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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

Directive no. 9200.4-35P

MEMORANDUM

SUBJECT: Remediation Goals for Radioactively Contaminated CERCLA Sites Using the Benchmark Dose Cleanup Criteria in 10 CFR Part 40 Appendix A, I, Criterion 6(6)

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TO: Addressees



PURPOSE

This memorandum addresses the use of the soil and structure cleanup criteria in 10 CFR 40 Appendix A, I, Criterion 6(6) when setting remediation goals at CERCLA sites with radioactive contamination. In particular, it clarifies the relationship between the soil standards under 40 CFR Part 192 and the radium benchmark approach under the 10 CFR 40 Appendix A, I, Criterion 6(6) in setting remediation levels for soil and structures. Because of the interrelationship between the standards under 40 CFR Part 192 and those under 10 CFR 40 Appendix A, I, Criterion 6(6), today's memorandum should be used in conjunction with the memorandum from OERR and ORIA, to the Regions entitled: "Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites" (OSWER Directive no. 9200.4-25, February 12, 1998). Today's memorandum will be of interest to site decisionmakers that have any of the following radionuclides as contaminants of concern: radium-226, radium-228, thorium-230, thorium-232, uranium-234 and/or uranium-238 in soil and/or structures at their CERCLA site.

This document provides guidance to Regional staff, in dealing with the public and the regulated community, regarding how EPA intends to implement the National Oil and

Hazardous Substances Pollution Contingency Plan (NCP). It describes national policy. This document is not a substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances.

BACKGROUND

All remedial actions at CERCLA sites must be protective of human health and the environment and comply with applicable or relevant and appropriate requirements (ARARs) unless a waiver is justified. Cleanup levels for response actions under CERCLA are developed based on site-specific risk assessments, ARARs, and/or to-be-considered material¹ (TBCs). The determination of whether a requirement is applicable, or relevant and appropriate, must be made on a site-specific basis (see 40 CFR Part 300.400(g)).

On January 5, 1983, EPA promulgated in Subpart B of 40 CFR Part 192 (48 FR 590 to 606) *Standards for Cleanup of Land and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites* (EPA's UMTRCA rule).² Included in these standards is a concentration criterion for radium-226 in soil. These standards were developed specifically for the cleanup of uranium mill tailings at 24 sites designated under Section 102(a)(1) of UMTRCA (Title I sites). The list of 24 Title I sites is a closed set chosen in 1979 that cannot be added to. Later, EPA determined that these standards were suitable for remediation of radium-228 at Title II sites (*see* Subpart E of 40 CFR Part 192 (48 FR 45947) *Standards for Management of Thorium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended*).

On October 16, 1985 the Nuclear Regulatory Commission (NRC) promulgated standards under 10 CFR Part 40 (NRC's UMTRCA rule) to address uranium mill tailings (50 FR 41852). Part of these 1985 regulations established soil cleanup standards for radium-226 and radium-228. The concentration criterion for soil is 5 pCi/g at the surface and 15 pCi/g in the subsurface. The radium soil standards under the NRC's UMTRCA rule were intended as conforming standards to EPA's UMTRCA soil standards under 40 CFR Part 192.³ Because EPA's soil standards under EPA's UMTRCA rule were

¹To-be-considered material, TBCs are non-promulgated advisories or guidance issued by Federal or State governments that are not legally binding and do not have the status of potential ARARs. However, TBCs will be considered along with ARARs as part of the site risk assessment and may be used in determining the necessary level of cleanup for protection of health and the environment.

²These standards were developed pursuant to Section 275 of the Atomic Energy Act (42 U.S.C. 2022), as amended by Section 206 of the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978 (42 U.S.C. 7918).

³Under section 18(a) of Public Law 97-415, the Nuclear Regulatory Commission Authorization Act for fiscal years 1982 and 1983, the Commission was directed to conform its regulations to EPA's with notice and opportunity for public comment.

applicable to NRC and Agreement State licensees (including those for which NRC's UMTRCA rule govern), and the NRC's UMTRCA rule standards were no more stringent, compliance with the EPA's UMTRCA rule (40 CFR Part 192) constitutes compliance with the NRC's UMTRCA rule (10 CFR Part 40) for radium 226 and radium-228 for these sites.⁴

On April 12, 1999, NRC amended its UMTRCA rule by adding Criterion 6(6) to Appendix A (69 FR 17506 to 17510) *Radiological Criteria for License Termination of Uranium Recovery Facilities* (Criterion 6(6) rule). The amendment uses the existing soil radium standard to derive a dose criterion (benchmark approach) for cleaning up byproduct material, including radium in soil, and for cleanup of surface activity on structures to be released for unrestricted use. In areas where there is more than one residual radionuclide, the benchmark dose applies to the sum of all radionuclides present in that area (i.e., radium, uranium, thorium, etc). NRC intends that the benchmark approach result in a common dose criterion across an entire uranium recovery (UR) site.

The Criterion 6(6) rule addresses the lack of remediation standards for residual radionuclides, other than radium in soil, for decommissioning of lands and structures (excluding radon) at uranium recovery facilities. Criterion 6(6) uses the existing soil radium standard (5 pCi/g surface and 15 pCi/g subsurface) to derive a dose criterion (benchmark approach) for cleaning up byproduct material, and for cleanup of surface activity on structures to be released for unrestricted use. The NRC intends to include the dose from the subsurface soil radium standard (from NRC's UMTRCA rule) when estimating the benchmark dose, only in those areas that require subsurface cleanup. NRC expects that a benchmark dose estimate to address most of the site contamination will be estimated solely from doses resulting from the radium surface standard.

The radium dose benchmark approach of the Criterion 6(6) rule requires licensees subject to the rule to calculate the potential peak effective dose equivalent (excluding radon) to an individual at the site within 1,000 years from exposure to the residual levels allowed under the radium soil standard. Licensees are then to remediate the site such that the residual site-related radionuclides (including radium) remaining on the site, both in soil and the surface radioactivity in structures, would not result in a dose greater than the radium soil standard. The radionuclides of concern being addressed by the Criterion 6(6) rule are thorium, natural uranium, and radium.

⁴For information related to 40 CFR 192 as an ARAR, please see memorandum from Steve Luftig (Director of OERR) and Larry Weinstock (Acting Director, OAR) to the Regions entitled: "Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites" (Directive no. 9200.4-25, February 12, 1998). As noted in the memorandum, because the risk from uranium and thorium byproducts is additive, and because the 5 pCi/g and 15 pCi/g standards are based on total acceptable risk, whenever the 5 pCi/g and/or 15 pCi/g standards are used as relevant and appropriate requirements (or TBC's) at CERCLA sites with some combination of radium-226 and radium-228 (or thorium-230 and thorium-232), these soil standards should apply to the combined level of contamination of radium-226 and radium-228 (or thorium-230 and thorium-232).

IMPLEMENTATION

The following subsections will clarify the use of 10 CFR Part 40 Appendix A, Criterion 6(6) is setting remediation levels for soil and structures.

CRITERION 6(6) RULE AS AN APPLICABLE REQUIREMENT

The standards contained within Criterion 6(6) are potentially applicable requirements only for the Title II sites designated under Section 206 of UMTRCA.

CRITERION 6(6) RULE AS A RELEVANT AND APPROPRIATE REQUIREMENT

If the majority of radiological risk is posed by contaminants of concern at a site in the soil and structures that are the same (i.e., radium-226, radium-228, thorium-230, thorium-232, uranium-234 and/or uranium-238) as those existing at NRC thorium mills and uranium recovery facilities, then the Criterion 6(6) rule's benchmark dose limit is a **potentially relevant and appropriate requirement for those contaminants (i.e., radium-226, radium-228, thorium-230, thorium-232, uranium-234 and/or uranium-238) found in soil and/or structures at the site.** The rule would generally not be an ARAR for radiological contaminants other than those specified above since other contaminants are not generally found at sites subject to these standards and were not considered in the rule.

Assumptions used in rulemaking documents during the development of the Criterion 6(6) rule and/or found in accompanying NRC guidance documents, such as NRC's dose assessment methodology or its land use assumption that the UR sites would be released for unrestricted use, would generally **not** be considered relevant and appropriate requirements under CERCLA nor used as guidance for making remedy decisions at CERCLA sites.

EPA's UMTRCA RULE (40 CFR 192) AS A RELEVANT AND APPROPRIATE REQUIREMENT

The Criterion 6(6) rule should not affect the ARAR status of requirements under the EPA's UMTRCA rule (40 CFR Part 192). In particular, the guidance in OSWER Directive 9200.4-25 "Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA sites", still applies. This means that when the 5 pCi/g and/or 15 pCi/g standards are used as RARs or TBCs, these soil standards should continue to apply to the combined levels of radium-226 and radium-228, as well as the combined levels of thorium-230 and thorium-232.

The Criterion 6(6) rule is a supplement to the radium standards of 40 CFR Part 192, to address other site-related radionuclides. Therefore, when the 5 pCi/g and 15 pCi/g standards under EPA's UMTRCA rule are not RARs for either radium-226 and/or radium-228, the Criterion 6(6) rule is generally not appropriate. In addition, when supplemental standards in 40 CFR Part 192, Subpart C are used instead of EPA's UMTRCA 5/15 pCi/g soil standards as RARs, then the Criterion 6(6) rule is generally not appropriate.

Even if EPA's UMTRCA soil standards were used as TBCs, we recommend that the Criterion 6(6) rule's benchmark dose approach should not be used as a TBC. This is consistent with EPA's prior guidance that, in general, dose assessments should only be conducted under CERCLA where necessary to demonstrate ARAR compliance⁵.

CONDUCTING DOSE ASSESSMENT FOR CRITERION 6(6) RULE ARAR COMPLIANCE

The Criterion 6(6) rule provides a benchmark approach for setting cleanup levels for radionuclides. Specifically the Criterion 6(6) rule specifies:

"Byproduct material containing concentrations of radionuclides other than radium in soil and surface activity on remaining structures, must not result in a total effective dose equivalent (TEDE) exceeding the dose from cleanup of radium contaminated soil to the above standard (benchmark dose), ..."

Site-specific application of the Criterion 6(6) rule as a RAR will involve both a dose assessment to establish potential cleanup levels for the residual radionuclides as well as a determination of whether the dose assessment developed under the rule is protective enough to establish cleanup levels under CERCLA.

Dose Assessment Methodology

Dose assessments (excluding radon) are conducted to convert the radium soil standards into a benchmark dose for all radionuclides at the site. When the Criterion 6(6) rule is considered a relevant and appropriate requirement, then dose assessments that are conducted to develop the benchmark dose for a site, and to show compliance of remediation goals for soil and structures with the benchmark dose (the "compliance dose"), should be conducted site-specifically, using Superfund **reasonably maximum**

⁵For further information regarding this EPA determination, see the memorandum from Stephen D. Luftig titled: "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination" (OSWER Directive 9200.4-18), August 22, 1997, p. 3. Further clarification of this EPA determination is also provided in the memorandum from Stephen D. Luftig titled "Distribution of OSWER Radiation Risk Assessment Q & A's Final Guidance" December 17, 1999, pp. 2-3 and the guidance entitled "Radiation Risk Assessment at CERCLA Sites: Q & A" (OSWER Directive 9200.4-31P) December 1999 pp 13-14.

exposure (RME) scenario parameters that are consistent with the reasonably anticipated land use⁶ of the site.

Both the benchmark dose and the dose analysis to confirm compliance with the benchmark dose (the "compliance dose") should be estimated as the sum of doses from all appropriate exposure pathways. For soil these pathways would typically include: direct ingestion of soil; inhalation of fugitive dusts; ingestion of contaminated ground water caused by migration of radionuclides through soil to an underlying potable aquifer; external radiation exposure from radionuclides in soil; and ingestion of homegrown produce that has been contaminated via plant uptake. For structures these pathways would typically include: external radiation exposure from radionuclides in building material; and inhalation of fugitive contaminated building materials.

The benchmark dose from soil should be met for the sum of exposures from both soil and structures. All radionuclides of concern should be included in dose assessments to show compliance with the benchmark dose. The dose assessments, both for the benchmark dose and the compliance dose evaluation, should be for the year of peak dose over the next 1,000 years. The compliance dose evaluation should also assess non-surface radioactivity in contaminated structures.

The benchmark dose assessment should only include estimates of doses from subsurface radium contamination only for those portions of the site where subsurface radionuclide contaminants require cleanup under CERCLA. This cleanup action could be triggered either by exceedances of ARARs (e.g., radionuclides may migrate to the through the soil to an underlying aquifer at levels exceeding the MCL) or where protective risk levels are exceeded (radionuclide contaminants levels result in risks outside the risk range, or when summed with other nonradiological contaminants and/or radionuclide contaminants at the surface will proceed to drive risk estimates outside of the risk range. If the benchmark dose includes estimates of doses resulting from subsurface contamination, both the benchmark and the compliance dose should be estimated based on the extent of the depth of the contamination using 15 cm increments (e.g., 15 through 30 cm, then 30 to 45 cm, etc.).

Criterion 6(6) Rule Dose Evaluation and Risk Assessment for Establishment of Cleanup Levels for CERCLA Sites

If the Criterion 6(6) rule is considered to be an ARAR at a CERCLA site, then a site-specific dose assessment needs to be made to determine whether the Criterion 6(6) rule is used to set cleanup levels under CERCLA. If a site-specific dose assessment

⁶In developing land use assumptions, decision makers should consult the guidance provided in the memorandum from Elliot Laws A.A. OSWER entitled: "Land Use in the CERCLA Remedy Selection Process" (OSWER Directive No. 9355.7-04), May 25, 1995.

indicates that the radium benchmark dose will be above 15 mrem/yr EDE, the dose limit that EPA generally considers minimally acceptable under CERCLA, then the NRC rule should generally not be used to establish cleanup levels at that CERCLA site. EPA has previously determined that dose limits greater than 15 mrem/yr generally will not provide a protective basis for establishing preliminary remediation goals (PRGs) under CERCLA.⁷ **Please note that 15 mrem/yr is not a presumptive cleanup level under CERCLA, but rather site decision-makers should continue to use the risk range when ARARs are not used to set cleanup levels.**

In addition to the dose assessments that are required to show compliance with Criterion 6(6) as a RAR, a site-specific risk assessment must generally be conducted to confirm that the residual levels allowed to meet the compliance dose evaluation, are sufficiently protective (e.g., generally meets the 10^{-4} to 10^{-6} risk range, hazard index less than 1) to be used as cleanup levels under CERCLA.⁸ This additional risk assessment step is recommended for two reasons. First, the benchmark dose concept in Criterion 6(6) was developed using the ICRP/NCRP regulatory approach, which assumes that doses less than 100 mrem/yr are protective, rather than the risk range generally used to determine protectiveness under CERCLA. This 100 mrem/yr approach has previously been determined by EPA to not be protective under CERCLA. In addition, there is no basis for demonstrating that even compliance doses below 15 mrem/yr will be protective for the radionuclides that may be addressed by the Criterion 6(6) rule. Please note that this risk assessment recommendation generally does not apply to other ARARs.

Since the NRC's UMTRCA rule radium standards in 10 CFR Part 40 are intended as conforming standards to EPA's UMTRCA standards under 40 CFR Part 192, when conducting a dose assessment to show compliance with Criterion 6(6) rule as a relevant and appropriate requirement, a concentration of 5 pCi/g should be used as the radium concentration for assessing a benchmark dose, in the subsurface as well as the surface. A concentration value of 5 pCi/g for radium in the subsurface, rather than 15 pCi/g, should be used as the starting point when developing a benchmark dose to demonstrate compliance with the Criterion 6(6) rule as a relevant and appropriate requirement at a CERCLA site. This recommendation is consistent with EPA's determination that soil cleanups occurring at UMTRCA sites using the 15 pCi/g "finding tool" standard in 40

⁷For further information regarding this EPA determination, see the memorandum from Stephen D. Luftig titled: "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination" (OSWER Directive 9200.4-18), August 22, 1997, p. 3. Further clarification of this EPA determination is also provided in the memorandum from Stephen D. Luftig titled "Distribution of OSWER Radiation Risk Assessment Q & A's Final Guidance" December 17, 1999, pp. 2-3 and the guidance entitled "Radiation Risk Assessment at CERCLA Sites: Q & A" (OSWER Directive 9200.4-31P) December 1999 pp 13-14.

⁸For further information regarding conducting risk assessments for radiological contaminants at CERCLA sites, see the guidance entitled "Radiation Risk Assessment at CERCLA Sites: Q & A" (OSWER Directive 9200.4-31P) December 1999.

CFR Part 192 would result in residual soil concentrations of no more than 5 pCi/g.⁹ If cleanup using the 15 pCi/g "finding tool" would not result in concentrations of 5 pCi/g or less, then 40 CFR Part 192 would not be expected to be an ARAR since the site would be inherently different from that for which the EPA UMTRCA regulations were written. As discussed earlier, if 40 CFR Part 192 is not an ARAR then Criterion 6(6) would also not be an ARAR.

RELATION OF TODAY'S GUIDANCE AND PREVIOUS EPA GUIDANCE ON NRC DECOMMISSIONING

It should be noted that today's memorandum does not alter previous EPA guidance regarding NRC's Radiological Criteria for License Termination (see 62 FR 39058, July 21, 1997). NRC's 1997 decommissioning rule should still generally not be used as the basis for establishing remediation goals under CERCLA, since the dose limits in that rule were determined by EPA to generally not provide a protective basis for establishing remediation goals.

However, since the 1999 Criterion 6(6) rule requires the establishment site-specifically of a benchmark dose that functions as an enforceable dose limit, this rule must be assessed on a site specific basis to determine if the dose limit is above the 15 mrem/yr level that EPA has previously determined was the highest acceptable dose limit.

HYPOTHETICAL SITE EXAMPLE OF IMPLEMENTATION OF TODAY'S GUIDANCE

Below is an example of how today's guidance might be implemented at a site where the Criterion 6(6) and EPA UMTRCA rules are considered relevant and appropriate requirements.

Example. Radionuclide contaminants of concern at site X are uranium 238, uranium 234, thorium-230, radium-226, and actinium-227. These contaminants are located both in soil (surface and subsurface) and structures. To comply with the EPA UMTRCA rule as a relevant and appropriate requirement, the remediation goal for both thorium-230 and radium-226 (each, not combined), would be 5 pCi/g both in the first 15 cm of depth at the surface, and any 15 cm that are contaminated in the subsurface. In addition, to comply with the Criterion 6(6) rule as a relevant and appropriate requirement, the following steps were taken. First, a benchmark dose of 12 mrem/yr was estimated on a site-specific basis using EPA Superfund risk/dose assessment exposure assumptions, if a

⁹For further information regarding this EPA determination, see the memorandum from Stephen D. Luftig title: "Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA sites" (OSWER Directive No. 9200.4-25), February 12, 1998.

residual level of radium-226 in the soil of 5 pCi/g existed in both the surface and subsurface. Then cleanup concentration levels were developed to attain the compliance dose of 12 mrem/yr for the peak dose year over the next 1,000 years of all radiological contaminants of concern. This means the sum of the doses from the cleanup concentration levels of all the radionuclide contaminants (uranium 238, uranium 234, thorium-230, radium-226, and actinium-227), in the soil and the structures, must not exceed 12 mrem/yr to an RME individual using exposure parameters consistent with the selected land use for the site in order to attain the compliance dose. Thus compliance with the Criterion 6(6) rule would achieve a remediation level of less than 5 pCi/g for radium-226 in soil as the dose from the other radionuclides are taken into account.

FURTHER INFORMATION

The subject matter specialist for this directive is Stuart Walker of OERR (703-603-8748. General questions about this directive, should be directed to 1-800-424-9346.

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