARARs for OU4.

40 CFR §191.03 Standards.

Requirement:

o 40 CFR 191.03(a) "Management and storage ... at all facilities regulated by the [Nuclear Regulatory] Commission [NRC] or Agreement States, combined annual dose equivalent to any member of the public in the general environment ... shall not exceed ..."

- o whole body 25 mrem/yr
- o thyroid 75 mrem/yr
- o any other critical organ 25 mrem/yr

o 40 CFR 191.03(b) "Management and storage ... at all facilities for the disposal ... that are operated by the Department [of Energy, DOE] and that are not regulated by the [Nuclear Regulatory] Commission or Agreement States shall ... provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment ... shall not exceed ..."

- o whole body 25 mrem/yr
- o any critical organ 75 mrem/yr

Discussion: DOE is NOT regulated by the NRC, and Agreement State regulations do not apply to DOE. Ohio is NOT an Agreement State. The standards in 40 CFR 191.03(a) are neither applicable nor relevant and appropriate to the waste while it remains on the FEMP site. DOE facilities managing waste regulated under §191, however, would be subject to the requirements under 40 CFR 191.03(b). Because the K-65 material does NOT have a transuranic isotopic activity level greater than 100 nanocuries per gram of waste, 40 CFR §191.03(b) cannot be applicable. However, these standards are potentially relevant and appropriate to management and storage of the K-65 material while at the FEMP.

Conclusion: 40 CFR 191.03(b) should be referenced in the OU4 FS/PP-DEIS as a potential relevant and appropriate requirement.

40 CFR §191.04 Alternative Standards.

Requirement: Establishes conditions for the USEPA to issue alternative standards in lieu of the standards under 40 CFR §191.03(b).

Discussion: Since DOE expects to comply with the standards under 40 CFR §191.03(b) for on-site management of the K-65 material, this requirement is not needed in order to be protective of human health and the environment. Since this requirement offers nothing substantive, it should not be considered as a potential ARAR.

Conclusion: 40 CFR §191.04 should not be referenced as a potential ARAR in the OU4 FS/PP-DEIS.

40 CFR §191.05 Effective Date.

Requirement: This section describes the date the regulation shall take effect.

Discussion: The effective date of a rule is administrative; therefore, it should not be considered as a potential ARAR.

Conclusion: 40 CFR §191.05 should not be considered as a potential ARAR in the OU4 FS/PP-DEIS.

40 CFR §191 Subpart B - Environmental Standards for Disposal

40 CFR §191.11 Applicability.

Requirement: This section describes the situations for applicability (and non-applicability) of Subpart B. "This Subpart applies to ... radioactive materials released into the accessible environment as a result of disposal of

- o spent nuclear fuel or
- o high-level or
- o transuranic radioactive wastes ... " [40 CFR §191.11(a)(1)].

Discussion: This requirement is not a potential ARAR since it is administrative in nature. However, it is helpful in the interpretation of the requirements of Subpart B. The requirements found in 40 CFR §191 Subpart B are not applicable to remediation of OU4 for the following reasons:

- o the K-65 materials are not spent nuclear fuel, and
- o are NOT high-level radioactive waste materials as defined at 40 CFR §191.02(h), and
- o are NOT transuranic radioactive wastes as defined at the pre-existing 40 CFR §191.02(i); as clarified in the preamble to the pre-existing rule [50 FR 38066]; as defined at DOE Order 5820.2A; and, as further clarified in the newly Final Rule 40 CFR §191 [58 FR 66398, No. 242, published December 20, 1993, effective January 19, 1994].

USEPA Region V and the USEPA Office of Radiation Programs (ORP) had previously directed that the pre-existing 40 CFR §191 Subpart B, with the singular exception of the quantitative release limits specified in Table 1, should be treated as TBC in remediation of K-65 wastes (Richard J. Guimond, USEPA ORP, to

David Ullrich, USEPA Region V, January 10, 1991). This USEPA direction to consider §191 Subpart B as TBC assumes the Subpart B requirements will be used in conjunction with other ARARs and TBCs, e.g., 40 CFR §192. This is clear from the following excerpts:

"Current assay of these [K-65] materials (approximately 113 nanocuries per gram of radium-226 and 30 nanocuries per gram of thorium-230) indicates that they are some three orders of magnitude more concentrated in these substances than are typical mill tailings, for which the standards at 40 CFR Part 192 were developed. These materials are capable of presenting a major exposure hazard ... and will continue to pose this level of hazard long after the 200 to 1,000 year period of control which is required by 40 CFR Part 192 standards.... A much longer period of isolation is thus essential for adequate protection....

Further, the disposal methods required to implement the 40 CFR Part §192 standards do not offer sufficient protection against intrusion to be suitable for the K-65 materials [emphasis added]. There is no direct requirement in 40 CFR Part 192 for protection against intrusion. In the case of mill tailings, sufficient protection against intrusion is provided by 40 CFR Part 192 only as an indirect result of the measures required to assure stabilization for 200 to 1,000 years against erosion. This will not suffice for the K-65 residues, both because of their thousand-fold greater level of radioactivity, and because protection against erosion designed to last for 200-1,000 years cannot be relied upon for the longer terms needed for K-65 residues [emphasis added].

For the above reasons, the longevity and intrusion protection provided by Part 192 is insufficient for the K-65 residues. On the other hand, groundwater protection and radon emission requirements of Part 192 [emphasis added] are general, health-based specifications that are relevant and appropriate requirements [emphasis in original] for protection of human health and the environment, but only if supplementary requirements to address the above noted deficiencies regarding intrusion and longevity of control are applied to the K-65 residues [emphasis added]....

In evaluating alternatives for permanent disposal [emphasis in original], the regulations at 40 CFR Part 191, Subpart B, should be treated as criteria 'to be considered' (TBC), in addition to relevant and appropriate requirements [emphasis in original] in the regulations at 40 CFR Part 192 as noted above.... A single possible exception is the set of quantitative release limits specified in Table 1, which is based on the containment capability of an assumed deep geological repository and which may not be achievable by other disposal methods".

[Memorandum, Richard J. Guimond, Director, USEPA Office of Radiation Programs, to David Ullrich, Director, USEPA Region V Waste Management Division, dated January 10, 1991]

Since this direction by the USEPA was received, the newly revised 40 CFR §191 has been promulgated, and the Subpart B requirements have become effective. Therefore, Subpart B requirements must be re-evaluated on an individual basis as to whether they should be considered potential ARARs.

Conclusion: Since this requirement contains no substantive requirements, it should not be referenced as an ARAR in the OU4 FS/PP-DEIS. However, the guidance provided by the USEPA in the referenced memorandum from Richard J. Guimond may still be used in considering whether various regulatory requirements under Subpart B of §191 are potentially relevant and appropriate requirements for on-site disposal of K-65 material.

40 CFR §191.12 Definitions.

Requirement: This section defines various terms used in Subpart B.

Discussion: Definitions are generally considered an administrative, rather than a substantive requirement. These definitions are useful for interpretation of the intent of the regulations. This section has added the definitions:

- "Implementing agency" to include DOE "for any other disposal facility...".
- "Radioactive material" which includes radionuclides with half-lives greater than 20 years that are co-disposed with spent nuclear fuel, high level, or TRU wastes [interpretation aided by discussion in preamble to Final Rule].

Conclusion: This requirement should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR since this requirement is administrative in nature.

40 CFR §191.13 Containment Requirements.

Requirement: This section contains the quantitative release limits for radionuclides associated with wastes regulated under 40 CFR §191. This requirement specifies that the design of a disposal system provide a "reasonable expectation" based upon performance assessments that cumulative releases of radionuclides to the accessible environment do not for 10,000 years exceed established release limits specified in Table 1 of Appendix A of §191.

Discussion: These release limits are based on the containment capability of an assumed deep geological repository. In accordance with previous USEPA correspondence referenced above (Richard J. Guimond to David Ullrich, USEPA Region V, dated January 10, 1991), this specific requirement is not relevant and appropriate for OU4 remediation of K-65 materials. Disposal of spent nuclear fuel, high level, and TRU waste generally will be carried out at special repositories, such as the Waste Isolation Pilot Plant, or the Yucca Mountain site. Design of these types of facilities will be conducted over several years, and will include the type of complex modeling required to demonstrate compliance with this requirement, including the assembly of the results of performance assessments into a complementary cumulative distribution function model required to demonstrate the probability of release exceedances, and compliance with the release limits.

Although parts of 40 CFR §191 may be relevant to the management of K-65 material on the basis of long term hazard from alpha emitting radionuclides, they may not be appropriate under the conditions of the screened alternative. USEPA guidance (CERCLA Compliance with Other Laws Manual, Draft Guidance, USEPA, OSWER Directive 9234.1-01, 8/8/88) gives several examples of situations where requirements might be relevant but not appropriate. One example of this type of situation is given on page 1-68 of the guidance manual. The example given is for RCRA landfill closure regulations which require capping of the disposal unit. The example requirement is relevant because of the types of wastes, but not appropriate because of the specific situation found at the CERCLA site (broad area of contamination, or an immobile waste form). By analogy, requirements which pertain to siting and design of a deep geologic repository, however relevant due to characteristics of the wastes, are not appropriate for on-site disposal alternatives involving OU4 CERCLA remediation wastes.

This requirement is designed to ensure protection of human health and the environment for specific wastes. In order to ensure protectiveness under the on-site disposal alternative, the OU4 FS/PP-DEIS has conducted a risk assessment to estimate human health risks associated with on-site disposal of K-65 material, and identified other potential ARARs for this alternative to ensure protectiveness for escape of radionuclides, and for control of inadvertent intrusion into the disposal unit. These will be discussed under 40 CFR §191.14 (Assurance Requirements), 40 CFR §191.15 (Individual Protection Requirements), and 40 CFR §191.24 (Disposal Standards).

Conclusion: This requirement is based on the containment capability of an assumed deep geological repository. In accordance with guidance received from the USEPA, this requirement is not relevant and appropriate for OU4 remediation of K-65 materials, and should not be included in the OU4 FS/PP-DEIS as a potential ARAR for OU4 remediation. In order to ensure protection of human health and the environment for the on-site disposal alternative, the OU4 FS/PP-DEIS has identified other potential ARARs which are sufficient to prevent escape of radionuclides from the disposal unit, and for control of inadvertent intrusion into the unit.

40 CFR §191.14 Assurance Requirements.

Requirement: This requirement is an adjunct to the containment requirements of 40 CFR §191.13 to provide confidence for long-term compliance:

- 40 CFR §191.14(a) - Requires active institutional controls over disposal sites as long as practicable. However, any performance assessments should not consider any contributions from active institutional controls for more than 100 years after disposal.
- 40 CFR §191.14(b) - Requires monitoring of disposal systems after disposal to detect deviations from expected performance, until there are no significant concerns to be addressed by further monitoring.
- 40 CFR §191.14(c) - Requires disposal sites be designated by permanent markers, records, and other passive institutional controls.

- 40 CFR §191.14(d) - Requires disposal systems use different types of barriers (including both natural and engineered barriers) to isolate the wastes from the accessible environment.
- 40 CFR §191.14(e) - Requires the selection of disposal sites avoid places where there has been mining for resources, or where there is a reasonable expectation of exploration for resources.
- 40 CFR §191.14(f) - Requires the selection of disposal systems so that removal of most of the wastes is not precluded for a reasonable period of time after disposal.

Discussion: This requirement contains substantive requirements which could augment the design of a waste disposal facility to ensure protectiveness of human health and the environment. The USEPA guidance memo supports the use of these (types of) requirements for management of K-65 material, e.g., institutional controls and intrusion barriers. The design and operation of an on-site disposal facility would comply with these requirements as follows:

- 40 CFR §191.14(a) - Active institutional controls over the on-site disposal facility will be exercised for 30 years.
- 40 CFR §191.14(b) - Monitoring of the on-site disposal system after disposal will include sampling of the active leachate detection and collection system, as well as groundwater monitoring of all portions of the underlying aquifer to detect any releases from the unit for 30 years, or until there are no significant concerns to be addressed by further monitoring.
- 40 CFR §191.14(c) - The on-site disposal facility will be designated by permanent markers. A notation that on-site disposal of the wastes has occurred will be permanently recorded in the FEMP deed; the location of the disposal cell clearly indicated on a survey plat will also be made a part of the permanent public record. Passive institutional controls for the FEMP site will be maintained for 30 years and will consist of locked gates, fencing topped by barbed wire, and warning signs.
- 40 CFR §191.14(d) - Both natural and engineered barriers will be used in the design of the on-site disposal facility to isolate the wastes from the accessible environment, and prevent accidental inadvertent intrusion into the waste cell.
- 40 CFR §191.14(e) - The location of the on-site disposal facility will not coincide where there has been in the past mining for resources, or where there is a reasonable expectation of future exploration for resources.
- 40 CFR §191.14(f) - The design of the on-site disposal systems will not preclude removal of the disposed wastes, if necessary, for a reasonable period of time after disposal.

Conclusion: This requirement contains substantive requirements for a waste disposal facility which help ensure protectiveness of human health and the environment. The USEPA guidance memo supports the use of these requirements for management of K-65 material. 40 CFR 191.14 should be referenced in the OU4 FS/PP-DEIS as a potential relevant and appropriate requirement for OU4 remediation.

40 CFR §191.15 Individual Protection Requirements.

Requirement: "Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 mrem ..." [40 CFR §191.15(a), 58 FR 66398, No. 242, December 20, 1993].

40 CFR §191.15 also (b) specifies how the annual committed effective dose is to be calculated, (c) explains that "reasonable assurance", rather than absolute proof is expected from the compliance assessments, (d) reiterates that compliance with this requirement does not negate the necessity to comply with other ARARs, and (e) establishes an effective date of January 19, 1994 for the requirement.

Discussion: The term "waste" as used here refers to spent nuclear fuel, high level, and TRU waste; this interpretation is aided by the discussion in the Preamble to the Final Rule.

As with §191.13, this requirement assumes use of complex computational models and performance assessments, analytical theories, and expert judgement to provide the "reasonable expectation" of performance against the dose rate standard. USEPA guidance for implementation of §191 Subpart B, found in Appendix C to the newly revised Final Rule, states that "...sole reliance on these numerical predictions to determine compliance may not be appropriate...", and goes on to state that "several sections [of this guidance] apply only to disposal in mined geologic repositories [emphasis added] and would be inappropriate for other types of disposal systems."

Moreover, the type of protectiveness demonstration required by this section is not appropriate for a CERCLA remediation, which should be timely, cost effective, and demonstrate primary protectiveness on the basis of risk. In screening alternatives for threshold compliance with the protectiveness requirements and identified ARARs, the CERCLA process ensures adequate protection of human health and the environment.

As with §191.13, this specific requirement may be relevant, but is not appropriate for OU4 remediation under the conditions of the screened alternative. Based on risk modeling conducted under the OU4 FS, and the use of other potential ARARs, this requirement is not needed in order to be protective.

Other ARARs which would be incorporated into the design and operation of an on-site disposal alternative for OU4 wastes include the following:

- 40 CFR §141.15, 40 CFR §141.16, OAC 3745-81-15, 40 CFR §257.3-4, 40 CFR §264 Subpart F, and OAC 3745-27-10(D) - SDWA and RCRA drinking water standards and groundwater monitoring for radionuclides to ensure compliance with the MCLs,
- DOE Order 5400.5 III - Derived Concentration Guides (DCGs) for release limits for radionuclides via all pathways, including groundwater, surface water, and air,
- 40 CFR §61 Subparts H and Q, 40 CFR §192, and DOE Order 5400.5 IV 6 b - CAA, UMTRCA, and DOE Order radon and radioactive particulate release rates and concentration limits,
- OAC 3745-27-07 - Ohio siting and location requirements for a solid waste disposal facility over a sole source aquifer, which includes setback, and vertical separation and liner requirements for the disposal facility bottom liner and distance above the uppermost aquifer,
- 40 CFR §241 Subpart B, and 40 CFR §264 Subparts B, C, D, F, G, S, 40 CFR §264.310, and ORC 3734.02(H) - RCRA solid and hazardous waste management requirements, including design, operation, monitoring, closure, and post-closure of disposal facilities,
- DOE Order 5400.5 II 1 a - Radiation dose limit to the public from all radionuclides, and all pathways,
- 10 CFR §61.7(b)(5), 10 CFR §61.42, 10 CFR §61.52(a)(2), and 10 CFR §61.56(b) - NRC requirements for design, including waste cover, waste stability specifications, and intruder barriers, and
- 40 CFR §192.02(a), 40 CFR §192.12(a), and 40 CFR §192 Subpart C - USEPA UMTRCA standards for disposal of byproduct material from uranium mining.

These additional requirements are designed to ensure protection of human health and the environment for the OU4 K-65 remediation wastes. It is important to note that although 40 CFR §191 does not specifically require treatment of high level, TRU, or spent nuclear fuel wastes prior to disposal, the on-site alternative for the K-65 wastes proposes stabilization by vitrification prior to disposal. Stabilization will control the leaching of radionuclides, and the release of radon from the waste. Moreover, the OU4 FS/PP-DEIS has conducted a risk assessment to estimate human health risks associated with on-site disposal of K-65 material. This risk modeling was conducted specifically to estimate worst case exposures due to predicted release of radionuclides under the various alternatives. Risk data indicate that for 1,000 years the worst case (peak) post-disposal escape of radionuclides from the on-site disposal facility would not exceed the USEPA threshold protectiveness criteria established in the NCP for excess upper bound incremental lifetime cancer risk to an individual of 10^{-6} . The peak release follows a steady increase in projected release rate following disposal, and is expected to occur between 400 and 500 years after disposal. Based on this risk modeling, the risks to human health and the environment are expected to decline following the modeled peak, and would exhibit a continued steady decline after the 1,000 year period, which would result in an even lower risk to members of the public.

Conclusion: Although this section may be relevant to the management of K-65 material, it is not appropriate under the conditions of the screened alternative for this CERCLA action. Based on risk modeling and use of other potential ARARs, this section is not needed in order to be protective. 40 CFR §191.15 should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR for OU4 remediation.

40 CFR §191.16 Alternative provisions for disposal.

Requirement: This section allows substitution of alternative provisions for any of the provisions of §191 Subpart B, provided the alternative provisions have been proposed in the Federal Register along with cost-benefit, and risk information associated with the disposal alternative; the public has had the opportunity to comment; and, public comments have been fully considered in the final version of the alternative.

Discussion: This requirement follows a process similar to the CERCLA process for selection of an acceptable alternative for remediation of a CERCLA site. While the requirement includes mainly administrative requirements, this section can be referenced in the OU4 FS/PP-DEIS as a potential ARAR since it allows use of alternative provisions to demonstrate compliance with §191 Subpart B.

Substantive compliance with this requirement, if included as an ARAR, would be achieved by DOE presentation of the proposed alternative and compliance methodology as described in this position paper to the USEPA for concurrence. The proposed alternative(s) must be compatible with the approach described in the OU4 FS/PP-DEIS, and would have to be demonstrated to show compliance with the nine criteria for selection of a remedial alternative under the CERCLA process. USEPA concurrence is required since the USEPA has final approval authority on ARARs referenced under CERCLA remediation.

Conclusion: 40 CFR §191.16 should be referenced in the OU4 FS/PP-DEIS as a potential ARAR for OU4 remediation.

40 CFR §191.17 Effective date.

Requirement: This section establishes an effective date of November 18, 1985 for the implementation of Subpart B.

Discussion: The effective date of a rule is administrative; therefore, it should not be referenced as a potential ARAR.

Conclusion: 40 CFR §191.17 should not be referenced as a potential ARAR in the OU4 FS/PP-DEIS.

**Newly Final Rule 40 CFR §191 Subpart C -
Environmental Standards for Groundwater Protection**

The newly Final Rule 40 CFR §191 created a new Subpart C which consists of §191.21 (Applicability), §191.22 (Definitions), §191.23 (General Provisions), §191.24 (Disposal Standards), §191.25 (Compliance With Other Federal Regulations), §191.26 (Alternative Provisions), and §191.27 (Effective Date).

40 CFR §191.21 Applicability.

Requirement: This section describes the applicability (and non-applicability) of Subpart C to:

- 40 CFR §191.21(a)(1) - Doses received by members of the public due to activities subject to Subpart B, and
- 40 CFR §191.21(a)(2) - Radioactive contamination of underground sources of drinking water as a result of such activities.

Discussion: The description of a requirement's applicability is generally considered an administrative, rather than a substantive requirement.

Conclusion: This requirement should not be referenced in the FS/PP-DEIS potential ARARs for OU4.

40 CFR §191.22 Definitions.

Requirement: This section defines various terms used in Subpart C.

Discussion: Definitions are generally considered an administrative, rather than a substantive requirement.

Conclusion: This new section should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR since it is administrative in nature.

40 CFR §191.23 General Provisions.

Requirement: This requirement establishes that compliance with Subpart C shall be based on underground sources of groundwater that have been identified on the date the implementing agency determines compliance with Subpart C.

Discussion: All potential underground sources of groundwater in the vicinity of the on-site disposal facility have been identified. This section does not offer any additional substantive requirements for the remediation of OU4.

Conclusion: This section should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR since it does not offer any additional substantive requirements for the remediation of OU4.

40 CFR §191.24 Disposal Standards.

Requirement:

40 CFR §191.24(a) - This section requires that the design of a prospective disposal system "provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR Part 141..."

40 CFR §191.24(b) - This section explains that due to inherent uncertainties, "complete assurance" of compliance is not required; rather, that a reasonable expectation of compliance, based on the record, is what is expected.

Discussion: This requirement refers to the primary Safe Drinking Water Act (SDWA) regulations for radionuclides in groundwater (the maximum contaminant levels (MCLs), currently codified at 40 CFR §141.15 and §141.16) in effect at the time the implementing agency determines compliance with Subpart C. Further, Subpart C provides an additional measure of public health protection by limiting the sites or methods for disposal so that off-site (i.e., outside the controlled area surrounding radioactive waste disposal facilities) underground sources of drinking water will not be degraded to radionuclide levels above applicable MCLs during the 10,000 year timeframe. Consistent with the SDWA, both currently used and potential underground sources of drinking water are included in this definition. These protections are targeted to all aquifers or their portions, with fewer than 10,000 mg/L total dissolved solids (TDS), which currently or potentially could supply a public water system (i.e., by definition, 15 or more connections or serving 25 or more people).

As with §191.13 and §191.15, this requirement assumes use of complex computational models, analytical theories, and expert judgement to provide the "reasonable expectation" of performance. This type of protectiveness demonstration is not appropriate for a CERCLA remediation, which should be timely, cost effective, and demonstrate primary protectiveness on the basis of risk. In screening alternatives for threshold compliance with the protectiveness requirements and identified ARARs, the CERCLA process ensures adequate protection of human health and the environment.

As with §191.13 and §191.15, this specific requirement may be relevant, but is not appropriate for OU4 remediation under the conditions of the screened alternative. Based on risk modeling conducted under the OU4 FS, and the use of other potential ARARs, this requirement is not needed in order to be protective.

Protection of the underlying aquifer from on-site waste disposal is paramount to this requirement. Additional requirements in the form of ARARs (described under 40 CFR §191.15) are included for the on-site disposal alternative to help ensure protection of human health and the environment, including the groundwater pathway. The on-site alternative for the K-65 wastes proposes stabilization by vitrification prior to disposal. Stabilization will control the leaching of radionuclides, and the release of radon from the waste. The on-site disposal alternative is expected to comply with the SDWA ARARs, and those of the RCRA solid and hazardous waste programs for protection of groundwater, identified in the FS/PP-DEIS.

The OU4 FS/PP-DEIS includes a risk assessment which estimates human health risks associated with on-site disposal of K-65 material. Risk data indicate that for 1,000 years the worst case (peak) post-disposal escape of radionuclides from the on-site disposal facility would not exceed either the SDWA MCLs in groundwater in the underlying aquifer, or the USEPA threshold protectiveness criteria established in the NCP for excess upper bound incremental lifetime cancer risk to an individual of 10^{-6} .

Conclusion: Although this section may be relevant to the management of K-65 material, it is not appropriate under the conditions of the screened alternative for this CERCLA action. Based on risk modeling and use of other potential ARARs, this section is not needed in order to be protective. 40 CFR §191.15 should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR for OU4 remediation.

40 CFR §191.25 Compliance with Other Federal Regulations.

Requirement: This requirement requires compliance with other applicable Federal regulations or requirements.

Discussion: The CERCLA threshold criteria described in the NCP require that screened alternatives comply with all ARARs. The remediation of OU4 is a CERCLA based remediation, subject to the CERCLA process. This requirement does not offer any additional substantive requirements.

Conclusion: This requirement should not be referenced in the OU4 FS/PP-DEIS as a potential ARAR.

40 CFR §191.26 Alternative Provisions.

Requirement: This section allows substitution of alternative provisions for any of the provisions of §191 Subpart C, provided the alternative provisions have been proposed in the Federal Register along with cost-benefit, and risk information associated with the disposal alternative; the public has had the opportunity to comment; and, public comments have been fully considered in the final version of the alternative.

Discussion: This requirement follows a process similar to the CERCLA process for selection of an acceptable alternative for remediation of a CERCLA site. While the requirement includes mainly administrative requirements, this section can be referenced in the OU4 FS/PP-DEIS as a potential ARAR since it allows use of alternative provisions to demonstrate compliance with §191 Subpart C.

Substantive compliance with this requirement, if included as an ARAR, would be achieved by DOE presentation of the proposed alternative and compliance methodology as described in this position paper to the USEPA for concurrence. The proposed alternative(s) must be compatible with the approach described in the OU4 FS/PP-DEIS, and would have to be demonstrated to show compliance with the nine criteria for selection of a remedial alternative under the CERCLA process. USEPA concurrence is required since the USEPA has final approval authority on ARARs referenced under CERCLA remediation.

Conclusion: 40 CFR §191.26 should be referenced in the OU4 FS/PP-DEIS as a potential ARAR for OU4 remediation.

40 CFR §191.27 Effective date.

Requirement: This section establishes an effective date of January 19, 1994 for the implementation of Subpart C.

Discussion: The effective date of a rule is administrative; therefore, it should not be referenced as a potential ARAR.

Conclusion: 40 CFR §191.27 should not be referenced as a potential ARAR in the OU4 FS/PP-DEIS.

Appendices to 40 CFR §191:

Requirement:

Appendix A contains quantitative release limits for specific radionuclides in Table 1, as referenced by §191.13;

Appendix B contains information to aid in calculation of annual committed effective dose, to support §191.15;

Appendix C is general guidance for implementation of requirements in Subpart B.

Discussion: Appendices are not, of themselves, generally considered as potential ARARs. However, the substantive requirements found in Appendices to a regulation become ARARs if referenced by a section of the regulation that is itself considered an ARAR. Appendix C is general guidance for implementation of requirements in Subpart B, and may be useful for interpretation and application of the requirements. This does not require consideration as an ARAR.

Conclusion: The Appendices to 40 CFR §191 should not be referenced as potential ARARs in the OU4 FS/PP-DEIS.