January 28, 1998

Dear Members of the Interagency Steering Committee on Radiation Standards:

Enclosed is the December 12, 1997, letter from Nuclear Regulatory Commission Chairman Shirley Jackson to Environmental Protection Agency Administrator Carol Browner concerning EPA's guidance entitled, "Establishment of Cleanup Levels for CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act of 1980) Sites with Radioactive Contamination." This letter is provided for your information. Call me at (301) 415-7437 if you have any questions or comments on this letter.

Sincerely,

[Original signed by]

John T. Greeves, Director
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
December 12, 1997 letter

cc: Vicki Lloyd, EPA/ORIA
John Karhnak, EPA/ORIA
Stephen Luftig, EPA/OERR
Colonel Robert Cherry, DOD/DNA
Andy Wallo, DOE/EH-41
Jeffrey Synder, DOL/OSHA
Rick Boyle, DOT
Carrie Jelsma, OMB
Miriam Forman, OSTP

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 28, 1998

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John T. Greeves

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

December 12, 1997

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
Washington D.C. 20460

Dear Administrator Browner:

In August 1997, we received a copy of OSWER No. 9200.4-18 entitled "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination." The stated purpose of the document is to provide clarifying guidance for what the U.S. Environmental Protection Agency (EPA) asserts would establish protective cleanup levels for radioactive contamination at Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) sites.

A specific point made in the CERCLA guidance is EPA's determination that the dose limits in the U.S. Nuclear Regulatory Commission's (NRC) final rule on "Radiological Criteria for License Termination" (issued July 21, 1997), generally will not provide a protective basis for establishing preliminary remediation goals for cleanups at CERCLA sites and that NRC sites cleaned up to the 25 mrem/yr all-pathways criterion will have to be remediated further to meet the CERCLA and National Oil and Hazardous Substances Pollution Contingency Plan requirements to be protective. This guidance also seeks to impose the 15 mrem/yr and separate groundwater requirements contained in the EPA draft cleanup rule withdrawn by EPA from the Office of Management and Budget in December 1996. These statements are of specific concern to us for several reasons.

First, this approach results in the imposition of the CERCLA risk range on radionuclides without the informed and open discussions that would be part of the rulemaking process to establish such radiation protection standards--a process which NRC recently completed. Secondly, the Commission's final rule is based on considerations of risk, radiation protection principles, national and international standards, and costs compared to associated benefits of cleanup. In issuing the rule, we concluded that the final rule not only protects public health and safety, but also establishes the framework to address the limited number of difficult cases which would otherwise require case-by-case exemptions. We believe this approach not only achieves cost effective regulation and adequate protection of public health and safety and the environment, but also is based on sound policy.

The third reason for our concern is that the CERCLA guidance raises questions regarding the finality of license termination decisions and possible EPA actions at sites that have complied with the NRC or equivalent Agreement State cleanup standards and had their licenses terminated. On August 6, 1997, I transmitted a draft Memorandum of Understanding (MOU) between our agencies that addresses these finality issues. The purpose of the MOU, "Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites," is to provide for finality in NRC license termination decisions in order to provide licensees and

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PDR

Enclosure

the public with a stable and predictable regulatory framework that is adequately protective of public health and safety and the environment. Further, the MOU is intended to provide for early consultation with EPA in those cases where a site's residual all-pathways dose exceeds 15 mrem/yr.

We have specifically examined the statements in the CERCLA guidance that assert the NRC rule is not protective, and we find a number of them to be inaccurate, misleading, or inconsistent with national and international standards. The NRC staff reviewed associated EPA documents and rationale and I have included the details of these staff findings in an enclosure to this letter.

We have not received a response either to the general issues raised in our August 6, 1997 letter or to the specifics of the MOU. We fully intend to proceed, and have proceeded, with implementation of the July 21, 1997 final NRC rule, both in preparation of regulatory guidance for the rule and in application of the rule for specific cases. In addition, as you are probably aware, we have sought legislation that would recognize the validity and adequacy of NRC's cleanup rule and ensure finality for NRC and Agreement State licensees.

Sincerely,
Original signed by
Shirley Ann Jackson

Shirley Ann Jackson

Enclosure:
Discussion of NRC Concerns
With EPA's CERCLA Guidance

Originating Office: EDO/RES
Ref: CR-97-207
Commission Correspondence

SAJ - Approved
GJD - Travel/staff-
no comments
NJD - Approved
EXM - Approved/edits

OFC	SECY	OCM/SAJ			
NAME	JShoemaker				
DATE	12/ 1/97				

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LETTER TO: HONORABLE CAROL M. BROWNER
FROM: SHIRLEY ANN JACKSON
DATED: 12/12/97
SUBJECT: CERCLA GUIDANCE

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Discussion of NRC Concerns with EPA's CERCLA Guidance

With regard to specific issues on the protectiveness of the NRC standard, we have reviewed the CERCLA guidance and find that the statement in the CERCLA guidance that the NRC rule is not protective to be inaccurate. The NRC staff reviewed associated EPA documents and rationale. The staff findings are described in detail below.

1. **EPA's derivation of 1E-4 as a protective value appears to be a policy judgment, and is inconsistent with international findings.**

The CERCLA guidance indicates that a risk level of 1E-4 is a level of protection that is not to be exceeded[1] and that the 25 mrem/yr dose criterion in NRC's final rule is not protective because it would exceed that level. A rationale for EPA's value of 1E-4 can be found in a Federal Register notice (FRN) for EPA's "National Emission Standards for Hazardous Air Pollutants (NESHAPs)" under the Clean Air Act (54 FR 38044, September 14, 1989). The FRN notes that in the Vinyl Chloride decision [Natural Resources Defense Council, Inc. v. EPA, 824 F.2d at 1146 (D.C. Cir. 1987)], the EPA was directed to determine an acceptable risk level based on a judgment of what risks are "acceptable in the world in which we live". In response to the Vinyl Chloride decision, the FRN indicates that EPA compiled a review of societal risks to place risk estimates in perspective and to provide background and context for the EPA's judgment on acceptability of risks "in the world in which we live". The FRN states that individual risk of premature death in EPA's survey ranged from 1E-1 to 1E-7, and that the level of approximately 1E-4 is within the range for individual risk in the survey and at a value that comports with many previous health risk decisions by EPA. The EPA risk value is applied in the CERCLA context [see 55 FR at 8715 (March 8, 1990)].

The International Commission on Radiation Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) use a different approach from EPA in setting an acceptable risk level.[2] ICRP and NCRP are organizations which are chartered, and internationally recognized, for the development of basic radiation protection standards. Their findings are contained in ICRP Publication 60 and in NCRP No. 116, respectively. Based on their review of health and societal issues, both documents (while acknowledging the difficulty of setting standards for an "acceptable" public dose limit) arrive at 100 mrem/yr as a level that is acceptable for exposure to radiation sources other than medical procedures. NCRP 116 notes that this value includes a review of risks of mortality faced by the public. The ICRP and NCRP approaches further reduce their 100 mrem/yr limit by the principle of "optimization," which includes considerations of constraints (e.g., 25 mrem/yr) and cost-effectiveness.

Also, EPA's use of the 1E-4 risk level is somewhat inconsistent with its own Federal Radiation Protection Guidance for Exposure of the General Public (FRG) as published for comment on December 23, 1994. Specifically, the FRG is consistent with the

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[1] As discussed in item 3. below, EPA has determined that 3E-4 is "essentially equivalent" to 1E-4.

[2] As Attachment B to EPA's August 22, 1997 CERCLA memorandum states, EPA has rejected the NCRP approach to standards setting which EPA correctly notes NRC uses.

recommendations of ICRP and NCRP, in that, FRG recommendation no. 3 endorses an annual public dose limit of 100 mrem/yr and recommendation no. 4 indicates that individual sources of radiation exposure should have "authorized limits" set at a fraction of the 100 mrem/yr. The FRG further states that setting such limits will often necessarily be based on broad judgments which may lead to somewhat higher values with further implementation of the ALARA process. While the FRG does not recommend a specific level for any one source, it does cite authorized EPA and NRC standards for certain sources that currently exist, including 40 CFR Part 190 for the uranium fuel cycle and 10 CFR Part 61 for low-level waste disposal, both of which set authorized fractions at 25 mrem/yr.

Using the principles of setting of "individual dose and risk limits" and "optimization of protection" (noted above) and an additional margin to allow for the potential for exposure to more than one radiation source, the NRC issued a final rule on radiological criteria for license termination. The rule includes an all-pathways dose criterion of 25 mrem/yr and further reduction based on ALARA (62 FR 39058, July 21, 1997).

The EPA approach of setting an acceptable risk level in the context of reviewing risks acceptable in society is similar to that followed by ICRP and NCRP, but, clearly, is no more scientifically credible than the ICRP or NCRP reports. The FRN on NESHAPs acknowledges that because of the uncertainties over health effects, EPA's decision will depend to a great extent on policy judgment. Therefore, there is no reason to conclude that risk limits set through EPA's process are any more appropriate for protection than those set by ICRP and NCRP nor is there a reason to conclude that NRC's rule is not protective. EPA's simple declaration that NRC's rule, developed through extensive rulemaking in accordance with the procedures of the Administrative Procedures Act and detailed analysis and evaluation, is not adequately protective is unsupported and scientifically unsound.

2. EPA inaccurately states that NRC's rule is not protective

The CERCLA guidance does not address several items which will further lower the estimated risk from the implementation of NRC's rule. These items are inherent either in the NRC rule or in the characteristics of radioactive materials and include the following:

a) the requirement in the NRC rule that doses be reduced below the rule's dose criterion through the ALARA ("as low as reasonably achievable"; defined in 10 CFR Part 20) process further lowers the risk for the large majority of NRC sites;

b) radioactive decay of key contaminant nuclides which, for the large number of NRC facilities with contaminant nuclides with half-lives equal to 30 years or less, will result in reduction of the risk near or below that which EPA arbitrarily declares to be protective; and

c) the uncertainties associated with estimating risks from radiation at such low dose levels. Although NRC indicated in the FRN for its final rule (at 62 FR 39062) that it was not altering its policy regarding use of the linear non-threshold model as part of the rulemaking, the FRN also stated that there are uncertainties as to whether adverse radiation effects occur at all at the low levels of radiation being discussed. The actual risk from 25 mrem/yr is well within the boundaries of scientific uncertainty

regarding the magnitude of the actual health effects at these low doses. Whether or not health effects result from a dose as small as 100 mrem/yr is uncertain, as evidenced by the following statement of the Committee on the Biological Effects of Ionizing Radiation (BEIR V) in its 1990 report:

> Studies of populations chronically exposed to low-level radiation, such as those residing in regions of elevated natural background radiation, have not shown consistent or conclusive evidence of an associated increase in risk of cancer.

This same point was made in a recent safety evaluation report for National Aeronautics and Space Administration (NASA) Cassini mission (July 31, 1997), that EPA participated in, which referenced a Health Physics Society position noting that for a lifetime dose "below 10 rem the risk of health effects are either too small to be observed or are non-existent." Further, the Cassini report concluded that at the low individual dose rates expected that there is a high probability there will be no resultant latent cancers.

3. EPA inconsistently uses its protective value of 1E-4

The CERCLA guidance states that the 25 mrem/yr dose criterion in NRC's rule results in an estimated lifetime risk of cancer incidence of 5E-4 and that this is not protective compared to 1E-4. On the other hand, the CERCLA guidance states that a 15 mrem/yr dose standard (estimated lifetime risk of cancer incidence of 3E-4) is acceptable because "3E-4 is essentially equivalent to the presumptively safe level of 1E-4".

The CERCLA guidance statements are inconsistent and raise two specific issues. First, it is not apparent why one value would be considered unacceptable while the other is acceptable even though both exceed the 1E-4 risk level. Second, EPA uses cancer incidence to assess acceptability of the radiation dose levels compared to the 1E-4 value, even though the FRN on NESHAPS (54 FR 38044) indicates that the value of 1E-4 was based on a survey which resulted in a range of lifetime risk of premature mortality of 1E-1 to 1E-7. Thus, the point of comparison for assessing acceptability of the risk should be premature mortality. Further, it should be noted that the NCRP and ICRP use cancer mortality as the basis for their decisions. If the risk coefficient for mortality is used, the calculated estimate of lifetime risk from 25 mrem/yr is 3.8E-4 (based on a risk coefficient of 5E-4 for mortality versus 7E-4 for incidence), which approximates the 3 E-4 value that EPA concluded as essentially equivalent to the protective value 1E-4.

4. EPA's use of MCLs for groundwater results in inconsistent risk levels for cleanup

NRC's approach of using an "all-pathways" dose criterion means that the dose to a member of the public from all pathways of exposure (air, water, food and direct radiation) would not be permitted to exceed 25 mrem/yr for unrestricted release. The groundwater pathway is included in the 25 mrem/yr dose criterion and licensees are specifically instructed to reduce the site-specific dose to levels below 25 mrem/yr when it is ALARA to do so. NRC has previously discussed its analyses of groundwater and the rationale for its all-pathways standard in the FRN (62 FR 39074, July 21, 1997) for its final rule, indicating there that

(1) an all-pathways dose criterion provides a consistent risk-based standard, (2) maximum contaminant levels (MCL) are not set at consistent risk levels (and include some set above the NRC's dose criterion), and (3) the costs of meeting certain MCLs may be extraordinarily excessive compared to the benefits obtained in certain cases. Further, it should also be noted that NRC analysis indicates that a decommissioned site meeting the 25 mrem/yr all-pathways dose criterion is unlikely to result in a community water system delivering water to the tap with concentrations above the MCLs, because of both the process of dilution, decay, and transport in nature as the nuclides move through the aquifer and the process of water extraction, treatment, and/or distribution.

3. EPA reference to NRC's alternate criteria is inaccurate

The CERCLA guidance characterizes the NRC rule as not protective in part because it indicates that NRC would allow a dose of up to 100 mrem/yr based on an exemption process. This ignores the statement of considerations in the FRN for NRC's cleanup rule (at 62 FR 39072) which described the nature of alternate criteria and the context of use of alternate criteria within the ICRP/NCRP radiation protection framework. It should be noted that EPA's draft cleanup rule (withdrawn by EPA from further consideration by OMB in December 1996) contained provisions that also allowed for exemptions from its all-pathways and separate groundwater standards. Specifically, the EPA's cleanup rule contained provisions to allow for restricted release, the use of institutional controls with 5-year reviews, and the use of alternate concentration limits and Technical Impracticability Waivers when the amount of residual contamination exceeds the regulatory limits.

The FRN issuing NRC's final rule states that, "for the very large majority of NRC licensed sites" the 25 mrem/yr dose criterion would be "appropriate and achievable," but that the Commission was concerned about certain difficult sites presenting unique decommissioning problems. The FRN for NRC's proposed cleanup rule (59 FR 43217) indicated that it was anticipated that licensees of these facilities might seek exemptions from the criteria of the rule. However, the statement of considerations for the final rule indicate that, because these facilities would have to follow processes similar to those covered by the rule (e.g., evaluation of impacts and benefits, consideration of public inputs, use of institutional controls, etc.), it was more appropriate to codify them in the regulations, rather than have them seek an exemption from the rule.

Licensees of these facilities would first have to evaluate release of their site for unrestricted use under 10 CFR 20.1402 of the rule or for restricted use under 10 CFR 20.1403. Only if those requirements could not be met would the Commission consider allowing alternate criteria. The FRN notes that the Commission expects that use of alternate criteria will be "confined to rare situations" and "unusual site specific circumstances."

In those rare cases where alternate criteria were considered, the rationale for their use derives from the radiation protection principles of NCRP and ICRP, namely the setting of a limit and reduction of the dose below that limit based on a system of constraints and cost factors. NRC's cleanup rule would limit the dose for one of these unusual cases by requiring that the dose be kept below the 100 mrem/yr limit in 10 CFR Part 20 by a consideration of actual sources at the specific site as well as by an application of ALARA principles. Specifically, use of alternate criteria would only be allowed under 10 CFR 20.1404 following:

(1) a detailed licensee analysis of all man-made sources in the vicinity of the site (10 CFR 20.1404(a)(1)); (2) a public discussion of the issues involved with the use of alternate criteria for that site (10 CFR 20.1404(a)(4)); and (3) EPA involvement in the process, and a specific approval by the Commission (10 CFR 20.1404 (b)).

Thus, the rare occurrence of use of alternate criteria, the requirements for justifying its use, and the detailed approval process required for its use, will result in alternate criteria being used only in those situations where it is appropriate and where it is protective under the radiation protection principles of NCRP and ICRP.

6. EPA is inconsistent concerning whether or not radon is included in the CERCLA guidance

In the Purpose section of the CERCLA guidance (page 1), EPA indicates that the policies described include radon as a contaminant of concern. However, potential ARARs in two cases discussed do not address the dose from radon, yet are described as acceptable.

In Attachment B (page 4) of the EPA CERCLA guidance, the 10 mrem/yr standard for air emissions of radioactivity(40 CFR Part 61, Subpart I, now NRC's "constraint" rule) is discussed as another standard that is consistent with a maximum allowable dose level of 15 mrem/yr. Since this air emission standard does not include dose from radon (see EPA CERCLA guidance paragraph 2 on page 4 of Attachment B), it is not comparable to a dose limit of 15 mrem/yr that includes dose from all radionuclides (that exceed background).

Also in Attachment B (page 5), the standards for cleanup of contaminated soils around uranium mills (in 40 CFR Part 192) are described as consistent with the maximum allowable dose standard of 15 mrem/yr. However, in their reassessment of doses from contaminated soil at the limits of 40 CFR Part 192, EPA does not include the dose from the radon emissions component of the residual radium. (Note that the dose and risk assessment performed for the final Environmental Impact Statement (EIS) for the cleanup standards (EPA, 1982, *Final Environmental Impact Statement for Remedial Action Standards for Inactive Uranium Processing Sites (40 CFR Part 192)*, Rep. EPA 520/4-82-013-1) indicated that the lifetime risk from exposure to radon progeny at the standard was 2E-2.) In its reassessment, the EPA provided results for the initial calculations and for two reassessments. The initial calculations were the same as described in a general document addressing dose calculations for many radionuclides and scenarios, referred to by EPA as the Technical Support Document (TSD) (EPA, September 1994, *Radiation Site Cleanup Regulations: Technical Support Document for the Development of Radionuclide Cleanup Levels for Soil* (Review Draft), Office of Air and Radiation). In the TSD, doses for radium-226 in soil were performed both with and without inclusion of the dose from the associated radon. The TSD results reported in the reassessment document are the results which *do not include the dose from radon*. This is inconsistent with the stated policy in the CERCLA guidance, which indicated that radon was included. Based on the values in the TSD, the dose without radon is estimated to be roughly one-tenth the dose if radon is included, indicating that (as expected) the dose from radon is the most important component of the total dose from radium-226 in soil.

Allowing higher concentrations of radium in soil will, in turn, provide higher doses from radon. Without this major component of the original analysis used to develop the standards in 40 CFR Part 192 (control of radon), higher doses to the public could result.

7. CERCLA guidance reassesses doses from radon that results in significantly lower doses

The EPA has reassessed the doses associated with concentrations of radium in soil at levels of the cleanup standards for uranium mills (concentrations not to exceed background by more than 5 pCi/g in the top 15 cm of soil and 15 pCi/g in any deeper 15-cm layer, in 40 CFR Part 192), and has indicated that the doses are less than 15 mrem/yr (page 5 of Attachment B and page 8 of Attachment B). The doses from such contamination levels appear to be significantly underestimated. The CERCLA guidance refers to another report (EPA, July 22, 1996, *Reassessment of Radium and Thorium Soil Concentrations and Annual Dose Rates*) for details of the dose estimates. NRC also reviewed this 1996 document and raises the following issues and concerns:

a. Dose assessment should address all potential site conditions

The EPA indicated in the 1996 document that the reassessment included "generic model site characteristics, and standardized default exposure factors," but then indicated that EPA was "...interested in choosing modeling assumptions that are "realistic" or "reasonable," based on site-specific information,..." This assessment should be applicable to all sites required to meet the 40 CFR Part 192 cleanup standards, but it has failed to do so (see comments below on changes to area and contaminated zone thickness parameters).

b. The estimate of the contaminated area and layer thickness are not representative

In the TSD assessment, the contaminated area was assumed to be 10,000 m^2 and the contaminated layer was assumed to be 2 m thick. In the 1997 reassessment, these parameters were assumed to be "...a contaminated zone area of 100 m^2 and thickness of 15 cm, as specified under 40 CFR Part 192." The revised parameter values are not supported by the standards of 40 CFR Part 192, and do not appear to be representative of potential sites regulated under the standards. Although the cleanup standards of 40 CFR Part 192 specify that the cleanup limits apply to 100 m^2 areas and 15 cm thicknesses of soil, there is nothing to specify or even suggest that these values should be used in dose assessments. For assessing the dose to a potential receptor (i.e., person) at a remediated site, the actual area and depth of contamination should be used. Near uranium mill tailings sites, areas of windblown contamination can be as large as tens to hundreds of acres (tens of thousands to hundreds of thousands m^2). Hence, the assumption of a contaminated area of 100 m^2 is unreasonably small. Further, regarding the contaminated zone thickness, the 40 CFR Part 192 standards clearly allow contaminated material thicker than 15 cm (the only thickness limitation is that the 5 pCi/g limit only applies to the top 15 cm of soil). Thus, the EPA assumption that the contaminated zone is only 15 cm thick may not be reasonable.

The changes to the contaminated area and thickness appear to reduce the estimated dose (not including the radon dose) by a factor of about 4, and therefore are very important to the results of the reassessment.

c. **Changes to shielding factor and transfer factors were not available for NRC review**

The reassessment also includes modification of the gamma exposure shielding factor and the soil-to-plant transfer factors from the values used in the TSD. Information to support these changes is provided in a reference (Mauro J., SC&A, *Reassessment of the Derived Concentrations Guideline Level for Radium in Soil*, memorandum dated January 16, 1996, to B. Hull, EPA-ORIA) which was not available in time for this review. Thus, these modifications have not been evaluated by the NRC staff.

8. **The CERCLA guidance lacks a basis for the assumption that the 40 CFR Part 190 standard of 25/75/25 mrem is equivalent to 10 mrem/yr**

The CERCLA guidance includes reference to a document that explains how the 40 CFR Part 190 standard of 25/75/25 is equivalent to 10 mrem/yr and the 40 CFR Part 191 standard of 25/75 is equivalent to 15 mrem/yr. The comparisons of the EPA-proposed 15 mrem effective dose equivalent (EDE) limit and the previous standards, described in *Comparison of Critical Organ and EDE Radiation Dose Rate Limits for Situations Involving Contaminated Land*, April 1997, are technically inconsistent. The inconsistencies relate to the use of current dose methodologies to calculate acceptable soil concentrations under past standards. This overall calculational method establishes bias in the resulting EDE and the calculated averages to lower values. The comparison document itself shows that the relative consistency of the previous standards and 15 mrem EDE are highly radionuclide-specific and scenario-dependent. This is in part because the previous standards were based on the assumption that all organ systems are equally radiosensitive, which based on today's understanding of radiobiology is an invalid assumption. Therefore, comparisons with the previous standards cannot provide a sufficient technical basis for the 15 mrem proposed EPA standard, because the level of risk associated with the previous standards were case-specific, unlike the consistent level of risk used in the NRC standard.