Department of Energy
Washington, DC 20585

June 13, 1995

Mary D. Nichols
Assistant Administrator
for Air and Radiation
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Dear Ms. Nichols:

By 2 December 1994 memorandum from J. William Gunter, Office of Radiation and Indoor Air, the Environmental Protection Agency distributed for review a November 1994 preproposal draft version of 40 CFR Part 193, Environmental Radiation Protection for the Management, Storage and Disposal of Low-Level Radioactive Waste.

We are pleased to provide consolidated Departmental comments on the preproposal draft standard. We enclose a summary document, with attachments, expressing our major concerns. We also enclose responses to the specific questions raised by the Agency in the preproposal draft. My staff discussed the Department's major concerns at a 19 April 1995 meeting with Agency and Nuclear Regulatory Commission staff.

To summarize our major concerns, which are similar to those expressed to the Agency regarding a previous version of the draft standard (e.g., see attached 9 September 1991 letter):

- The draft groundwater protection requirements will drive low-level waste management and disposal facilities away from areas where the groundwater is already contaminated, and toward areas where the groundwater is pristine; hence, more groundwater would probably be put at risk than would be the case without the standard.

- The standard will significantly disrupt the Department's low-level waste management and environmental restoration programs, because many existing and planned disposal facilities will probably require closure and relocation.

- The Agency lacks, and should provide, justification that issuance of the standard will result in benefits to public health and safety and the environment that would clearly offset the large costs of the standard.

- The standard is inconsistent with Executive Order 12866 (Regulatory Planning and Review), which requires consideration of the costs and benefits of alternative approaches for major rules, and with the recommendations of

the Vice President's National Performance Review, which states that the Agency's media-specific approach to pollution control ignores connections between air, water, and waste. It recommends Agency development of other mechanisms for pollution control in light of complex, multi-media environmental problems.

We have also examined the potential impacts of the standard on commercial entities, based on our relevant authorities under the Atomic Energy Act and the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Amendments Act). The standard will be costly to commercial entities and will disrupt efforts by States and interstate compacts to develop new low-level waste disposal capacity as required by the Amendments Act. The standard also appears to be inconsistent with the requirements of the Regulatory Flexibility Act, which calls for an analysis of rulemaking impacts on small entities.

Although this standard is unlikely to significantly improve health and environmental protection, a scientifically-sound general environmental standard would be useful to the Department. Therefore, we recommend that the Agency consider issuing a multi-media standard that is generally applicable to all low-level waste activities authorized by the Department or licensed by the Nuclear Regulatory Commission or by Agreement States. Flexibility should be left for the implementing agencies to apply the standard in a manner that, on balance, is protective and the most cost-effective. This approach would be consistent with the recommendations of the Vice President's National Performance Review and Executive Order 12866.

We also believe that the Agency should place greater emphasis on development of general environmental standards for disposal of very low activity radioactive wastes by methods other than a low-level or mixed waste disposal facility. As you know, the Department has been working with the Agency and the Nuclear Regulatory Commission toward this end. We encourage the Agency to continue this effort as a priority activity, and look forward to supporting the Agency in its development of protective and cost-effective standards.

Sincerely,

/S/

Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

Enclosures

Department of Energy (DOE) Consolidated Comments

on the Environmental Protection Agency (EPA)

30 November 1994 Preproposal Draft of 40 CFR Part 193,

Environmental Standards for the Management, Storage and Disposal

of Low-Level Radioactive Waste (LLW)

The preproposal draft standard consists of three subparts:

- Subpart A, Environmental Standards for Management and Storage. Applies an annual 15-millirem (mrem) (ede)[1] limit to the public from operations at a LLW disposal facility and an "away-from-generator" management and storage facility. The limit applies to all pathways of exposure.

- Subpart B, Environmental Standards for Disposal. Applies an annual 15-mrem limit to the public from disposal of LLW. The point of compliance is "outside permanent markers." EPA proposes three options for time of compliance: (1) 1000 years, (2) peak dose, or (3) set by implementing agency.

- Subpart C, Environmental Standards for Protection of Underground Sources of Drinking Water. For those subject to Subparts A and B, applies drinking water maximum concentration limits (MCLs) to underground sources of drinking water (USDWs). Options specified: (1) MCLs not to be exceeded regardless of pre-existing contamination, and (2) up to the MCLs, if the pre-existing contamination is below the MCLs and up to one additional MCL if the pre-existing contamination is above the MCL. Neither the time of compliance nor the point of compliance is specified. The standard refers to activity in the USDW itself rather than activity in water as it may be used.

It defines LLW as follows: "...not high-level or transuranic radioactive waste or spent nuclear fuel, as defined in 40 CFR Part 191, or residual radioactive materials that are subject to 40 CFR Part 192, or naturally occurring and accelerator-produced radioactive material."

Context of Comments

For many years the Department of Energy (DOE) has reviewed EPA's development of its Part 193 standard, as have other organizations such as the Nuclear Regulatory Commission (NRC), States and

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[1]ede - effective dose limit.

Compacts, and others. A timeline citing salient points from this review is included as Attachment 1.

A consistent theme has been DOE's and NRC's concerns about the unclear need for the LLW standard and the likelihood that the standard would achieve very few benefits at very large costs. Major difficulties have been identified with the draft EPA requirements for groundwater protection, among other concerns. These concerns have been repeatedly communicated to EPA in the form of correspondence and direct discussions with EPA staff.

In April 1989, EPA transmitted a version of the standard to the Office of Management and Budget (OMB) for publication as a proposed rule. But because of concerns expressed by DOE and NRC, OMB suspended review of the standard "...until the agency completes discussions with the other affected agencies and fully reviews the major issues..." DOE's concerns were expanded and provided to EPA in a 9 September 1991 letter, wherein DOE observed that at great costs, the risks avoided from implementing the standard would be minimal. (DOE suggested, in fact, that the standard was as likely to increase as to decrease net risks.) This letter included a detailed and critical review of the technical underpinnings of the standard as provided by EPA in the form of a published Background Information Document (BID), dated June 1988, and an unpublished Economic Impact Assessment (EIA).

More recently, EPA has provided for review a new version of the standard, dated 30 November 1994.[2] This draft retains features of the April 1989 draft standard that had been of major concern to DOE and to others. The preproposal draft standard refers to a revised BID and EIA, but these documents are not available. However, from statements of EPA staff and other information, we understand that the revised BID will not be significantly changed from the existing BID.[3]

At a 19 April 1995 meeting between DOE and EPA staff, and attended by NRC staff, EPA staff provided additional comment about the intent of some of the requirements within the preproposal draft standard. (See attached meeting record.)

The comments that follow represent consolidated DOE comments on the 30 November 1994 version of the preproposal draft standard.

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[2]The preproposal draft standard was provided to DOE, NRC, and others. However, EPA did not announce the availability of the preproposal draft standard in the Federal Register.

[3]EPA staff have informed us that few changes have been made to the analysis in the BID. We have also reviewed the information on the revised BID that EPA provided to Dr. Carol Marcus pursuant to her Freedom of Information Act request.

We present overall comments as well as comments on each of the subparts of the preproposal draft standard. We provide comments from the standpoint of the impacts of the standard on commercial entities as well as DOE. Impacts to commercial entities are of concern because (1) DOE is charged under the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Amendments Act) with assisting States and Compacts in developing new LLW disposal capacity; (2) DOE contracts with commercial entities to treat and dispose of LLW; hence, impacts on commercial entities directly affect DOE's costs of managing its LLW; (3) DOE retains responsibility under the Atomic Energy Act for promotion of peaceful uses of nuclear materials; (4) the recognition that safe LLW management is of national interest; and (5) technical completeness.

During our review of the preproposal draft standard (including the preamble), we noted a large number of inaccuracies, misleading statements, and other problems. Many of the same problems and errors that DOE observed in previous drafts of the standard have been repeated (e.g., see DOE's 9 September 1991 comments, attached, on the April 1989 draft standard). We have generally not commented specifically on these problems, nor have we provided a page-by-page markup. Instead, because of the preliminary status of the draft standard we have limited our comments to substantive issues.

Overall Comments

EPA has not provided justification that any gains made by promulgation of the standard will offset the large costs and uncertainties that its development and promulgation will impose, and will continue to impose after promulgation. As part of this concern, we note:

- The standard will likely result in few benefits, if any, but at excessively large costs to DOE and to taxpayers. Previous analyses performed by EPA suggest that implementing the standard might save no more than three to thirteen health effects over 10,000 years. Regarding costs, our preliminary estimate is that annual DOE expenses from implementing the standard will exceed $200 million, not considering the costs associated with disruptions in DOE's LLW management and environmental restoration activities. Hence, a Regulatory Impact Analysis is needed. (See below and Attachment 2.)

- The standard will disrupt DOE LLW management programs. DOE has been managing waste at most of its sites for several decades, and disposal records for early years are often poor. Groundwater under several new and existing DOE LLW management facilities already contains natural and man-made radionuclides -- the latter because of past LLW management

practices, including use of cribs and injection wells. To minimize the potential for contamination of multiple groundwater sources, DOE has in some cases sited new LLW disposal facilities downgradient of plumes from older LLW disposal facilities. In other cases, under arrangements with the States and EPA, remedial actions take place alongside LLW disposal.

But because of the standard, and the difficulties of demonstrating compliance with its requirements, DOE may need to discontinue LLW disposal operations at several DOE sites. DOE would need to site new disposal facilities in areas having minimal radionuclide concentrations (natural and man-made) in groundwater. Most DOE disposal sites appear to be at risk. Costs for replacing these disposal facilities could amount to billions of dollars in annual costs, including storage and transportation costs. Additional risks would be imposed on workers and the public. (See Attachment 2).

- The standard will disrupt and delay DOE's environmental restoration programs by increasing the difficulty of disposing of wastes generated from these programs. As one example, costs to DOE's Formerly Utilized Site Remedial Action Program (FUSRAP) may exceed $300 million. The standard may also disrupt DOE's program to treat and vitrify high-level waste at the Savannah River Site.

- States and Compacts believe that EPA's development of the standard raises considerable uncertainties that will significantly delay their efforts to site and develop new LLW disposal capacity pursuant to the Amendments Act.[4] Many LLW generators now lack disposal capacity, and for every year of delay caused by the standard development process, commercial generators will be compelled to spend millions of dollars in storage costs. For customers of a single prospective disposal facility in Ward Valley, California, we estimate that a five-year delay would amount to total storage costs averaging $33 million per year. Annual national storage costs will probably exceed $100 million. In addition, when disposal capacity **is** available, delays will result in larger disposal costs. For the California site, a five-year delay could cause roughly $100 million in

[4]Uncertainties will affect DOE as well as commercial entities, and will continue after promulgation of the standard. Problems include the linkage of the standard to drinking water maximum concentration limits which are subject to reduction, the lack of clarity of the standard, and possible future EPA requirements addressing human intrusion.

extra preoperational costs. (See point (a) in Attachment 3.)

For commercial away-from-generator processing and storage facilities, additional costs would result from the difficulties and uncertainties associated with compliance with the annual 15-mrem limit specified in Subpart A, and with the groundwater protection requirements specified in Subpart C. These costs would be passed on to customers. (See specific comments on Subpart A.)

- Further restrictions in disposal capacity are likely to result in additional disruptions in research programs that require use of longer-lived isotopes (e.g., those isotopes that can't be readily managed using hold-for-decay procedures). Such research becomes more expensive, which means that less research can be accomplished using available funding. Research also tends to be shifted to other countries where there are more disposal options. In addition, research facilities and other licensees will make greater use of sanitary sewer disposal and incineration.[5] This means that EPA's efforts to reduce hypothetical long-term public radiation exposures from LLW disposal facilities will increase short-term public radiation exposures from disposal of LLW by other authorized methods.

- The standard might result in closure of existing commercial LLW disposal facilities. Consider, for example, the U.S. Ecology disposal facility licensed by the State of Washington and located within the Hanford Reservation. U.S. Ecology would be required to assess the possible contribution from DOE operations when assessing compliance with Subpart C, although U.S. Ecology has no direct control over DOE operations. Hence, compliance assessments would be uncertain. Closure of the U.S. Ecology disposal facility would deprive its customers of disposal capacity.[6] If only five years were needed to site, construct, and license a

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[5]Personal communication, Carol Marcus, Ph.D., M.D., to G. Roles, DOE, on 12 April 1995. Among other activities, Dr. Marcus is a member of the Society of Nuclear Medicine, the American College of Nuclear Physicians, the Cal Rad Forum, and the Conference of Radiation Control Program Directors.

[6]U.S. Ecology's customers include about 240 waste generators, not including 12 brokers that manage LLW, typically for very small entities. About 100 of the listed generators are hospitals, universities and colleges, and research facilities. EPA is a customer, as are municipal water supply districts, which must dispose of NARM waste removed from drinking water in compliance with EPA regulations.

replacement disposal facility for the Northwest Compact, customer storage costs could average as much as $45 million per year. (See Attachment 3.)

- o Subpart C will discourage disposal of LLW in previously contaminated areas, and encourage disposal of LLW in pristine areas having minimal existing or potential groundwater contamination. Option 2 for groundwater protection as proposed by EPA could actually discourage remediation of contaminated areas. (See below.)

- o The preproposal draft standard is inconsistent with Executive Order 12866, Regulatory Planning and Review. By DOE's analysis in Attachment 2: (1) because the standard represents a significant regulatory action, EPA should prepare a Regulatory Impact Analysis (EPA currently lacks such an analysis); and (2) EPA's standard is inconsistent with the Regulatory Philosophy and twelve Principles of Regulation which are set forth in the Executive Order and incumbent on Federal agencies.[7]

- o The preproposal draft standard is inconsistent with the Regulatory Flexibility Act which requires a Regulatory Flexibility Analysis of rulemaking impacts on small entities. Many commercial licensees[8] are small entities, including hospitals, universities, and laboratories. See Attachment 3.

- o The preproposal draft standard is inconsistent with the Vice President's Report of the National Performance Review which calls for EPA to develop other mechanisms than a media-specific approach to pollution control in light of complex, multi-media environmental problems.

- o Unlike previous versions of the standard, the preproposal draft standard does not include a general environmental standard for disposal of very low-activity radioactive wastes by methods other than a low-level or mixed waste disposal facility. This is an unfortunate omission. We believe that EPA should place greater emphasis on this

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[7]We also refer EPA to the President's 4 March 1995 memorandum on the ongoing Regulatory Reform Initiative. Among other things, this memorandum reminds the heads of departments and agencies of the importance of the regulatory philosophy set forth in Executive Order 12866.

[8]Of roughly 24,000 NRC and Agreement State licensees, we estimate that about 2000 to 2500 licensees routinely generate LLW, annually or every few years. All, however, have the potential for generating LLW.

important issue, on which the Department has been working with EPA and with NRC.

We also note:

- EPA should justify the need for this standard in light of the small "baseline" risks that might be associated with LLW disposal in the absence of the standard, and by the probability that the standard will reduce these small risks by only a few health effects, if any. In EPA's analyses for its April 1989 draft standard, which resembles the current draft standard, EPA's estimated that roughly 50 health effects would occur in the absence of the standard. EPA estimated that implementing the standard would save from 3 to 13 health effects over 10,000 years, although EPA did not subtract from this estimate the risks to workers and the public that implementing the standard would cause.

  Thus, "baseline" risks from LLW disposal are about a factor of 20 smaller than the criterion of 1000 health effects over 10,000-years that EPA used to establish its standard for disposal of high-level waste, 40 CFR Part 191. In the written record for this rulemaking, EPA strongly maintained that this criterion represented an acceptable number of health effects, and cautioned against the automatic application of such a strict criterion to other disposal systems that could not provide as good protection as a geologic repository. (See Attachment 4.)

- The preproposal draft standard is imprecisely drafted. It lacks clarity about several critical matters, such as the point and time of compliance for Subpart C, the use of standard adult dose conversion factors and physiological assumptions for Subparts A and B, the scope of persons and facilities subject to Subpart A, and acceptable demonstrations of compliance for those subject to Subpart A. Without this needed clarity, commenters will be unable to adequately assess the impacts of the standard on their operations, nor provide focused comments. Lack of clarity leads to confusion about the interpretation of the standard, invites litigation, increases costs, delays siting new disposal capacity, and leads to inconsistent implementation.

- EPA defines LLW in an unusual manner, one that is inconsistent with the definition of LLW in the Low-Level Radioactive Waste Policy Act, which was used as the basis for the definition of LLW in NRC and DOE regulations and directives. Two major problems with EPA's proposed definition are as follows:

1) LLW has been historically defined in a manner that excludes uranium and thorium tailings and wastes as defined under Section 11(e)(2) of the Atomic Energy Act. But EPA's definition would exclude residues subject to 40 CFR Part 192, which only cover tailings and wastes cited in Titles I and II of the Uranium Mill Tailings Radiation Control Act (UMTRCA). Hence, very large quantities of Section 11(e)(2) byproduct material that are NOT covered by Titles I and II of UMTRCA (e.g., FUSRAP wastes) would be subject to the standard. These wastes are more appropriately regulated by standards similar to 40 CFR Part 192.

2) EPA proposes to exclude naturally-occurring and accelerator produced radioactive material (NARM) from its definition of LLW, yet does not define NARM. An explicit definition of NARM should be provided. Accelerator-produced material is regulated by the Department under its authority under the Atomic Energy Act and is disposed of as LLW.

- The preproposal draft standard references a revised BID and EIA as technical and economic justification. Although both documents are essential for a proper review of the draft standard, neither document is available. Several technical shortcomings have been documented for the existing BID. Hence, the revised BID and EIA must be made available for detailed technical review before the standard is proposed.

- EPA should set forth separate limits for radiation doses from radon isotopes. EPA's 15-mrem limit in Subparts A and B is inconsistent with its own regulations, 40 CFR Parts 61 and 192, which set forth separate requirements for radon isotopes. EPA's 15-mrem limit is also inconsistent with DOE's annual limit of 25 mrem from all sources in pending 10 CFR Part 834. This limit also considers radon isotopes separately from other isotopes.

- EPA should consider and clarify the applicability of the standard to mixed LLW and to greater-than-Class-C LLW, and also to the above-grade disposal methods that some Compacts are considering. In addition, EPA must clarify the applicability of the standard to situations where LLW is mixed with NARM, with uranium or thorium mill tailings, or with transuranic waste. All three of these situations currently exist.

<u>Comments on Subpart A</u>

EPA would impose an annual 15-mrem limit in Subpart A, but does not provide compelling justification that this limit is preferable to any other numerical limit (such as 25 mrem, which was EPA's proposed limit for Subpart A in previous drafts of the standard).

If the standard is issued in its present form, the Subpart A limit should be selected on the basis of a cost-benefit analysis that considers risks both avoided and caused by implementing the standard. To establish a LLW management dose limit, a range of alternative dose limits should be considered, where the annual 100-mrem primary dose limit would be the upper bound of the range of dose alternatives considered. The optimum limit should then be selected considering incremental public doses and risks averted by the standard, incremental worker and public doses and risks caused by the standard, and incremental costs associated with the specific dose limit.

We note:

* The statements that the annual 15-mrem (ede) dose limit represents equivalent risis to the dose limits cited in other standards (e.g., 40 CFR Parts 190, 10 CFR Part 61), are arguable. In the case of Subpart A, the pathway of most concern is the direct radiation pathway.[9] The dose from direct radiation is a whole body dose, and a whole body dose of 25 mrem is exactly equivalent to 25 mrem (ede). Nonetheless, the argument is moot because the standard should be based on a cost-benefit analysis rather than by comparison to other regulatory requirements.

* EPA makes a statement that a annual 15-mrem limit implies a lifetime risk of 5E-4. This risk estimate should be qualified as an upper-bound, and very unlikely, maximum individual risk.

  The cited risk value implies the assumption that radiation exposure (at the 15-mrem limit) occurs for **70 years** (0.015 rem/yr x 5E-4 health effects/rem x 70 yr = 5.25E-4 health effects over 70 years), to an individual that does not move from the fenceline of the nuclear facility for the entire period of exposure. This assumption is clearly extraordinarily unlikely and conservative.

  First, it is difficult to imagine many LLW disposal facilities or away-from-generator processing and storage facilities operating for 70 years. We understand that LLW disposal facilities planned by States and compacts are projected to operate for time frames of about 20 to 30 years. EPA's own analysis in its existing BID assumed operation of a LLW disposal facility for 20 years. Second,

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[9]EPA asserts that the primary reason it proposes to impose Subpart A is because existing NRC regulations don't provide sufficient public protection from the direct radiation pathway.

even for a realistic time of facility operation, it is very unlikely that continous exposure at the specified dose limit would occur over the entire time of operation.

* On page 24 if the preproposal draft, EPA cites the annual 100 mrem limit that is recommended by the International Commission on Radiation Protection and National Council on Radiation Protection and Measurements (as well as EPA), and is applicable to all radiation sources except for background and medical procedures. EPA states that it "does not believe it is appropriate to allocate all of this limit to the management, storage, and disposal of LLW since they are just three of many sources of radiation exposure." EPA then concludes that 15-mrem represents an acceptable fraction of the 100-mrem limit.

  But the initial premise is speculative. EPA provides no information about the probable sources of radiation exposures other than those associated with "management, storage, and disposal of LLW." Neither does EPA provide an assessment of the significance of these sources.

  In addition, no basis is presented for the position that 15 mrem represents an acceptable fraction of 100 mrem while a different limit does not. Although 15-mrem might be shown to represent an acceptable fraction of 100 mrem, other values (e.g., 50 mrem, 25 mrem) should be considered in a cost-benefit evaluation of alternative dose limits.

In addition, we note the following:

- o EPA would require that implementing agencies impose this subpart on licensees and authorized facilities who would have to provide assurances of compliance. Modifications to the design, construction, and operation of affected facilities may be needed, as may regulatory submittals and approvals. Because of the costs associated with these activities, EPA must justify the need for the subpart. But a compelling justification has not been provided.

  To justify the subpart for commercial LLW disposal facilities, EPA claims that because 10 CFR 61.41 does not specifically reference a direct radiation pathway, possible public risks from LLW management might be excessive. Also, EPA claims that no specific standard exists for away-from-generator processing and storage facilities. But this justification is not compelling. 10 CFR Part 20 applies to **all** NRC and Agreement State licensees. It imposes an annual 100-mrem limit, plus a requirement to reduce doses to levels as low as reasonably achievable (ALARA) for all pathways and sources at a licensed facility (not just LLW management).

To justify the subpart for DOE operations, EPA states that because DOE 5820.2A excludes the air pathway from its 25-mrem LLW all-pathways performance objective, up to 35 mrem/yr would be allowed at DOE sites from LLW management operations. But this justification is incorrect. EPA has misunderstood the intent and context of DOE's order. In any event, the cited language has little practical consequence in terms of public dose, as documented in the annual site environmental reports prepared by DOE sites in accordance with DOE directives, and by the annual NESHAPS reports that DOE submits to EPA. Existing DOE directives and ALARA programs have reduced and maintained public doses to levels well below 25 mrem/yr. Maximum individual doses to members of the public for most sites are less than 1 mrem/yr; waste management operations normally account for only a small fraction of this dose.

EPA should also consider that in 1995, DOE will promulgate a regulation, 10 CFR Part 834, that will limit annual doses to members of the public from management of **all** radioactive waste, not just LLW, to 25 mrem (except for radon isotopes, which are appropriately controlled via a separate standard).

- o EPA must also consider that other, separate EPA actions will reduce potential public doses from licensed commercial operations. This makes EPA's justification for the need for the subpart even less compelling:

  - By 23 December 1994 Federal Register Notice, EPA proposed its Federal Radiation Protection Guidance. It imposes an annual 100-mrem public dose limit from all pathways plus a strengthened ALARA requirement. Populations as well as individuals must be considered. This would apply to NRC and DOE activities at all facilities.

  - By 28 January 1994 Federal Register Notice, EPA imposed its NESHAPS requirements (10 mrem/yr from the air pathway) on all NRC and Agreement State licensees other than nuclear reactors (already covered by 40 CFR Part 190). DOE is already subject to NESHAPS requirements under the provisions of the Clean Air Act.

- o In its 21 October 1994 letter from Margo Oge to Robert Bernero, EPA has offered to exempt NRC from the entirety of Part 193 if NRC adopts a groundwater protection requirement in its rules. This amounts to a de facto EPA acknowledgement that neither Subpart A nor B are important

for commercial facilities.[10]

- To justify Subpart A, EPA also raises the spectre of large risks from potential "spills." But "spills" represent accident situations, not consistent with routine operation of a facility which is the focus of the standard. One must therefore question this justification, unless EPA can provide monitoring or other data to support its claim that excessive risks will result in the absence of its standard. CERCLA requirements (reportable quantities) already address spills. (DOE has addressed this in DOE 5400.5.) Furthermore, EPA has provided guidance for addressing accidents in their Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (EPA 400-R-92-001).

- As away-from-generator processing or storage facilities are defined, Subpart A could apply to any building other than the one at which the waste was generated. Hence, many more entities could be affected than supposed by EPA. (EPA provides no estimates about the characteristics or numbers of affected entities.) Also, in DOE's September 1991 comments, DOE pointed out that a large number of entities which are not principally in the waste storage or processing business (e.g., brokers, transporters, sealed source and device manufacturers and distributors) might be subject to the standard. EPA still has not clarified the universe of facilities to which the subpart would be applicable. This clarification is essential if EPA intends to impose the standard in its current form.

- Although EPA does not specify how compliance is to be demonstrated, EPA provides a detailed list of pathways to be considered in all-pathways compliance evaluations. This implies that compliance evaluations must be very detailed and considerable effort must be spent addressing insignificant pathways. If EPA is to impose the standard in its current form, then EPA should delete the detailed list of pathways, and clarify what it expects from those that would be subject to the standard.

- It may be next to impossible for many facilities to demonstrate compliance directly, if at all. Hence, if EPA is to impose the subpart, EPA must evaluate alternative ways by which compliance can be demonstrated. Costs for compliance must be considered, estimated, and justified.

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[10]An NRC memorandum from R. Nelson to J. Kennedy summarizes a 9 March 1995 meeting between NRC and EPA staff. At this meeting, EPA staff indicated that although NRC might be excluded from Subpart B, NRC would probably not be exempted from Subpart A.

As one problem, an annual 15-mrem standard represents, for direct radiation, a dose rate of only 1.7 microrem per hour (urem/hr). But the natural background dose rate for external radiation is typically 5.8 to 24 urem/hr, and there are hourly, daily, monthly, and seasonal variations.[11] Even assuming a low background level of 5.8 urem/hr, a 1.7-urem/hr standard represents only a 30% change. To illustrate the difficulty, we have included (Attachment 5) a pair of graphs that show the variations in hourly dose rates at Chester, New Jersey, as a function of time. The range in hourly dose rate exceeds EPA's standard: For a period betweeen July 1980 and July 1981 the hourly dose rate ranged from about 13 to more than 16 uR/hr. The hourly dose rate ranged from a low of less than 9 uR/hr to a high of more than 16 uR/hr over a period from 1977 to 1980.

Another problem is that DOT transportation regulations allow for much larger hourly radiation levels than those set forth in the standard -- i.e., 200 mrem/hr at the surface of a transport vehicle or package or a group of packages, or up to 10 mrem/hr at a distance of 2 meters (see 49 CFR 173.441). A transport vehicle containing LLW and parked outside the fence of a facility regulated under Subpart A would be in compliance with DOT regulations. But if one parked the vehicle inside the fence, the facility could conceivably violate the 15-mrem limit within two hours. Even if doses from transport vehicles were to be excluded from the standard, there would still remain the question of how a licensee could distinguish doses from different sources using common measurement techniques.[12]

A third problem is that NRC and Agreement State licensees (and DOE-authorized facilities) may under certain conditions discharge radionuclides into sanitary sewers. (Most licensees that dispose of radionuclides in this way are probably small entities.) How would a licensee consider the

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[11]An annual dose rate of 15 mrem divided by 8766 (365.24 days/year x 24 hours/day) results in an hourly dose rate of 1.7 urem/hr. The dose from terrestrial radionuclides is typically 23 mrem/yr for the Atlantic and Pacific coastal states, up to 90 mrem/yr in Rocky Mountain states, and about 50 mrem/yr elsewhere in the U.S. The cosmic ray contribution varies from 28 mrem/yr at sea level to over 125 mrem/yr at 3200 m. This gives external dose rates that range from 5.8 to 24 urem/hr.

[12]The reason why the direct radiation pathway was not specifically cited in 10 CFR 61.41 is precisely because of the potential for conflicts with DOT regulations. DOE pointed out the potential for these regulatory conflicts in its 9 September 1991 letter to EPA.

potential public doses from this practice when demonstrating compliance with the 15-mrem limit?

A fourth problem is the intended imposition of the Subpart C requirements for protection of underground sources of drinking water to away-from-generator processing and storage facilities. Based on the language of the preproposal draft standard, many of the facilities will probably be small entities having limited economic resources. How would compliance be demonstrated, either directly or otherwise? Considerable effort and cost might be required for detailed groundwater investigations, compliance analyses, and so forth. **Where** would compliance be demonstrated -- under the facility? Offsite? Would the MCLs be applied to radionuclide concentrations as they may exist in the groundwater itself, or to radionuclide concentrations in water after it is assumed to be withdrawn from the ground?

- The point of compliance must be clarified if EPA imposes the standard in its current form. Many DOE facilities (and at least one commercial facility) are located within large reservations and miles from easy access by the public. Would the point of compliance for such facilities subject to Subpart A be at the boundary of the facility exclusion zone or at the boundary of the larger DOE site?

Comments on Subpart B

- EPA provides essentially no justification that the annual 15-mrem limit in the preproposal draft standard is preferable over the annual 25-mrem limit in previous versions of the standard, or for that matter, preferable over any other limit.

  The only rationale that EPA provides for the 15-mrem limit is a statement that a 15-mrem (ede) limit has been recently imposed by EPA in Subpart B of 40 CFR Part 191. But absent a cost-benefit analysis that considers risks both caused and avoided by the standard, this comparison would only be reasonable if the 15-mrem limit was to be applied similarly in Parts 191 and 193. But it is not apparent that this situation is the case.

  The point of compliance for the 15-mrem limit is different for Part 191 than for the preproposal draft standard. For 40 CFR Part 191, the 15-mrem limit is to be applied to "a member of the public in the accessible environment," which means that the limit is to be applied beyond the controlled area. Part 191 defines a controlled area as "(1) a surface location, to be identified by passive institutional controls, that encompasses no more than 100 square

kilometers and extends horizontally no more than five kilometers in any direction from the outer boundary of the original location of the radioactive wastes in a disposal system; and (2) the subsurface underlying such a surface location." But for the preproposal draft standard, the point of compliance is "outside permanent markers," whatever EPA means by this requirement.

Unless EPA proposes to define the point of compliance in the same manner for 40 CFR Part 193 as it does for Part 191, it must be assumed that the points of compliance for the two standards are different. Because they are different, the impacts and difficulties implied by complying with the two standards must also be different.

Clearly, a cost-benefit analysis is needed that justifies the dose limit selected for Subpart B. Similar to the analysis discussed above for Subpart A, the dose limit should be selected from a set of reasonable alternative dose limits (e.g., 15 mrem, 25 mrem, 50 mrem), where the 100-mrem primary dose limit would represent the upper bound of the range of dose alternatives considered. The optimum dose limit would be selected on the basis of cost-benefit analysis that considers the risks both avoided and caused by the standard.

- It is not apparent that any benefits provided by imposing the subpart will offset the costs and confusion associated with EPA's standard-setting effort. The proposed 15-mrem limit is less than a factor of two smaller than the existing limit in DOE 5820.2A.

- EPA states that a 15-mrem (ede) limit corresponds to a lifetime risk of 5E-4. But again, a 5E-4 lifetime risk implies that an individual is assumed to receive a 15-mrem dose annually for 70 years. This assumption is very unlikely and conservative. EPA assumes a 30-year exposure time for its assessments under Superfund. EPA also assumes a 30-year exposure time for its analyses for its radioactive contamination standard now under develoment (40 CFR Part 196). And these assessments are performed for situations where there is some expectation that persons might actually use land where radioactive contaminants exist, and actually might become exposed to these contaminants.

  This suggests that EPA could adopt a larger dose limit (say 30 mrem/yr) and still maintain lifetime risks to 5E-4, assuming a 30-year exposure time consistent with EPA's analyses for CERCLA and for 40 CFR Part 196. And as noted above, the "actual" risk implied by a 30-mrem limit for waste disposal would be smaller than 5E-4 because of the very hypothetical nature of the performance assessments.

Doses are projected to hypothetical persons living hundreds if not thousands of years in the future, not "real" persons who might occupy and use property immediately after it had been deliberately released after decommissioning. In any case, 5E-4 is the upper-bound risk. Most individuals would be subject to far smaller doses. Therefore, it is necessary to compare incremental risks both caused and avoided, as well as costs, to justify an appropriate dose limit.

- Regarding time of compliance, EPA proffers three options, of which one option is "peak dose." But the "peak dose" option is immediately eliminated by EPA's statement in the preproposal draft that calculations beyond 10,000 years should be considered "invalid." In addition, EPA must appreciate that the option of "peak dose" as a time of compliance will result in inefficient use of disposal capacity. At one DOE site located in a humid environment, disposal facility inventory limits derived from consideration of peak dose would be reduced by a factor of six for Ni-59 from those derived from consideration of a 10,000-year time of compliance. For other radionuclides, such as isotopes of thorium, uranium, and transuranics, the reduction in allowable inventory limits would generally range from factors of four to seventy. For Th-232, the inventory reduction would represent several orders of magnitude. The effect could be even larger for disposal facilities located in arid environments.

  As noted in DOE's attached response to EPA's specific questions for public comment, DOE recommends a time of compliance of no more than 1000 years, if the standard is imposed in its present form.

- EPA's detailed definition of "all-pathways" may require expenditure of significant resources to address insignificant pathways. In DOE's performance assessments, DOE customarily **considers** a detailed set of pathways, and then winnows these pathways down to those that are significant for calculational purposes. But if one had to **calculate** potential human doses from each pathway that could be identified, no matter how trivial, then costs for compliance with the subpart would be elevated. (One DOE site estimated an additional cost of $500,000 per performance assessment.) Compliance assessments would take longer to complete. If EPA intends to impose the standard in its present form, than the detailed list of pathways should be deleted. A more general statement should be provided that lists the types of pathways that should be considered, making clear that those pathways that would be subject to detailed, quantitative evaluation would be determined based on their significance on a case-specific

basis.

- o If the standard is to be issued in its present form, then EPA must clearly define the point of compliance, giving consideration to the issue of future land use. DOE plans to retain ownership of disposal facility land. However, EPA states that the standards are to apply "outside the area delineated by permanent markers and in records of government ownership." The duration of the effectiveness of the markers is not addressed. Does this mean that EPA intends for markers and records to be effective in perpetuity, or does EPA intend to require an assumption that at some future time a disposal facility would be indistinguishable from other land? For the latter case, which would be inappropriate, the disposal facility would become part of the general environment. An intruder would be considered a member of the public. Such an assumption may preclude disposal of waste having all but the least activity.

  If issued in its present form, the standard must clarify that the point of compliance shall be assumed to be fixed throughout the time of compliance, and that a potential inadvertent intruder is not considered a member of the public for purposes of the standard.

Comments on Subpart C

We do not see the need for separate requirements addressing the groundwater pathway. EPA should consider issuing a multi-media standard of general applicability -- that is, a standard applicable to DOE as well as NRC and Agreement States. Flexibility should be left for the implementing agencies to apply the standard in a manner that, on balance, is protective and the most cost-effective. This approach would be consistent with the Vice President's Report of the National Performance Review which calls for EPA to develop other mechanisms than a media-specific approach to pollution control in light of complex, multi-media environmental problems. If a media-specific groundwater standard is to be issued, then it should be evaluated and selected on the basis of its merit rather than on an EPA statement of policy.

Our analysis of the proposed Subpart C requirements indicates that by either option proposed by EPA, the requirements would likely result in few, if any, benefits in terms of enhanced protection of public health and safety and the environment. In fact, the requirements might cause more risks and environmental problems then they would solve.

But to comment specifically on the proposed requirements in Subpart C:

- o Option 1 is unworkable:

- The option may require closure of existing LLW management and facilities at SRS, Hanford, and elsewhere, but would not reduce risks to groundwater resources. Rather, because new facilities constructed in pristine environments would be needed to replace closed facilities, more groundwater resources would be placed at risk than in the absence of the standard.

- The option (also, option 2) is predicated on the assumption that groundwater contamination underneath LLW management facilities is at constant and time-invariant levels.[13] But this is inaccurate. Groundwater systems and contamination levels are dynamic rather than static. Concentrations of radionuclides underneath a LLW management or disposal facility will vary depending on time and depth, as well as horizontal distance from a source. These considerations increase the difficulty of demonstrating compliance with the standard.

- Compliance for this option (also, option 2) must be demonstrated based (in part) on the results from environmental monitoring programs, which are subject to various sampling and measurement uncertainties, statistical and otherwise. These considerations increase the difficulty of demonstrating compliance with the standard.

- Background concentrations of naturally-occurring radionuclides can be large and variable. Some groundwater samples at SRS at both Saltstone and E-Area Vaults are twice current drinking water MCLs for radium. Other samples, at the same wells but at different times, do not exceed detectable limits. One sample (20.5 pCi/L) exceeds proposed revised MCLs for Radium-226. EPA's standard places the continued operation of these disposal facilities at risk, even though DOE's disposal operations did not cause these high levels of radium-226 in groundwater.

- The U.S. Ecology disposal facility is licensed by the State of Washington and sited within DOE's Hanford Reservation between the 200-E and 200-W Areas. Compliance demonstrations could be very difficult for DOE as well as U.S. Ecology because neither can directly control the potential for release from the other's sites.

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[13]Statement of EPA staff at a 19 April 1995 meeting among EPA, DOE, and NRC staff.

- EPA is unclear about the application of the option to multiple radionuclides, and to the timing of contaminated plumes. For example, if contamination levels exceeded MCLs for, say, alpha-emitting radionuclides, either now or in the future, would disposal of all radionuclides be prohibited or would disposal of beta-gamma radionuclides be acceptable? If the MCLs are currently exceeded for tritium (or another isotope) in groundwater beneath a disposal facility, but one expects that within a reasonable time the contamination will be reduced to levels less than MCLs because of radioactive decay and system "flushing," how would the MCL limit be applied? That is, would waste disposal be allowed, based on the projection that by the time that the projected plume from the waste disposal facility arrives at the point of compliance, the existing contamination would be reduced?

o Option 2 provides no relief over Option 1, and is also unworkable:

  - Compliance demonstrations under this option could be even more difficult than those under Option 1.

    As noted above, contamination plumes vary depending upon time, depth, and distance from source. At any given time, radionuclide concentrations in groundwater under one part of a LLW management facility might exceed MCLs, while concentrations under another part of the facility might not. (At the E-Area Vault disposal facility at Savannah River Site, monitoring wells indicate that the tritium concentrations in groundwater under about half of the disposal facility site greatly exceed MCLs, while the tritium concentrations in groundwater under the other half of the site do not exceed MCLs.)

  - This option would allow the unreasonable situation where if contamination was 99% of the MCL, only 1% of the MCL would be allowed. But if contamination was 101% of the MCL, an additional MCL would be allowed.

  - This option would discourage groundwater remediation under some (realistic) situations. Assume that a disposal facility is downgradient from a source of contamination so that the groundwater under the site exceeds drinking water MCLs for certain radionuclides. Under this situation, there would be no incentive to remediate the groundwater because the disposal facility operators would have 100% of the MCLs to work with. But if the groundwater was remediated, then there would be smaller -- but larger than zero -- radionuclide

concentrations in the groundwater. Hence the disposal facility operators would have **less** than 100% of the MCL to work with. In this case, groundwater remediation would penalize the efficient use of the disposal facility.

- Again, EPA is unclear about the application of the option to multiple radionuclides, and to the timing of contaminated plumes. For example, if contamination levels exceeded MCLs for one radionuclide, would all radionuclides be allowed an additional MCL, or just the one radionuclide? If the MCLs are currently exceeded for tritium (or another isotope) in groundwater beneath a disposal facility, but one expects that the contamination will be reduced to levels less than MCLs because of radioactive decay and system "flushing," how would the MCL limit be applied? Another realistic situation would be one where contamination in groundwater underneath a disposal facility does not currently exceed MCLs, but it is known that hundreds or thousands of years in the future, migration from an upgradient source might cause the MCLs to be exceeded under the facility. How would this situation be handled?

- The option would again drive LLW management and disposal facilities away from areas having contaminated groundwater and toward areas having uncontaminated groundwater.

We have several difficulties with EPA's justification for its proposed requirements in Subpart C:[14]

* EPA states that its principal justification for Subpart C is to assure that no future society need remove radionuclides from drinking water because of LLW management. But no such assurance can be provided. The Safe Drinking Water Act requires review of drinking water MCLs every three years and adaption of more restrictive standards when feasible. (See Attachment 6.)

* As a secondary justification, EPA indicates that it wishes to assure a minimal need for future generations to institute cleanup of closed disposal sites (e.g., EPA states on page 38 of the preproposal draft that "absent protection, the disposal system itelf could become subject to expensive

[14]Also refer to DOE's comments on EPA's proposed amended 40 CFR Part 191 (14 April 1993 letter from P.D. Grimm, DOE, to M.H. Shapiro, EPA). For example, see pages 30-32 and 53-56.

clean-up by future generations"). But again, no such assurance can be provided. "Cleanup" would not occur unless there was a determination that it was required under a statute such as CERCLA, which would only be invoked if there was a release to the environment in excess of a "federally permitted release."[15]

Releases to the environment from LLW disposal facilities in compliance with a license or authorization pursuant to the Atomic Energy Act constitute federally permitted releases. However,by linking groundwater protection standards to drinking water MCLs which are subject to possible reduction on a three-year review cycle, EPA fosters a situation whereby the allowable federally permitted release could also be reduced on a three-year review cycle. A disposal facility designed and constructed under the assumption of one federally permitted release limit, could be subject in the future to compliance with a smaller federally permitted release limit. Hence, the imposition of the standard, rather than the lack of it, could result in the need for "expensive clean-up by future generations."

* By linking groundwater protection requirements to drinking water MCLs, which are subject to reduction pursuant to legislated mandate, EPA ensures uncertainty in LLW disposal requirements. This will discourage development of new disposal capacity, and discourage efficient use of existing disposal capacity. (See Attachment 6.)

* By incorporating drinking water MCLs into requirements for waste disposal, EPA is using the MCLs in a manner that is inconsistent with their development, justification, and use. MCLs are to be applied to **tap water**, and have been imposed by EPA based on analyses that **only** considered the feasibility for removal of radiouclides from water, before consumption, at large municipal drinking water treatment systems. (See Attachment 6.)

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[15]Federally permitted releases, which are defined in Section 101(10) of CERCLA, are exempt from CERCLA and EPCRA emergency release notification requirements, and the liability provisions of CERCLA Section 107. A federally permitted release includes "(K) any release of source, special nuclear, or byproduct material, as those terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.], in compliance with a legally enforceable license, permit, regulation, or order issued pursuant to the Atomic Energy Act of 1954." Releases to the environment in compliance with DOE's annual 25-mrem (ede) all-pathways LLW disposal limit in DOE 5820.2A constitute a federally permitted release.

* EPA justifies the use of MCLs for the preproposal draft standard by claiming that it would be consistent with other EPA standards. But in fact, EPA applies MCLs in different ways depending upon the standard. There are significant differences in compliance methods, points of compliance, and other critical factors, which means that the claim of consistency across the different standards is illusory.

  For example, for disposal of hazardous waste, EPA specifies a disposal facility design and requires monitoring (using non-radiological MCLs, among other things, as compliance limits) to assure compliance. But for LLW management, EPA wants a demonstration that MCLs can be met at the (unspecified) point of compliance for potentially thousands of years. Clearly, the application of the MCLs in these two cases is so different as to represent different standards.

  As another example, the point of compliance for the application of the MCLs in 40 CFR Part 191 is outside the controlled area of the disposal facility as discussed previously. For the Part 193 standard, EPA has not specified a point of compliance, although EPA staff have indicated that they expect that it will be the same as that for Subpart B (see footnote 16).

* EPA argues that without the standard, future societies might be forced to spend large amounts of money decontaminating groundwater. (For example, on page 46 of the preproposal draft standard, EPA states that the costs of cleaning up groundwater may far exceed the likely costs of siting, designing, and operating the facility to meet an MCL limit. Also on page 46, EPA states that "aquifer restoration is usually required when releases to the ground water exceed drinking water standards.") But the argument is not compelling.

  First, the economic comparison is wrong. The proper comparison is the costs for waste disposal today versus the costs for future removal of radionuclides from drinking water, not the costs for removal of radionuclides from groundwater. Costs for future removal of radionuclides from drinking water should be far less than those required today for removal of radionuclides from groundwater.

  In any event, EPA's own analysis for its 1991 proposed amendments to existing radioactive MCLs (18 July 1991 FRN, 56 FR 33050) indicates that EPA expects that 35% of existing drinking water suppliers will be forced to remove naturally-occurring radionuclides from groundwater. Non-radioactive contaminants may also need removal. In this case, the need to remove additional radionuclides contributed hypothetically from a LLW disposal facility would seem

neither a complicated nor onerous supplement to treatment processes that would be already required by EPA.[16]

Second, the argument is speculative. No justification is presented to support an argument that the costs of cleaning up groundwater may far exceed the likely costs of siting, designing, and operating a disposal facility to meet an MCL limit.

Third, EPA takes the essential position that there is no limit to the real money that must be spent today to avoid the hypothetical need for future societies to spend money to remove radioactive materials from a very few drinking water plants. But in most if not all cases, the "need" to remove contamination from drinking water will occur many hundreds to thousands of years in the future. EPA therefore has not adequately assessed the risks and benefits of this position. At a workshop convened by the National Academy of Public Administration (NAPA) for the Department, a set of Proposed Intergenerational Equity Principles were developed. Among other things, the principles noted that near-term concrete concrete hazards have priority over long-term hypothetical hazards. These principles should be seriously considered by EPA when it develops the LLW standard. (See the Department's response to question four of EPA's specific questions for public comment.)

In addition, we note:

- Because Subpart C specifies neither the time of compliance nor the point of compliance, and cites radioactivity in the USDW itself rather than radioactivity in the water as it may be used, considerable questions are raised regarding how compliance is to be demonstrated.[17] Compliance analyses may result in disposal facility inventory limits that are significantly more restrictive than those determined by

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[16]At SRS, concentrations of naturally-occurring radionuclides in groundwater are large and occasionally exceed drinking water MCLs. Hence, future societies using the groundwater under the SRS site as a drinking water source may likely need to treat the water to remove radionuclides irrespective of the Saltstone and E-Area Vault disposal facilties.

[17]At a 19 April 1995 meeting, EPA staff informed DOE and NRC staff that EPA intended that the same point and time of compliance would be used for Subpart C as would be used for Subpart B. EPA indicated that it would consider modifying the standard to allow consideration of dilution by "uncontaminated" water as groundwater is assumed to be used.

several existing DOE and commercial performance assessments, no matter which MCL option is selected. (See point (h) of Attachment 3.)

- EPA must provide justification why it is necessary to impose Subpart C on all commercial away-from-generator processing or storage facilities, whatever they turn out to be, but not to all other commercial entities that generate LLW.

ATTACHMENT 1

Abbreviated Timeline of Development of, and Concerns With,

40 CFR 193

Circa 1980 - EPA begins rule development process (e.g., EPA begins to develop the PRESTO computer code which is used to assess regulatory alternatives).

8/31/83 - EPA issues an Advance Notice of Proposed Rulemaking for a low-level radioactive waste (LLW) standard.

Subsequently, EPA prepares a draft LLW standard which EPA makes available for review. Among other things, the draft standard proposes an annual 25-millirem (mrem) all-pathway requirement for protection of an individual from waste disposal, a 4-mrem annual limit for below regulatory concern (BRC) waste, and groundwater protection requirements. For the latter, EPA proposes a "zero-degradation" standard for Class I aquifers, plus an annual 4-mrem limit for Class II aquifers, which EPA derives based on consideration of maximum concentration limits (MCLs) for drinking water.

12/10/87 - Note, C. Welty, DOE, to J. Gruhlke, EPA, expressing considerable concern with the groundwater protection provisions in EPA's draft LLW standard. Among other things, DOE objected to the no-degradation requirement for Class I aquifers, as well as EPA's proposal to apply the MCLs as a LLW management limit without presenting a risk-based rationale for doing so, and in a manner inconsistent with the derivation and purpose of the MCLs. The point of compliance for groundwater protection required clarification.

11/17/88 - Letter, M. Knapp, NRC, to N. Miller, Office of Management and Budget (OMB), documenting major concerns with the draft LLW standard.

11/22/88 - Letter, J. Tseng, DOE, to N. Miller, OMB, elaborating about DOE's concerns with EPA's groundwater protection provisions in the draft LLW standard. DOE emphasized the problems with the no-degradation requirement for Class I aquifers, and the problems with EPA's proposal to apply the MCLs as a LLW management limit without presenting a risk-based rationale for doing so, and in a manner inconsistent with the derivation and purpose of the MCLs. A significant problem was EPA's requirement, when demonstrating compliance for a particular facility, to consider **all** sources of radioactivity, whether natural or man-made, and whether or not caused by the facility under consideration.

4/4/89 - Letter, J. Greeves, NRC, to A. Fraas, OMB, stating that

NRC and EPA were at impasse on most major points.

4/6/89 - EPA transmits its latest version of the draft standard (4/89 version) to OMB, for review before publication as a proposed rule. It resembles previous versions reviewed by DOE, although naturally-occurring radionuclides are removed from consideration in the groundwater protection requirements.

11/16/89 - Letter, J. Tseng, DOE, to A. Fraas, OMB, objecting to the draft standard, particularly the specific provisions of the groundwater protection requirements. DOE noted similar problems to those previously expressed to EPA and OMB, and noted that EPA had failed to specify a point of compliance for the groundwater standard. DOE observed that the standard would result in few benefits at very large costs.

1/5/90 - Letter, R. Bernero, NRC, to J. MacRae, OMB, recommending that EPA discontinue its plans to issue the LLW standard.

1/9/90 - Letter, J. MacRae, OMB, to W. Reilly, EPA, suspending OMB review of the draft standard until EPA resolves the major issues raised by NRC and DOE.

9/9/91 - Letter, R. Pelletier, DOE, to W. Gunter, EPA, transmitting a detailed critique of EPA's April 1989 draft standard. Totalling about 200 pages, the critique observed that (1) EPA's technical support (e.g., EPA's Background Information Document [BID] and draft (unpublished) Economic Impact Assessment [EIA]) was technically flawed and failed to demonstrate achievability of the standard, (2) the requirements in the draft standard could be implemented only at very large costs, with very little benefit, and could as likely increase overall risks to humans as decrease overall risks, (3) the draft standard, lacked, but needed, both a Regulatory Impact Analysis and a Regulatory Flexibility Analysis, (4) the no-degradation standard for Class I aquifers lacked justification and contradicted other EPA requirements and guidance, and (5) the draft requirements for naturally-occurring and accelerator produced material (NARM) lacked justification and would likely result in a new "orphan" class of waste.

12/2/94 - EPA distributes for review a preproposal draft standard, dated 30 November 1994. This draft standard consists of three subparts: (A) an annual 15-mrem all-pathway limit for above-ground LLW management, (B) an annual 15-mrem all-pathways limit for LLW disposal (protection of an individual), and (C) groundwater protection provisions. Compared with previous versions, this draft deletes separate requirements for NARM and BRC wastes, as well as the no-degradation requirement for Class I aquifers. (The draft deletes the previous groundwater classification scheme.) Otherwise, the draft standard retains the essential features of the April 1989 standard that had

previously been of concern, and in fact, restores the requirement to consider naturally-occurring radionuclides in the groundwater protection provisions. **All** sources of radioactivity must be included, whether natural or man-made, and whether or not caused by the LLW management facility under consideration. No BID or other supporting documentation is provided.

Winter and Spring, 1994-5 - States, Compacts, and industry groups review the preproposal draft standard and object strenuously to it. A major concern is that the standard raises regulatory uncertainties at a critical time in the development of new LLW disposal capacity.

1/31/95 - At a meeting of the Low-Level Waste Forum, a group comprised of LLW site development authorities and regulators, the participants state their opinion that 40 CFR Part 193 is unnecessary and would disrupt siting and licensing efforts for new disposal facilities.

2/21/95 - At a briefing of NRC's Advisory Committee on Nuclear Waste, NRC staff strongly criticizes the draft, citing the lack of need for the standard, the difficulty in demonstrating compliance with it, the impact on siting and licensing activities, and several other concerns.

3/8/9 - EPA responds to a Freedom of Information Act request by Dr. Carol Marcus, American College of Nuclear Physicians, to provide records pertaining to EPA's justification for the preproposal draft. The records suggest that EPA has made only minor changes to the analyses in the existing LLW BID. (EPA staff verbally confirmed this impression at a 28 March 1995 meeting with DOE's Performance Assessment Task Team.) EPA apparently still only considers radiological impacts from isolated LLW disposal facilities such as those that might be newly constructed by a State or Compact, and doesn't consider situations comparable to DOE sites where radioactive waste has been managed for decades. (It is not clear whether EPA considers radiological protections published in DOE LLW disposal facility performance assessments.) EPA still apparently does not consider the risks to workers and the public caused by implementing the standard. The BID analysis still appears to be less stringent than analyses that would be required as compliance demonstrations per the specific language of the standard.

4/19/95 - At a meeting between DOE and EPA staff, EPA staff provided additional comment about the intent of some of the requirements within the preproposal draft standard.

REFERENCES

BID U.S. Environmental Protection Agency, Low-Level and NARM Radioactive Wastes, Draft Environmental Impact Statement for

Proposed Rules, Volume 1: Background Information Document, EPA 520/1-87-012-1, Office of Radiation Programs, June 1988.

EIA U.S. Environmental Protection Agency, Draft Environmental Impact Statement for Proposed Rules, Vol. 2, Economic Impact Assessment, Low-Level and NARM Radioactive Wastes, EPA 520/1-87-012-2, Office of Radiation Programs, August 1988.

ATTACHMENT 2

Analysis of the 30 November 1994 Preproposal Draft of

40 CFR Part 193 with Respect to Executive Order 12866

This document analyzes EPA's 30 November 1994 preproposal draft of 40 CFR Part 193, Environmental Standards for the Management, Storage and Disposal of Low-Level Radioactive Waste (LLW), with respect to the requirements of Executive Order 12866, Regulatory Planning and Review. The objectives of this Executive Order are to reform and make more efficient the regulatory process. In its preproposal draft, EPA states that it has not prepared a Regulatory Impact Analysis pursuant to the Executive Order because its action does not represent a significant regulatory action. This position cannot be supported.

We perform this analysis in two parts: First, we address EPA's determination about whether the site represents a significant regulatory action. Second, we address the consistency of EPA's proposed action with Section 1, Statement of Regulatory Philosophy and Principles, of Executive Order 12866.

Significant Regulatory Action

Executive Order 12866 requires preparation of a Regulatory Impact Analysis if a regulation is a significant regulatory action. A significant regulatory action is a regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health and safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Contrary to EPA's assertion in its preproposal draft, EPA's LLW standard represents a significant regulatory action based at least on the costs that would be associated with the standard

(item (1)), and its inconsistency and interference with actions planned by DOE (item (2)). Regarding item (4), the standard is inconsistent with the principles set forth in the Executive Order.

Costs. Regarding DOE, it is difficult to determine a precise cost figure because costs for compliance will depend on decisions that have yet to be made about standards and priorities for environmental restoration, because costs will depend on projections about source terms from wastes that have already been disposed and for which precise data is lacking, because of the lack of clarity of the standard, and because of the size and complexity of the DOE complex.

Nonetheless, information is sufficient to indicate that the standard will be very expensive to implement. We note:

EPA has not provided any estimate of costs for implementing the preproposal draft standard, but it did estimate for the April 1989 draft standard (which similar in its essentials to the preproposal draft standard) that implementing the standard would cost roughly $2.5 billion over 20 years for disposal of roughly 4.7 million m^3 of LLW (2.9E+6 m^3 commercial; 1.8E+6 m^3 DOE). This implies an annual cost for implementing the standard of roughly $530 per m^3 of waste.

This cost was based on the unrealistic assumption that all current DOE disposal was by shallow land burial with no waste form requirements, while all current commercial disposal was by "Part 61" disposal wherein all Class B and C wastes were solidified. Then, assuming that the standard required an annual 4-mrem limit (which was similar to but not as strict as the actual proposed groundwater protection requirement), EPA calculated the costs associated with the assumption that rather than disposing of wastes by "existing" methods, the same wastes would be given further processing and disposed by engineered disposal methods as necessary to meet the limit. For humid sites, the assumption was that all waste would be solidified and disposed using engineering methods.

Disposal of 1.8 million m^3 of waste over 20 years implies the annual disposal of 90,000 m^3 of DOE LLW, which by EPA's calculations should cost DOE about $50 million per year. But actual waste volumes will be much larger. References [IDB1991] and [IDB1993] can be used to approximate DOE's operational LLW and mixed LLW volumes over the same period of time considered by EPA. These volumes total about 2,200,000 m^3 of LLW and about 300,000 m^3 of mixed LLW. For environmental restoration wastes, DOE's 1995 Baseline Environmental Management Report [DOE1995a] projects roughly 20 million m^3 of LLW and mixed LLW over 75 years. Combined, these estimates imply an average LLW and mixed LLW generation rate of about 400,000 m^3 per year. This implies

an annual additional cost to DOE exceeding $200 million.

But this estimate is likely to significantly underestimate actual costs. Much more will be involved than merely subjecting LLW to additional waste processing and using a different disposal facility design in some environmental settings. Whole sites might be closed, and waste would have to be stored for probably many years at additional costs until new disposal facilities could be sited, constructed, and approved. Meanwhile, the existing closed sites may be vulnerable to additional costs associated with application of more stringent cleanup criteria under the CERCLA process than those applied today.

Many DOE management operations may have difficulty meeting the standard. This problem primarily arises from the location of DOE's LLW disposal facilities in areas where the groundwater is already contaminated, or may become contaminated, from other sources. To provide a few examples:[1]

a) The implications of the standard for LLW management at the Hanford site are difficult to calculate. DOE is concentrating disposal operations in the 200-East and 200-West Areas, and plans to construct the Environmental Restoration Disposal Facility downgradient from the 200-West area for waste removed from the 100- and other areas as part of DOE's environmental restoration program. Another disposal facility is planned east of the 200-East area.

The 200-Areas have been used for management and disposal of radioactive waste for about 50 years. Besides burial of solid radioactive waste (including waste that would now be considered transuranic waste), DOE has discharged large quantities of liquids into cribs, wells, ponds, ditches, etc. In addition, DOE is storing large quantities of liquid high-level and other wastes in tanks. Waste management activities have resulted in contaminated groundwater as well as large quantities of contaminated soil. An appreciation of the extent of groundwater contamination at Hanford can be gained from examination of the plume maps in [HAN1993].

One difficulty that the standard presents is that to demonstrate compliance with Subpart C for a particular LLW management facility, DOE must consider the contribution of

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[1]Although this section identifies specific examples where DOE disposal facilities may have problems in demonstrating compliance with the draft standard, one must not construe that these disposal facilities (which include state-of-the-art disposal facilities) represent a current or future risk to the health and well-being of the public. The Department maintains and will continue to maintain these disposal facilities in a manner that is protective of the public and that ensures that current and future doses to the public will be low.

all current and potential future sources of radioactive contamination in groundwater under that facility. But the radioactive source terms that must be considered will depend on environmental restoration and waste management decisions that have not yet been made. One cannot reliably estimate, for example, the contribution from any residual activity left in the HLW tanks, after the bulk of the liquid waste has been removed, until the removal and decommissioning process is completed. Neither can one reliably estimate the future contribution of activity into groundwater from contaminated soils until one makes decisions about residual contamination levels and future land uses.

Another consideration is the U.S. Ecology commercial disposal facility sited between DOE's 200-East and 200-West disposal facilities. This disposal facility has been licensed to operate since 1965 and is sited on land that was leased by the Federal government to the State of Washington until the year 2063. The disposal license has been issued by the State of Washington, an Agreement State.

By EPA's standard DOE must consider the possible dose contribution from the U.S Ecology disposal facility when analyzing the performance of DOE disposal facilities. However, this task would likely be difficult and the analysis uncertain, because the early records of waste disposal in the disposal facility are probably unreliable, and because DOE has no direct control over current and future radionuclide inventories annually disposed at the U.S. Ecology facility.

b) At the Savannah River Site (SRS), EPA has constructed the Defense Waste Processing Facility (DWPF) which will treat and vitrify liquid high-level waste. The DWPF was constructed at a cost exceeding a billion dollars. To dispose of the large quantities of very low activity liquids generated as part of the high-level waste pre-treatment and vitrification program at Savannah River Site, DOE has constructed the Saltstone disposal facility where DOE is grouting the liquids within large concrete bunkers. The saltstone grout formulation has been developed based on many years of field as well as laboratory testing. This disposal facility complies with South Carolina State groundwater protection criteria and operates under a permit issued by the State. A performance assessment has been prepared for this disposal facility which has been approved by DOE's peer review panel and by DOE [WSRC1992].

But EPA's Subpart C may preclude operation of the Saltstone disposal facility, because of high and variable background concentrations of naturally-occurring radionuclides in the groundwater underneath the disposal facility. (For radium,

samples range in concentrations from below detectable limits to twice existing drinking water limits.) Merely to replace the Saltstone disposal facility at SRS could exceed $100 million, assuming that a suitable disposal site could be found at SRS [JC1995]. Additional costs would result from disruptions to the high-level waste treatment and vitrification program. But because SRS appears to be in an area having high background levels of naturally-occurring radionuclides in groundwater, it may be difficult to relocate the disposal facility at SRS. This would require development, funding, and construction of facilities to process and solidify the liquid waste, and transport the waste to a different site. Worker and public doses and risks would increase.

c) Also at SRS, DOE has constructed a highly-engineered, state-of-the-art, facility for disposal of contaminated trash and other LLW (E-Area Vaults). This disposal facility was sited downgradient of the existing shallow land disposal facility based on the conclusions of an Environmental Impact Statement [DOE1987] and on a record of decision published in the Federal Register on 9 March 1988 (53FR7557). DOE's overall strategy of waste management and disposal was supported by EPA in their comments on the EIS. DOE has also prepared a performance assessment for this disposal facility which has been approved by DOE's peer review panel [WSRC1994]. DOE has coordinated the construction of this disposal facility with the State of South Carolina.

But EPA's Subpart C may preclude operation of this disposal facility, because of migration of radionuclides from the existing burial facility, and because of high and variable concentrations of naturally-occurring radionuclides in groundwater. In this event, long-term storage of LLW would be required until a suitable alternative is chosen. Costs for replacement of the E-Area Vaults at SRS could exceed $150 million, not including costs for LLW storage [JC1995]. As discussed above, transportation across the country to a different disposal facility might be needed, at additional cost and doses and risks to workers and the public.

d) The LLW disposal facility at the Radioactive Waste Management Complex (RWMC) at Idaho National Engineering Laboratory has operated since 1952. Current disposal operations are surrounded by past disposal trenches and pits that may contain hazardous materials pursuant to RCRA. Hence, these old trenches and pits are being assessed under CERCLA. Records for early disposals are often uncertain, although it is known the older pits and trenches contain transuranic waste. Further operation of the RWMC might be precluded because of difficulties in arriving at a defensible waste inventory at the older pits and trenches

within reasonable time. Pre-operational costs for establishing a new, highly engineered, disposal facility in an uncontaminated area at the Laboratory are projected at about $175 million [INEL1993].

e) If the standard requires replacement of the LLW disposal facility at G-Area at Los Alamos National Laboratory, preoperational costs for establishing a new shallow land disposal facility at the Laboratory could exceed $60 million [MP1995].

f) The standard would apply to much of the waste from DOE's Formerly Utilized Sites Remedial Action Program (FUSRAP). Imposition of the standard would for all practical purposes preclude any onsite remedy at these sites and require offsite disposal for most of the remedial action waste. The cost difference for this choice, for FUSRAP alone, is in excess of $300 million. Offsite disposal would be necessary because of radon emanation from the waste. It would be impossible to demonstrate compliance at any reasonable cost, because background levels of radon vary by more than 15 mrem/yr.

Additional costs would undoubtedly result from CERCLA actions taken at disposal facilities that were forced to close because of the standard. The standard would represent an applicable or appropriate requirement for disposal of waste generated from these CERCLA actions, which could include removals. Overall, annual additional costs to DOE for implementing the standard may be in the range of billions of dollars.

Costs are likely also to be high for commercial entities. Compliance with the standard would probably be very difficult for the existing commercial disposal facilities, particularly the U.S. Ecology disposal facility within DOE's Hanford Reservation. Storage and other costs associated with commercial entities are addressed in Attachment 3. These costs are likely to exceed $100 million per year.

Inconsistency and interference with DOE actions. The EPA action is inconsistent with existing DOE programs, including those involving regulatory agreements to address areas of environmental contamination, and will cause serious interference with these programs. A few examples follow:

a) At several DOE sites (e.g., Hanford, INEL, SRS, ORNL), DOE has entered into agreements with EPA and the States to perform remedial action at areas of radioactive and chemical contamination. Typically, LLW disposal is conducted within areas undergoing remedial action (or over contaminated groundwater), sometimes very near cleanup efforts. By either option in Subpart C, the standard would likely

disrupt these remedial action programs. It would force DOE to shift LLW disposal to uncontaminated areas.

b) Disposal of operational LLW at several DOE sites might be precluded until new disposal facilities can be sited, funded, and operated. Waste would have to be stored in the interim, at greater risks to workers and at greater costs.

c) At the Savannah River Site, if operation of the Saltstone disposal facility is precluded at the standard, then operation of the Defense Waste Processing Facility might be significantly constrained until a suitable alternative for treatment and disposal of the waste liquids can be devised, approved, funded, and implemented.

d) As noted above, imposition of the standard would for all practical purposes obviate any onsite remedy at FUSRAP sites and require offsite disposal for most of the remedial action wastes generated at these sites. As a result, risks to workers and to the public from management and transportation of waste to disposal facilities would be larger than if the standard was not promulgated.

Section 1, Statement of Regulatory Philosophy and Principles

This section of Executive Order 12866 is divided into two subsections: (a) Regulatory Philosophy, and (b) the Principles of Regulation.

Section 1(a), Regulatory Philosophy. This requirement is stated as follows:

> Federal Agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

EPA is inconsistent with this regulatory philosophy. First, 40 CFR Part 193 is not required by law, and EPA has not demonstrated a compelling need for the standard. On the contrary, the standard appears to be largely duplicative of existing NRC and DOE requirements. It is also frequently inconsistent with the regulations of EPA and other Federal agencies. Second, it is not apparent that EPA has evaluated the costs and benefits of available regulatory alternatives, including the alternative of adopting a less-prescriptive generally-applicable standard, and the alternative of not regulating -- i.e., not issuing the standard. Neither has EPA demonstrated that it has selected a regulatory approach that would maximize net benefits. On the contrary, at significant costs to DOE and to commercial entities, the approach taken by EPA would:

1) Raise regulatory uncertainties that will continue beyond the promulgation of the standard;

2) Increase the difficulty of siting, designing, licensing, and operating new LLW disposal facilities;[2]

3) Result in increased storage of LLW, at increased risks to workers and the public, as well as increased costs;

4) Promote the inefficient and expensive development of large numbers of small LLW disposal facilities;

5) Discourage siting of LLW management and disposal facilities in areas having groundwater that was already contaminated, thereby promoting siting of these facilities in pristine areas having minimum contamination, and probably putting more groundwater at risk than if EPA did not issue its current standard;

6) Under one option identified by EPA for groundwater protection, discourage restoration of some existing areas of groundwater contamination;

7) Severely disrupt FUSRAP and other environmental restoration programs; and

8) Increase the difficulty of disposing of LLW in humid environments, which would promote costly transportation of LLW across the country to arid environments.

Regarding the last point, besides the issue of environmental

[2]This is the stated opinion of State regulatory agencies, Compact commissions and developers, LLW disposal facility operators, and waste generators. See [NEI1995a], [IE1995], [SW1995], [SE1995], [TN1995], [SC1995], [CA1995], [MW1995], [CNSI1995], [NEI1995b], [DOA1995], [ACURI95], [USE1995], [AZ1994], and [AZ1995].

equity, this problem will increase short-term risks to workers and the public because more LLW will be transported for greater distances than in the absense of EPA's standard.

Although EPA has not yet provided any assessment of the risks that would be associated with implementation of the current standard, EPA analyses for an earlier (April 1989) version of the standard projected a gross savings of from three to thirteen health effects over 10,000 years. In its previous assessment, EPA did not consider and balance any putative reductions in long-term risks resulting from implementing the standard with the increases in short-term risks to workers and the public that would also result from implementing the standard. In DOE's 9 September 1991 letter to EPA, DOE observed that it appeared that implementing the April 1989 draft standard might cause about as many risks as it would save.

Section 1(b), The Principles of Regulation. Section 1(b) states that to ensure that Federal agencies' regulatory programs are consistent with the required regulatory philosophy expressed in Section 1(a), agencies should adhere to a set of 12 principles. These principles are presented below, along with an analysis of the inconsistencies between these principles and EPA's preproposal draft standard:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

EPA has not provided a compelling explanation that there are problems sufficient to warrant its LLW standard. Although EPA has cited some minor differences among DOE and NRC requirements, and has questioned some of the particular features of these requirements, EPA has not provided a quantified assessment about whether the implementation of these existing requirements, nor existing and planned waste management actions by DOE or commercial entities, will result in any problems. The information presented in EPA's preproposal draft, in fact, suggests a lack of problems warranting an EPA action.

For Subpart A, EPA states that there is a need for the subpart largely based on nuances of the language of 10 CFR Parts 61 and 20, which apply to commercial activities, but presents no operational data to demonstrate that the regulatory language has resulted in actual public doses sufficient to be of concern. On the contrary, EPA would appear to believe that neither Subpart A nor B is really necessary for commercial entities based on its own 1994 letter from Margo Oge to Robert Bernero of NRC.

Furthermore, EPA has recently undertaken other regulatory actions

that will apply to the facilities covered by Subpart A -- e.g., EPA has extended its NESHAPS regulations for airborne emissions to non-fuel cycle licensees, and has proposed Federal Radiation Protection Guidance. EPA believes that these actions will result in reduced doses and risks to the public. Hence, what problem exists to warrant Subpart A?

Regarding DOE, EPA cites certain language of DOE 5820.2A as evidence of a need for EPA action, but fails to demonstrate that significant public risks actually exist. But in fact, DOE annually publishes site environmental reports, and submits NESHAPS compliance reports to EPA, that refute EPA's suggestion of significant public risks.

EPA also fails to reference 10 CFR Part 834 which will be promulgated in 1995. This regulation will set forth an annual limit to members of the public of 25 mrem from **all** radioactive waste (not just LLW) at a DOE site (except for radon which is considered separately). In addition, doses and releases in effluents must be reduced to levels as low as reasonably achievable (ALARA). DOE activities are already subject to environmental protection requirements in DOE 5400.5 and other orders, as well as EPA's NESHAPS requirements for the air pathway. Again, what problem exists to warrant Subpart A?

Regarding Subpart B, EPA's states that there is essentially no difference among the dose limits that EPA proposes and those dose limits that already exist in NRC and DOE regulations and directives. Hence, there is no problem to overcome.

Regarding Subpart C, EPA has presented no assessment of the risks that existing requirements, as well as the designs and constructions of existing and planned disposal facilities, will place on groundwater. All EPA has done is to state its policy for groundwater protection.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

It is not apparent that EPA is consistent with this principle. One alternative that could be considered might be to modify 40 CFR Part 190 to include radioactive waste management, providing a generally-applicable multi-media dose limit using more modern dose methodology (e.g., 30-40 mrem/yr) for all activities associated with the nuclear fuel cycle.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user

fees or market permits, or providing information upon which choices can be made by the public.

EPA has not presented a compelling argument that there is a need for the standard. Nor has EPA identified and assessed available alternatives to direct regulation, such as not issuing a standard. Another alternative, although one that would still constitute direct regulation, would be a multi-media standard of general applicability that did not set forth separate limits for particular media such as air or water.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances within its jurisdiction.

EPA has not demonstrated that a significant risk exists from LLW management and disposal under existing NRC, EPA, and DOE regulations, guidance, and directives. On the contrary, the only evidence provided by EPA indicates that the risks presented by LLW management and disposal are insufficient to warrant a high regulatory priority.

Regarding risks associated with commercial processing or storage of LLW, EPA has not provided any evidence that current or potential future doses to the public exceed current regulatory requirements, or for that matter, has not provided **any** estimate of existing public risks. EPA has already proposed general Federal Radiation Protection Guidance which would be applicable to NRC and Agreement State licensees, and has extended its NESHAPS program under 40 CFR Part 61 to all NRC and Agreement State licensees other than nuclear power reactors. These actions will continue to keep radiation risks low across all NRC and Agreement State licensees. Hence, the proposed standard will provide few if any health benefits.

DOE is already subject to the provisions of the Clean Air Act, including NESHAPS requirements in 40 CFR Part 61, and will in 1995 promulgate a regulation, 10 CFR Part 834, that limits annual doses to members of the public from management of **all** radioactive waste (not just LLW) to 25 mrem (except for radon isotopes, which are appropriately controlled via imposition of separate standards). This regulation also requires the further reduction of doses and releases of radioactive materials to the environment to levels as low as reasonably achievable. Hence, it is not apparent that sufficient risks exist from above-ground management and storage of LLW at DOE sites to warrant the proposed standard.

Regarding risks after disposal of LLW, EPA has indicated that disposal of LLW at nearly any site environment and using nearly

any disposal technology[3] will result in risks that generally do not exceed 10 health effects over 10,000 years. Past EPA work ([BID], [EIA]) estimated that in the absence of the standard, total population risks from 20 years of disposal of all DOE and commercial LLW would be roughly twenty times smaller than those risks that the Agency considers to be acceptable for a high-level waste repository. (See Attachment 4.) Hence, there appears to be no need for the standard on the basis of risk.

Finally, EPA's own assessment in its 1987 "Unfinished Business" report assigns a low ranking to the relative risks posed by radionuclides and radiation other than that from indoor radon [EPA1987]. Given this low ranking, we don't understand the apparently high level of EPA regulatory priority for this standard.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulation in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

EPA's proposed action is inconsistent with this principle. EPA has not demonstrated that the standard will be cost-effective. On the contrary, the regulatory uncertainties that EPA has introduced will increase the difficulty of managing and disposing of LLW in a cost-effective manner. The proposed standard for groundwater protection could easily foster inefficient construction of large numbers of disposal facilities containing restricted inventories of radionuclides. By either option in Subpart C, the standard will reduce flexibilty in environmental restoration efforts. (The second groundwater protection option considered by EPA could actually discourage environmental restoration efforts at some sites.) The standard will drive disposal facilities away from areas having groundwater that has high background levels of radionuclides (man-made and natural) and toward areas having low background levels of radionuclides. It will drive LLW disposal facilities away from sites located in humid environments and toward sites located in arid environments. This would require transportation of additional LLW across the country, at increased risks to workers and the public. It would be inconsistent with the principle of equity as expressed in this Executive Order and as intended by Congress for LLW disposal in the Low-Level Radiactive Waste Policy Act, as amended.

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[3]Some disposal options considered in the 1988 BID [BID], including the worst-performing options, could not actually be licensed to operate in the manner assumed for the BID analysis.

(6) Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

EPA has provided no information about the costs of implementing the standard, which are likely to be very large. Nor has EPA presented any numerical assessment about any net benefits that would result. (By net benefits we mean the results of an analysis that would balance the possible risks that might be avoided by implementing the standard with those risks that might be caused by implementing the standard, such as doses to workers and risks to the public resulting from the transportation of LLW). Based on EPA assessments for past versions of the standard, we expect that net benefits from implementing the standard will be minimal. (See previous discussion.)

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, economic, and other information concerning the need for, and consequences of, the intended regulation.

EPA has presented no scientific, economic, or other information about either the need for the standard or its economic and health consequences. EPA makes several references to an updated BID and an Economic Impact Assessment which are not publicly available. Our review of the existing BID [BID] noted several technical difficulties (see DOE's 9 September 1991 comments).

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

It is not apparent that EPA has considered alternative forms of regulation. One alternative form of regulation would be a standard that specified a generally-applicable dose limit applying to all media, rather than EPA's current approach of establishing standards applicable to specific media.

Another concern exists with the way that EPA sets forth standards in Subparts A and B that require consideration of "all-pathways" of human exposure, and then provides a detailed definition of "all pathways." The implication for Subpart A, and more specifically for Subpart B, is that each and every one of all subpathways must be quantified no matter how insignificant. This approach would likely be wasteful of resources and would not embrace a performance-objective approach consistent with this Regulatory Principle.

(9) Wherever feasible, agencies shall seek views of appropriate

> State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

EPA has sought input from state and local groups. This input suggests that EPA has not harmonized its proposed regulatory action with the functions of important governmental entities.

Some of the most important governmental entities whose functions and opinions need to be considered include State Compacts, whose function is to site and develop new LLW disposal capacity. These State Compacts are highly disturbed by EPA's proposed action, and believe that EPA's proposed action will be detrimental to their function.

For example, during the 31 January 1995 meeting of the Low-Level Waste Forum, Compact and state officials informed EPA that the proposed standard was unnecessary and would disrupt siting and licensing efforts for disposal facilities [NEI1995a]. Similar views were expressed at a 22-23 February EPA Planning Forum [IE1995]. States and Compacts have also expressed this view to EPA in writing, for example by letter from the Southwestern Low-Level Radioactive Waste Commission [SW1995], the Southeast Compact Commission [SE1995], the Midwest Interstate Low-Level Radioactive Waste Commission [MW1995], the State of Tennessee [TN1995], the State of California [CA1995], the State of South Carolina [SC1995], and the State of Arizona ([AZ1994], [AZ1995]).

In addition, EPA's standard could have a significant effect on compliance agreements formulated among DOE, State governments and regulatory agencies, and EPA. At many DOE sites, these agreements involve remediation of contaminated grounds and waters, and disposal of LLW in or close by these contaminated areas. This practice is cost-effective: it minimizes the amount of land committed to waste disposal, and minimizes the amount of groundwater that can be affected by waste disposal. It is of national interest to continue this practice. However, by either option in Subpart C, this practice may be precluded.

> **(10)** Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

EPA is inconsistent with this principle. First, the preproposal draft is duplicative of EPA's NESHAPS regulations. EPA's proposed Subpart A covers all pathways, including air pathways, and thus duplicates (in part) EPA's NESHAPS requirements under 40 CFR Part 61. It is duplicative of NRC's existing 10 CFR Parts 61 and 20, as well as equivalent State regulations. It is duplicative of DOE requirements under its directives, DOE 5820.2A and 5400.5, as well as DOE's regulation 10 CFR Part 834, which will be promulgated in 1995. It also may be noted that both 10 CFR Parts 20 and 834 would fall under the umbrella of EPA's proposed Federal Radiation Guidance.

EPA's standard is furthermore inconsistent with other Federal regulations. First, EPA proposes to define LLW in a matter considerably different from that in DOE directives and NRC regulations. These existing definitions were derived from the definition of LLW in the Low-level Radioactive Waste Policy Act of 1980. In addition, EPA proposes to establish a 15-mrem limit under Subpart A, including the direct radiation pathway, while castigating NRC from omitting the direct radiation pathway in 10 CFR 61.41. However, NRC consciously excluded the direct radiation pathway from Section 61.41 to avoid the potential for conflict with Department of Transportation (DOT) regulations. But EPA has failed to address this conflict with DOT regulations.

EPA's 15-mrem limit in Subparts A and B is inconsistent with its own regulations -- 40 CFR Parts 61 and 192 -- which appropriately set forth separate requirements for radon isotopes. The 15-mrem limit is also inconsistent with DOE's pending 10 CFR Part 834 which considers radon isotopes separately from other isotopes.

One of the most glaring inconsistencies is with EPA's regulations for hazardous waste disposal. For groundwater protection in Subpart C of the preproposal draft, EPA applies drinking water MCLs in a radically different way than it does for hazardous waste. For disposal of hazardous waste, EPA specifies a disposal facility design and requires monitoring (using MCLs, among other things, as compliance limits) as a demonstration of compliance. But for LLW management, EPA wants a demonstration that MCLs can be met at an unspecified point of compliance for potentially several thousands of years. The application of the MCLs is so different as to represent different standards.

Consider mixed low-level radioactive waste. Consider a situation where a hazardous constitutent under RCRA is also radioactive -- for example, consider a stable, hazardous hyrdocarbon where one or more of the carbon atoms is C-14. EPA assumes perpetual containment for the hazardous portion of mixed waste but not for the radioactive portion of mixed waste. Through this lack of consistency EPA has taken the regulatory position that matter can exist in two simultaneous places.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of different sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

EPA's preproposal draft standard is inconsistent with this principle. As noted elsewhere, the standard will impose significantly increased costs and burdens on commercial users of radioactive materials, including small entities (see Attachment 3),[4] as well as DOE generators.

Among the costs will be those associated with cumulative regulations. Consider "away-from-generator processing and storage facilities," for which EPA proposes to impose additional requirements in Subparts A and C. Many of the licensees to which the requirements would be applicable will conduct many activities, other than LLW management, that involve radioactive material. Nonetheless, EPA would require a separate determination of compliance just for LLW management. Licensees will need to prepare submissions for review and approval by regulatory agencies. The costs and burdens associated with demonstrating compliance with this standard will be added to those costs and burdens that result from existing regulatory requirements, including those costs associated with EPA's imposition of NESHAPS requirements on NRC and Agreement State licensees other than nuclear power plants.

Similar costs and burdens may apply to DOE away-from-generator treatment and storage facilities, whatever these facilities turn out to be. To the extent that Subpart A is applicable to DOE, DOE facilities would have to make a separate determination of compliance with Subpart A. These separate compliance demonstrations would be largely duplicative of existing DOE requirements and would be wasteful.[5]

(12) Each agency shall draft its regulations to be simple and

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[4]If the standard results in the closure of the U.S. Ecology disposal facility in the center of the Hanford Reservation, roughly 240 commercial entities will lose LLW disposal capacity. Of these entities, about half are hospitals, schools and universities, and research organizations. A dozen are brokers, companies that provide LLW handling service to (typically) very small LLW generators. The customers include EPA as well as municipal water treatment districts, which must dispose of NARM waste removed from drinking water per EPA regulation [WASH1995].

[5]At a 19 April 1995 meeting, EPA staff informed DOE and NRC staff that they intended that Subpart A would not apply to DOE away-from-generator processing and storage facilities [DOE1995b].

> easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

EPA is inconsistent with this principle. EPA has fostered regulatory uncertainty merely by initiating the rulemaking process. This uncertainty will not end following the promulgation of the rule. Such uncertainty invites litigation. Examples are provided below.

For Subpart A, EPA has defined an away-from-generator processing and storage facility in such a manner that almost any building different from the one where waste is actually generated could be considered an away-from-generator storage facility. Thus, Subpart A could potentially apply to hundreds of NRC and State licensees and DOE facilities. EPA has not clarified its applicability to brokers, waste transportation companies, sealed source and device manufacturers, hospitals and research laboratories, and other licensees and persons who possess and use radioactive materials.

In addition, EPA fails to indicate what might constitute a demonstration of compliance for Subpart A, although by providing an extensive list of pathways to be considered EPA implies that each pathway must be quantified, no matter how trivial. Of significant concern is the fact that EPA's proposed 15-mrem/year standard represents a dose limit that is smaller than fluctuations in natural background radiation. How would an away-from-generator processing or storage facility demonstrate that it meets EPA's criteria given this background variation? How would such a facility demonstrate that it meets this criteria considering the significantly larger hourly dose rates allowed by DOT for transportation of radioactive material? How would such a facility consider possible doses from disposal of radioactive waste into the sanitary sewer? What constitutes a demonstration of compliance with the groundwater protection provisions?

For Subpart A and especially Subpart B, EPA is unclear about the assumptions to be made about human actions and physiology, such as the use of standard dose conversion factors. This is significant because one would be required (at least in Subpart B) to perform analysis to project hypothetical doses to hypothetical future members of the public. Nobody today can predict the age distributions or the physiologies of these hypothetical individuals, nor predict their consumption of specific foods, including water, nor predict with certainty any activities that might lead to exposures to radionuclides. The only workable approach would be to make reasonable assumptions based on typical current individuals and activities. But without statements to this effect incorporated into the standard, EPA fosters confusion and invites litigation.

For Subpart C, EPA has linked its groundwater protection criteria to drinking water MCLs, with the stated goal of ensuring that no drinking water facility will ever have to remove radionuclides from drinking water because of LLW management and disposal. But under the Safe Drinking Water Act, drinking water requirements must become more restrictive when feasible (see Attachment 6). When this happens, EPA will be under great pressure to meet its stated goal by imposing the new MCLs as design requirements. This promotes great uncertainty because no one will know if today's design will be adequate for tomorrow's MCLs.

This problem would exist no matter which option for groundwater protection is chosen by EPA. By either option presented in the preproposal draft, EPA makes the essential assumption that existing concentrations of radionuclides within groundwater underneath a LLW disposal facility are constant. But this is not the case. Measured concentrations of naturally occurring radionuclides can vary significantly with time, location, and depth under a disposal facility. Concentrations of man-made radionuclides in groundwater downgradient of a source such as an injection well or a soil column will vary depending on time, depth, and distance from the source.

Also, very importantly, EPA provides no information regarding how one demonstrates compliance with Subpart C. EPA specifies neither a time nor a point of compliance (although at a 19 April meeting, EPA staff informed DOE and NRC staff that the intent is to impose the same time and point of compliance as for Subpart B [DOE1995b]). Subpart C is worded in terms of radionuclide levels existing in groundwater as opposed to concentrations in water as it is withdrawn from the ground and used. This interpretation would require compliance analyses that are more restrictive than those performed in many performance assessments for existing and planned disposal facilities.

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ATTACHMENT 3

Analysis of Impacts of the LLW Standard on Commercial Entities

EPA certifies that the standard will not have a significant impact on a substantial number of small entities. But the the standard will probably be very costly to commercial entities, including small entities. In accordance with the Regulatory Flexiblity Act, EPA must consider the impacts of the standard on commercial entities and examine alternatives that will reduce these impacts on small entities. We note:

a) By initiating the standard development process, EPA has caused considerable regulatory uncertainty about future requirements for LLW disposal. This uncertainty will hinder commercial programs to dispose of waste and to develop new disposal capacity pursuant to the Low-Level Radioactive Waste Policy Act, as amended.[1] Compacts will be compelled to slow their activities until the standard is promulgated. This will result in the need for additional LLW storage for longer time periods, which increases costs and radiation doses to waste generators, which include small entities.

To illustrate the magnitude of the storage costs, we use the price that one commercial broker, Thomas Gray, is charging for LLW storage: 30 cents per cubic foot of waste per day for contact-handled LLW (the charge includes neither disposal nor transportation but only storage).[2] For only a **single** prospective disposal facility -- the U.S. Ecology facility in Ward Valley, California -- storage of 100,000 ft^3 of LLW (annual projected receipts for the disposal facility) by waste generators would cost nearly $11 million for the **first** year of storage (not considering extra costs for wastes requiring shielding or other special storage provisions). Transportation to and from the storage facility would cost extra, as would waste disposal when it eventually occurs.

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[1]This is the opinion of State regulatory agencies, Compact commissions and developers, LLW disposal facility operators, and waste generators.

[2]Personal communication to G. Roles, DOE, from J. Shaffner, U.S. Ecology, on March 29, 1995. The assumption of 30 cents per ft^3 per day will probably overestimate storage expenses for some LLW, and underestimate storage expenses for other LLW: Some licensees (e.g., utilities) could store LLW at their own facilities for a reasonable length of time. But many others will have no room nor licensed authorization to do so and would be compelled to seek offsite storage services. Some licensees could store contact-handled LLW at less expense (on a cubic foot basis) than others, because of economy of scale. But these savings would be offset by the larger storage costs that would be expected for LLW requiring shielding or other special handling, and by the addditional expenses faced by many waste generators who lack storage capacity and must further reduce waste volumes.

And storage costs will increase each year, because each year more waste will be generated that will require storage. So storage of LLW for two years at an annual generation rate of 100,000 ft^3 amounts to $11 million in the first year, but $22 million in the second year, averaging $16.5 million over the two years.

How long would LLW storage last? If it requires two years for EPA to complete the standard, and up to three years for a regulatory agency to adopt the requirement, review a revised siting or license application, and issue (or reissue) a license, then the EPA standard could cause a delay up to a five years. For the California disposal facility, a five-year delay would amount to annual storage costs averaging $33 million, not including transportation and disposal costs.

For the Southeast Compact, we assume that the volume of waste delivered to the projected new disposal facility in North Carolina would be similar to that being disposed in the Chem-Nuclear Systems, Inc. disposal facility near Barnwell, SC, which is scheduled to close later in 1995. (Barnwell accepted about 700,000 ft^3 of LLW in 1994). For a year of delay, the storage cost to Southeast Compact members, assuming 500,000 ft^3 of waste,[3] would be roughly $55 million. It would cost roughly $110 million for two years of delay. (This estimate does not include transportation costs nor eventual costs for disposal.)

In addition, when LLW disposal capacity **is** available, the delays will result in larger disposal costs. For example, preoperational costs for the proposed U.S. Ecology disposal facility in California are largely financed through debt. The longer the delay, the larger the interest costs that would be passed to the customer. If the EPA standard causes a five year delay in opening the disposal facility, and it costs $10 million per year to maintain the license application, then a five-year delay translates to $50 million, which becomes about $100 million when one considers the costs of financing the debt.[4] These costs would be passed on to customers, which will include small entities, at a rate of about $5 million per year over 20 years.

b) Regulatory uncertainties will not end upon promulgation of the standard, even discounting its lack of clarity:

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[3]Current estimated annual volume for Barnwell site. Personal communication from W. House, CNSI, to G. Roles, DOE, 3 April 1995.

[4]Personal communication to G. Roles, DOE, from J. Shaffner, U.S. Ecology, on March 29, 1995.

First, EPA proposes to link its groundwater protection standard to MCLs that are subject to review and possible change to more restrictive levels every three years. When change occurs, there will be great pressure for EPA to make corresponding changes in the groundwater protection criteria in Subpart C. Second, EPA has suggested (e.g., statement of L. Weinstock, EPA, at a 16 November 1994 NRC meeting on LLW performance assessment) that EPA plans to issue followup guidance on compliance with the standard. If this is the case, then there is a strong possibility that the guidance, when issued, will differ from current interpretations of the standard, and because of this, result in uncertainties, delays, and additional expense.[5] Third, EPA has stated that in the future, it may propose standards for protection of an inadvertent intruder. This suggestion raises considerable uncertainties about disposal facility design, construction, and operation, and waste acceptance criteria.
These uncertainties cannot help but hinder development of new disposal capacity, resulting in larger costs to waste generators as discussed above.

c) The EPA standard sets forth different federal requirements than those in effect today. If a commercial disposal facility cannot demonstrate that it can meet the new requirements, then it may be forced to cease operations. Disposal facility customers will have no disposal capacity and will be compelled to store waste, which will prove to be difficult and costly to many waste generators, including small entities.

For example, although disposal volumes are variable, we understand that the commercial disposal facility operated by U.S. Ecology on DOE's Hanford Reservation annually accepts about 140,000 ft^3 of waste.[6] A 30 cents per cubic foot per day charge for storage translates to a storage cost, for customers of the U.S. Ecology site, of $15 million in the first year of storage, should the standard result in the closure of the disposal facility. If only five years was required to select and license a new disposal facility for the Compact, storage costs would average $45 million per year. This estimate does not include transportation costs or costs for eventual disposal.

d) Some existing disposal facilities may become Superfund

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[5]But at a 19 April 1995 meeting, EPA staff informed DOE and NRC staff that no such followup guidance is intended.

[6]The U.S. Ecology disposal facility is licensed to operate by the State of Washington, an Agreement State. The disposal facility is sited on land that was leased by the Federal Government to the State in 1964. The lease expires in 2063.

sites if they could not demonstrate compliance with EPA's LLW standard. These disposal facilties would become Superfund sites **not** because they are in violation of **current** federally-permitted release requirements pursuant to CERCLA, but **only** because EPA has changed the definition of a federally-permitted release. Costs for the Superfund action would be passed on to potentially responsible parties, which would consist of all former disposal facility customers, including small entities. EPA is also a customer.

e) EPA proposes an annual individual protection requirement in Subpart B of 15 mrem. Although this limit may arguably be functionally similar to the existing performance objective in 10 CFR 61.41, under one option EPA proposes to require a time of compliance of peak dose. This is more stringent than many performance assessments being conducted by compacts. This restrictive and unrealistic requirement would result in inefficient use of disposal capacity: to meet the requirement one must severely restrict the inventories of certain critical radionuclides, meaning that more disposal facilities using more land resources must be constructed at larger costs.[7] Some existing disposal facilities might be unable to demonstrate compliance with the standard assuming that one must extend compliance analyses to peak dose. The disposal facilities may be forced to close, resulting in costs to facility operators and customers as addressed in points (c) and (d) above.

f) Under Option 1 of Subpart C, EPA proposes to prohibit exceedance of drinking water MCLs under any circumstance in any underground source of drinking water. And according to EPA's very broad definition of an underground source of drinking water, the groundwater beneath practically all current and future disposal facilities would probably be so defined. Even without consideration of time of compliance, point of compliance, and other problems (addressed below in point (h)), this requirement may prove to be very difficult for some disposal facilities to demonstrate.

As a case in point, the U.S. Ecology commercial disposal facility is sited in the middle of the Hanford Reservation

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[7]Assume that one can construct a disposal facility to accept a given quantity of waste at a given cost. If one constructs two disposal facilities and disposes of half the waste in each one, the costs for waste disposal will be larger than if **all** waste could be disposed in a single disposal facility. (If disposal costs are $\$X/ft^3$ for the single large disposal facility and $\$Y/ft^3$ for each of the two smaller facilities, then $Y > X$.) This is because, as a practical matter, each of the two smaller disposal facilities must spend the same amount of preoperational costs as the single larger disposal facility, but there will be smaller waste volumes in the two smaller facilities over which to amortize preoperational costs.

downgradient of DOE's 200-West Area and Environmental Restoration Disposal Facility (ERDF). To demonstrate compliance with either option of EPA's proposed groundwater protection standard, U.S. Ecology must consider the potential contribution from all sources of radioactive material to groundwater, including any release from DOE operations. This places the continued operation of the U.S. Ecology disposal facility at risk, because U.S. Ecology has no direct control over DOE activities on the Hanford Reservation. This leaves U.S. Ecology with an uncertain ability to characterize existing and possible future releases to groundwater from the 200-West Area and ERDF. If U.S. Ecology could not demonstrate compliance with EPA's requirements, it would have to cease operations, depriving its customers of disposal capacity (see points (c) and (d)).
g) Under Option 2 of Subpart C, EPA proposes to prohibit exceedance of drinking water MCLs in groundwater if existing contamination is less than MCLs, but to allow a delta of one MCL if existing contamination exceeds MCLs. This option provides no relief over Option 1. For some existing disposal facilities it may be more difficult to meet.

Again using the case of the U.S. Ecology facility, radionuclide concentrations in groundwater from existing and projected plumes of contamination from DOE waste management activities are not fixed but vary depending on space and time. At any time in the present or future, portions of the groundwater beneath a given portion of the U.S. Ecology disposal facility may either exceed or be smaller than the MCL for a particular radionuclide. U.S. Ecology has no direct control over DOE operations. If DOE discharges additional radioactive material to groundwater, or for that matter performs groundwater restoration, compliance demonstrations may be difficult and uncertain for U.S. Ecology. The MCL target, and ease of demonstrating compliance, would change depending on the magnitudes of the radionuclide concentrations that may be measured at any given time or place underneath the disposal facility.

h) By either groundwater protection option in Subpart C, EPA proposes to establish restrictive standards. As the requirement is now stated, EPA would:

1. Impose a small dose level for beta-gamma emitters (4 mrem) plus additional requirements for other radionuclides;

2. Establish a point of compliance that can be interpreted as being located under the waste itself;

3. Fail to specify a time of compliance, which could be interpreted as peak dose; and

4. Establish limits that are written in terms of radionuclide concentrations as they are projected to exist in the groundwater itself rather than as they are projected to exist in water as it may be actually consumed (i.e., after being withdrawn from the ground via a well).

The last three points might each result in less efficient use of disposal capacity: disposal inventories for certain critical radionuclides might be limited severely, meaning more disposal facilities must be constructed at larger cost (see footnote 6). Again we note that existing disposal facilities might not be able to demonstrate compliance and may be forced to close (see points (c) and (d)).

As a practical matter, commercial developers **do** perform analyses in compliance with 10 CFR 61.41 (or equivalent Agreement State regulation) which emphasize possible doses to humans from the groundwater pathway. But these analyses are performed as deltas above background and take credit for dilution as the water is withdrawn for consumption from a well (which is less restrictive than the proposed EPA requirements). The point of compliance is not under the waste but outside a buffer zone around the waste.[8]

i) For Subpart A, EPA proposes an annual 15-mrem standard, but is profoundly unclear about how one identifies on a practical basis an "away-from-generator processing or storage facility." As the standard is written, it could literally be interpreted as applying to any building different than the one where waste is generated. A large number of licensees might fall into the definition of such a facility, including universities, waste transporters, brokers, and so forth.

Furthermore, EPA provides no written guidance about how a licensee is expected to demonstrate compliance with the limit, although at a 28 March 1995 meeting of DOE's Performance Assessment Task Team, J. Gruhlke of EPA stated that compliance would be demonstrated by "measurement." This suggests that this requirement might prove to be difficult and costly to implement. An annual 15-mrem standard translates to an average dose rate of about 1.7 microrem per hour (urem/hr), which is very small compared to background dose rates that can vary considerably depending on weather, seasons, and other factors. Background dose

[8]At a 19 April 1998 meeting, EPA staff informed DOE and NRC staff that EPA's intent was to require the same time and point of compliance as those required for Subpart B. Also, EPA staff agreed to consider accounting for dilution with "uncontaminated" water as groundwater is withdrawn for hypothetical use.

measurements recorded at one site, for example, vary over the years by about 7 urem/hr (see Attachment 5).

Another problem is that DOT transportation regulations allow for much higher hourly radiation levels than those set forth in the standard -- i.e., 200 mrem/hr at the surface of a transport vehicle or package or a group of packages, or 10 mrem/hr at a distance of 2 meters (49 CFR 173.441). A transport vehicle containing LLW and parked outside the fence of a facility regulated under Subpart A would be in compliance with DOT regulations, but if parked inside the fence the facility could conceivably violate the standard within a few hours. Even if doses from transport vehicles were to be excluded from the standard, there would still remain the question about how a licensee could discriminate doses from different sources using common measurement techniques.

In addition, EPA proposes to require that away-from-generator processing or storage facilities must comply with groundwater protection provisions pursuant to Subpart C. But EPA has provided no guidance as to how such facilities could demonstrate compliance, and has provided no cost estimates.

Obviously, any additional costs borne by operators of disposal facilities and away-from-generator processing and storage facilities would be passed on to customers, which include small entities.

j) Also for Subpart A, EPA has not considered that many of the licensees to which the requirements will be applicable (and EPA is not clear on this matter) will conduct many activities, other than LLW management, that involve radioactive material. Nonetheless, EPA would require a separate determination of compliance just for LLW management. Licensees will need to prepare submissions for review and approval by regulatory agencies. The costs and burdens associated with demonstrating compliance with this standard will be added to those costs and burdens that have resulted from other regulatory requirements.

k) EPA has set forth a laundry list of pathways, which suggests that persons demonstrating compliance with Subparts A and B must quantify each pathway in compliance assessments, no matter how trivial. Costs of demonstrating regulatory compliance will be passed on to customers, which will include small entities.

ATTACHMENT 4

Projected Health Effects from Low-Level Waste Disposal are Insignificant

Past and expected calculations performed by the Environmental Protection Agency (EPA) suggest that in the absence of EPA's planned standard for management of low-level radioactive waste (LLW), 40 CFR Part 193, only about 50 health effects would result from disposal of LLW over 10,000 years. Past and expected EPA calculations also imply that implementing the standard would save, at most, only about 3 to 13 health effects over 10,000 years. This situation is compared against EPA's justification for its requirements in its environmental standard for high-level and transuranic waste and spent fuel, 40 CFR Part 191, for which a criterion of 1000 health effects over 10,000 years was considered acceptable.

Discussion of EPA Analyses. EPA has made available for review a 30 November 1994 version of its LLW management standard, 40 CFR Part 193, but provides no risk-based justification. Although the 30 November 1994 preproposal draft standard references a revised Background Information Document (BID) and Economic Impact Assessment (EIA), neither document is available for review. However, we have reviewed EPA's April 1989 draft LLW standard, which immediately preceded the 30 November 1994 preproposal draft standard (see DOE's 9 September 1991 comments to EPA). We have also reviewed the 1988 BID [BID88] that EPA published in support of its April 1989 draft standard, as well as EPA's draft (unpublished) EIA for the April 1989 draft standard [EIA88]. In addition, we possess EPA's response to a Freedom of Information Act (FOIA) request by Dr. Carol Marcus about EPA's justification for the 30 November preproposal draft standard. The information provided under this FOIA suggests that EPA has made few modifications to its 1988 BID, and will arrive at largely similar conclusions. At a 28 March 1995 meeting of DOE's Performance Assessment Task Team, EPA staff confirmed that only minor modifications had been made to the analysis in the 1988 BID.

In the 1988 BID, EPA examines several disposal scenarios, where the disposal scenarios are meant to represent different levels of disposal technologies that can be implemented at different levels of costs. Based on an assumed radioactive waste inventory, EPA models disposal of this inventory into each disposal scenario assuming three alternative disposal site environments (two humid and one arid environment). EPA then estimates that each disposal scenario in each environmental setting would result in a particular maximum dose to an individual in the general environment as well as a particular population risk (cancers over 10,000 years). By setting a maximum limit for an individual in

the general environment, EPA postulates that it would be allowing a certain number of health effects. But by setting a different disposal limit, EPA postulates that it would be saving (for a smaller dose limit) or allowing (for a larger dose limit) a calculated number of additional health effects.

Previous work by EPA indicated that only small risks would be associated with almost any LLW disposal technology that could be realistically implemented [BID88]. This position is still the case: EPA's 30 November preproposal draft standard states that for "almost any combination of disposal-system setting and disposal technology," exposures to radionuclides migrating from a LLW disposal system would result in "relatively few health effects, i.e., less than ten over 10,000 years."[1] Ten health effects over 10,000 years means an average of one health effect every 1000 years, or one health effect roughly every 30 generations. This risk cannot be considered to be significant. It is even less significant when one considers that for many of the disposal scenarios and site environments considered by EPA in its analysis, the projected health effects over 10,000 years for putative "10 CFR 61" disposal ranged from 2.5 to 4.4 depending on the site environment.

Of course, more than one LLW disposal facility will operate. However, because of the low risks associated with each disposal scenario, by EPA's analysis, even if the risks from all projected DOE and commercial sites were aggregated, the total risks for all LLW disposed over 20 years according to existing DOE and NRC regulatory requirements would amount to only a few tens of health effects over 10,000 years, perhaps about 50.[2]

These few health effects amount to a baseline against which EPA determines the savings in health effects that would result from

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[1]The only exception noted by EPA is a putative "sanitary landfill," a "disposal technology" that as depicted by EPA would violate basic radiation safety principles as well as EPA guidance under RCRA for sanitary landfill design, construction, and operation. If considered a LLW disposal facility, it could not be authorized by DOE under DOE 5820.2A and could not be licensed by NRC under 10 CFR Part 61. Under EPA RCRA regulations it would be classified as an open dump. These points were made to EPA in DOE's September 1991 letter.

[2]In a 4 April 1989 letter from John Greeves, NRC, to Dr. Art Fraas, OMB, NRC stated that "EPA's analyses demonstrate that the current practices of disposing of waste under DOE orders and 10 CFR Part 61 would result in only 46 health effects over 10,000 years." And in its unpublished 1988 EIA, EPA estimated (EIA Table 8-2) a total of about 28 health effects over 10,000 years for disposal of commercial LLW according to 10 CFR Part 61, and (EIA Table G-1) a total of 18-19 health effects over 10,000 years for disposal of DOE LLW, based on the incorrect assumption that disposal of all DOE LLW is by shallow land burial. This implies
a total of 46-47 health effects over 10,000 years, considering both commercial and DOE LLW [EIA88].

implementing the standard. For EPA's April 1989 draft standard, EPA projected a savings of from three to thirteen health effects over 10,000 years from implementing its standard. These saved health effects were based on EPA's projections of the combined impacts of DOE and commercial wastes from 1985 to the year 2004, and were bought at the price (according to EPA) of $2.5 billion. In DOE's review of EPA's April 1989 standard and BID, DOE concluded that EPA's estimate of health effects saved was highly uncertain. Among other problems, DOE observed that EPA did not consider the risks to public and workers that implementing the standard would **cause** (e.g., risks associated with waste processing and transportation), and if these risks were included in the analysis, the **net** health effects saved would be considerably smaller. In fact, DOE thought that about as many risks might be caused by implementing the standard as might be saved. In any case, given the uncertainty in the risk estimates they are not significantly different.

EPA's analysis for its HLW standard. Three (or even 50) health effects are seen to be particularly insignificant if one compares this result with the basis for EPA's standard for management and disposal of spent fuel, high-level waste, and transuranic waste, 40 CFR Part 191. For that standard, applicable, in EPA terms, to the "most hazardous" of all radioactive wastes,[3] EPA used as a criterion a limit of 1000 health effects over 10,000 years. In its 29 December 1982 Federal Register Notice for the proposed Part 191 standard, EPA stated that this criterion represented a level of risk comparable to that associated with uranium ore that had never been mined. EPA stated unequivably that "this long-term population risk is clearly very small" (47 FR 58202).

EPA also stated (47 FR 58202):

> We estimated that this quantity of waste, when disposed of in accordance with the proposed standards, could cause no more than 1000 premature deaths from cancer in the first 10,000 years after disposal: an average of no more than one premature death every 10 years. Any such increase would be far too small to be detectable in any manner compared to today's incidence of cancer, which kills about 350,000 people per year. Similarly, any such increase would be undetectable compared to the approximately 4,000 premature cancer deaths per year that the same linear dose-effect relationship predicts for natural background radiation.[4]

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[3]On page 13 of the 30 November preproposal draft, EPA states that "The most hazardous of all radioactive wastes are spent nuclear fuel and high-level waste."

[4]The estimate of 4,000 projected annual cancer deaths from radiation is based on old risk factors (pre-BIER V) and old estimates of average annual radiation exposures (exposures to radon were not included). A more recent

EPA then defended this risk criterion when it promulgated the final rule on 19 September 1985, and retained the same risk criterion when it repromulgated 40 CFR Part 191 on December 20, 1993, indicating that EPA regarded its criterion (1000 health effects in 10,000 years) as being still valid and protective.

In its 19 September 1995 FRN, EPA stated that one of the big reasons for choosing the criterion was that geologic repositories were capable of providing "such good protection." EPA cautioned against the assumption that such a strict criterion should be automatically extrapolated to other disposal systems (that might not perform as well as a geologic repository) (50 FR 38076).

Of course, when EPA proposed 40 CFR Part 191 in 1982, it assumed that waste disposal would occur in only a few repositories. There will be a larger number of LLW disposal facilities. But as noted above, even if one added the putative health effects from all LLW disposal facilities in the absense of EPA's standard, the calculated health effects would not total more than several tens of health effects. This long-term population risk would still be about a factor of twenty smaller than the 1000 health effects that EPA claimed were insignificant for high-level waste disposal. It would constitute a risk about a factor of twenty smaller than that from uranium ore that had never been mined.

REFERENCES

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EIA88 U.S. Environmental Protection Agency, Draft Environmental Impact Statement for Proposed Rules, Volume 2, Economic Impact Assessment, Low-Level and NARM Radioactive Wastes, EPA 520/1-87-012-2, Office of Radiation Programs, August 1988.

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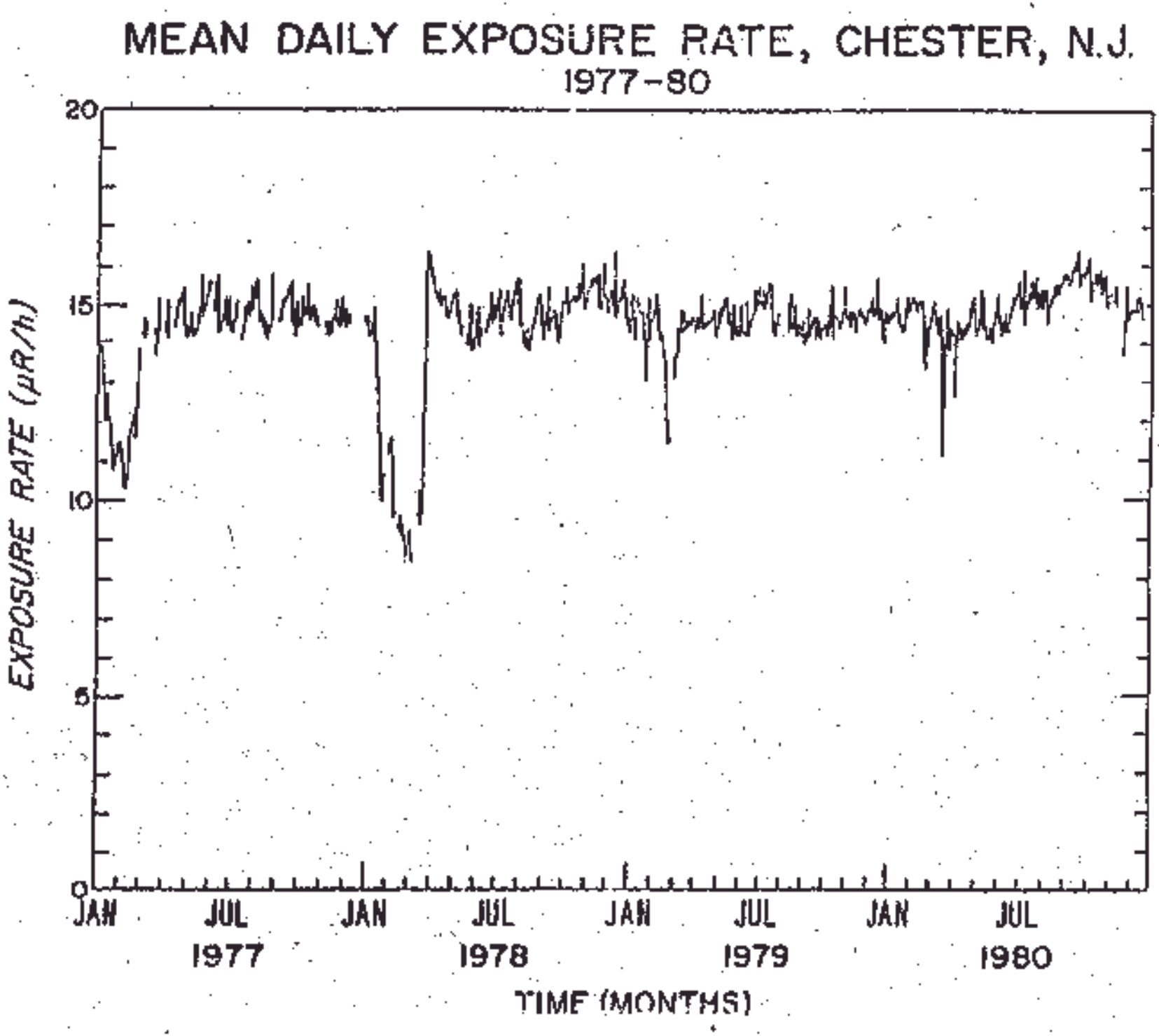
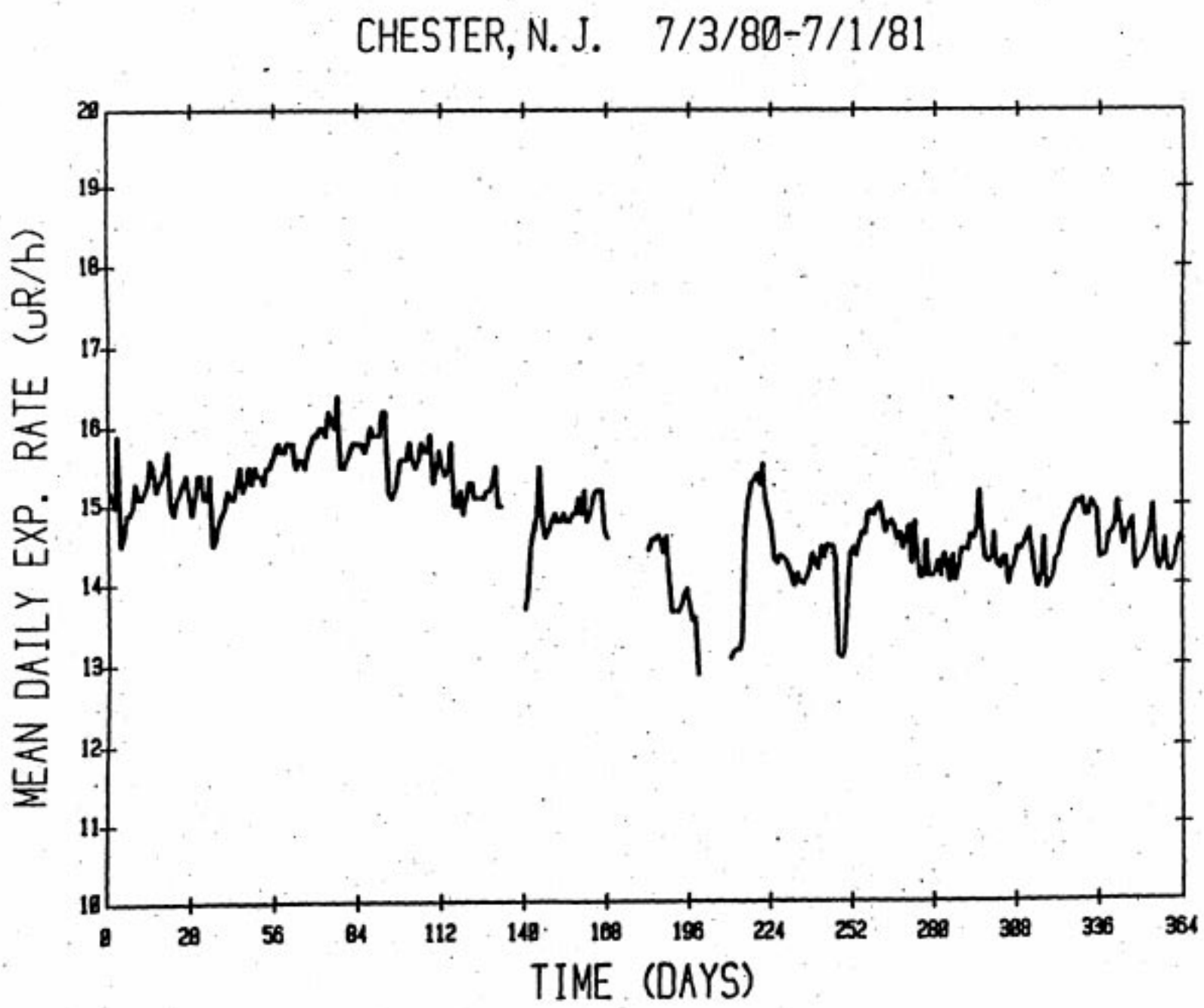
analysis would result in higher estimates of "radiation cancer deaths" from natural background radiation according to the linear model.

ATTACHMENT 5

Example Variations in Mean Daily Exposure Rates

(Measurements for Chester, New Jersey)


MEAN DAILY EXPOSURE RATE, CHESTER, N.J.
1977-80
EXPOSURE RATE (μR/h)
20
15
10
5
0
JAN
JUL
JAN
JUL
JAN
JUL
JAN
JUL
1977
1978
1979
1980
TIME (MONTHS)


CHESTER, N. J. 7/3/80-7/1/81
MEAN DAILY EXP. RATE (uR/h)
20
19
18
17
16
15
14
13
12
11
10
0
28
56
84
112
140
168
196
224
252
280
308
336
364
TIME (DAYS)

ATTACHMENT 6

Legislated Variability in Drinking Water Limits

As its principal justification for imposing maximum concentration limits (MCLs) for drinking water as a groundwater protection standard in draft 40 CFR Part 193, the Environmental Protection Agency (EPA) states that it wants to assure that low-level radioactive waste (LLW) management would never cause the need for future water treatment operations to remove radionuclides from drinking water.

But from review of the specific requirements of the Safe Drinking Water Act, which is the legislation that authorizes EPA to set standards for radionuclides and other materials in drinking water, is it clear that no such assurance can be provided. The Safe Drinking Water Act requires periodic review of drinking water standards; it also mandates that EPA set more restrictive standards when feasible to do so. This means that (1) EPA's stated assurance cannot be provided, and (2) by linking waste management standards to drinking water MCLs, which are subject to reduction, EPA ensures uncertainties in LLW standards.

Discussion. Regarding the Safe Drinking Water Act (the Act), the drinking water MCLs that have been, and will be, promulgated pursuant to the Act apply to water AFTER it has been processed by a drinking water treatment facility. Furthermore, the actual words of the Act are fairly stringent. Section 1412(b)(4) of the Act requires the following:

> Each maximum contaminant level goal [MCLG] established... shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. Each national primary drinking water regulation for a contaminant for which a [MCLG] is established...shall specify a maximum level [MCL] for such contaminant which is as close to the [MCLG] as is feasible.

Section 1412(b)(5) of the Act defines "feasible" as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)."

Furthermore, Section 1412(b)(9) of the Act states that: "National primary drinking water regulations shall be amended whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons, but in any event such regulations shall be reviewed at least once every three years." It also states that EPA's review and conclusions

must be published for comment in the Federal Register.

Based on the provisions of the Act, EPA has proposed modifying its existing drinking water regulations for radionuclides. These amended regulations were proposed in the Federal Register on 18 July 1991, but have not yet been promulgated.

From the provisions of the Act and EPA's proposed regulatory amendments, important matters to consider include:

a) In carrying out the Act, EPA has proposed setting the MCLGs for radionuclides to zero (see 18 July 1991 FRN).

b) EPA has proposed to establish the MCLs considering only the feasibility of removal of radionuclides from water at drinking water plants, and has not considered the feasibility and costs of applying the MCLs as waste disposal or as groundwater remediation criteria (see 18 July 1991 FRN).

c) The requirement to review the regulations every three years means that the MCLs are subject to change at short intervals.

d) The regulatory change that can take place is to provide "**greater protection**." Hence, EPA can only make the regulatory requirements more restrictive -- i.e., lowered MCLs.

e) For many radionuclides -- e.g., beta-gamma emitting radionuclides -- EPA has repeatedly stated that it expects that **no** drinking water plant will be required to actually remove radionuclides from drinking water to meet the MCLs (e.g., see the 18 July 1991 FRN and DOE's 9 September 1991 comments). For these radionclides, by the logic of EPA's analysis as discussed in point (b) above, a more restrictive MCL than the 4-mrem limit proposed in the 18 July 1991 FRN might be equally "feasible" within the context of the Safe Drinking Water Act as interpreted by EPA.

Additional discussion on the Safe Drinking Water Act and the questionable use of radionuclide MCLs as groundwater protection limits is provided in [REG1991] and in DOE's 9 September 1991 comments to EPA on its April 1989 draft LLW standard.

REFERENCES

REG1991 Regnier, E.P., Regulations for Radionuclides Under the Safe Drinking Water Act and 40 CFR 191 Ground Water Requirement, Presented at the EPRI Workshop - Technical Basis for EPA HLW Criteria, September 24-26, 1991.

Response to EPA Questions Associated with 40 November 1994

Preproposal Draft of 40 CFR Part 193

Summary of highlighted issues

1. What should be the lead time for DOE LLW facilities to come into compliance with these standards?

This question is premature. The response is highly dependent on the form of the standard, and the Department suggests that the proposed EPA approach of setting forth a media- and function-specific standard should be reconsidered in favor of a multi-media standard of general applicability. If the form of the standard were to be retained, many changes and clarifications would have to be made. However, if the standard were to be issued in its present form, the lead time would have to be very long to prevent significant impact on Department restructuring and environmental restoration activities.

Setting aside the issues concerning the form of the standard, the lack of clarity in the current standard makes a response to this question difficult. For Subpart A, for example, it is not possible to determine which DOE facilities would or would not constitute an away-from-generator processing or storage facility.[1] For Subparts A and B, the standard leaves considerable questions about demonstrations of compliance. For an away-from-generator processing or storage facility subject to Subpart A, there are difficulties in demonstrating compliance and questions with respect to hourly environmental dose rate variations, inconsistencies with DOT regulations, sanitary sewer disposals, and so forth. Subpart B seems to imply that a quantified estimate of each and every one of the pathways listed in the standard must be provided, no matter how trivial. Years might be required to develop models and obtain sufficient field data to make defensible assessments (of trivial doses). For Subpart C, clarification of many issues such as the point and time of compliance are critical.

A significant uncertainty is that to demonstrate compliance with Subpart C for a particular LLW management facility, DOE must consider the contribution of all current and future sources of radioactive contamination in groundwater under that facility. Many DOE sites have been disposing of waste for decades, and in many cases there are uncertainties about radionuclide quantities

[1]At a 19 April 1995 meeting, EPA staff informed DOE and NRC staff that EPA's intent was to exclude DOE away-from-generator processing and storage facilities from Subpart A.

and distributions in wastes that have previously been disposed. In addition, the radionuclide source terms that must be considered will depend on environmental restoration and waste management decisions that have not yet been made. For example, assume that a disposal facility is located hydrologically downgradient from an inactive soil column where soil contamination extends to the aquifer. To demonstrate compliance with the standard for the disposal facility, the future radioactive contribution to groundwater from the contamination in the soil column must be assessed. But predictions about movement of contamination from the soil column to the groundwater cannot be made until decisions are made about the amount of contamination that will be left in the soil column after environmental restoration is completed. These decisions will depend on decisions about the future use of the land over the soil column and future EPA cleanup standards.

Hence, based on the current language of the draft standard, it would likely take several decades for DOE to demonstrate compliance. DOE has recently published a Baseline Environmenal Management Report that projects environmental restoration activities for 75 years in the future. Many existing disposal facilities may have to be replaced.

In any case, as a general point for the timing of compliance with any standard, DOE is subject to budgetary constraints that are not under DOE's control.

2. What should the lead time be for NRC/Agreement-State-licensed LLW facilities to come into compliance with these standards?

We believe that our above comments regarding Subparts A and B would also be applicable to existing commercial disposal facilties and away-from-generator processing and storage facilities.

Regarding Subpart C, we would expect that existing LLW disposal facilities could require as long to come into compliance as would DOE. For compliance with the groundwater protection provisions, the U.S. Ecology facility would have to consider possible contributions from DOE sources, and U.S. Ecology has no control over DOE activities. Even disregarding future DOE disposal operations upgradient of the U.S Ecology disposal facility, U.S. Ecology would have to consider the projected contribution from radioactivity released into soil and groundwater from previous DOE operations, as well as the contribution from any radioactivity that is left after environmental restoration is completed (including, for example, any radioactive material left in liquid waste storage tanks in the 200-West area after the bulk of the waste has been removed). Because environmental restoration is likely to continue for several decades,

development of a final source term is also likely to require several decades.

3. Would it be desirable for EPA to pursue an approach in which NRC adopts requirements for protection of underground sources of drinking water consistent with 40 CFR Part 193 in return for the exemption of commercial facilities from 40 CFR Part 193?

We don't understand this question. EPA is preparing the standard pursuant to its authority under the Atomic Energy Act to develop standards of general applicability for radiation protection of the public. EPA has no enforcement function under this authority. DOE and NRC are responsible for preparing and issuing regulations that implement the standards. When EPA issues a standard of general applicability, implementing standards issued by DOE and NRC must be consistent with EPA's. If this is the case, no exemption is needed. If they are not consistent, and EPA intends to exempt the Commission, then EPA must explain their basis for the exemption and why it is available only to facilities licensed by NRC or an Agreement State.

4. What time period should be used for determining compliance with 40 CFR Part 193, 1000 years, no specific time period, or some other option?

A preferred option would be one that established a time of compliance of no more than 1000 years.

In most cases, rational decisions cannot be made using data beyond 1000 years, or even beyond times shorter than 1000 years. On that basis EPA should consider alternative approaches. The National Academy of Public Administration (NAPA) has been conducting a study for the Department relating to environmental equity. In a workshop on the issue ("Deciding for the Future: Balancing Risks and Benefits Fairly Across Generations" June 1994) a set of Proposed Intergenerational Equity Principles were developed. The principles recognize that every generation is a trustee for those that follow and note that there is an obligation to protect future generations provided that the "interests of the present generations and its immediate offspring are not jeopardized." They also noted that near-term concrete hazards have priority over long-term hypothetical hazards but that the preference for the present and near-future is reduced where there are questions of irreversible harm or a plausible threat of catastrophic effects.

This approach to environmental equity suggests that it would only be appropriate to consider compliance with low risk environmental standards for thousands of years if there was no impact on the well-being of current or near-term generations. Hence, compliance with environmental standards should be limited to a reasonably

forseeable future such as a few hundred years with the recognition that each subsequent generation has a responsibility to ensure that the next few generations are protected (a rolling future). Considerations of threats that occur many thousands of years in the future should be limited to plausible catastrophic events or irreversible effects (neither of which exist for low-level waste). While NAPA is still in the process of considering these principles, their analysis would seem to suggest that a compliance period exceeding 1000 years would be inappropriate.

In preparing performance assessments for DOE LLW disposal facilities, the analysis has frequently been extended beyond 10,000 years. However, there is no requirement to do so, and compliance with performance objectives is not required for these extended times. These extended analyses have been performed to aid one's understanding of the dynamics of the performance assessment model, and to provide a mechanism for checking the appropriateness of the assumptions of the performance assessment model. It would not be appropriate to consider a time of compliance beyond 1,000 years.

It is EPA's stated opinion on page 18 of the preproposal draft standard that beyond a 10,000-year time of compliance, the range of hydrological and geological conditions considered in performance assessment compliance models would be invalid. EPA also indicates that its Science Advisory Board (SAB) agrees with this position. Therefore, by EPA admission (and apparent SAB concurrence), any requirement that would impose a time of compliance beyond 10,000 years would result in invalid calculational results. The Department supports these conclusions but notes that there are many other parameters, both social and technical that would invalidate estimates beyond a few hundred years.[2] Therefore, a 1000-year time should be the maximum compliance period considered for low-level waste disposal.

5. Should waste be required to be in a form which can be located and recovered for a reasonable amount of time given the protection that has been afforded under programs that provide no-migration of chemically hazardous waste for 10,000 years?

There is no reason for such a requirement. All solid LLW is disposed at known locations, and could theoretically be

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[2]We also refer EPA to the 1992 report by the National Research Council, "Radioactive Waste Repository Licensing." In this report, the Board on Radioactive Waste Management stated on page 33 that with respect to attempting to predict quantitatively the long-term behavior of a geologic repository, that "this use of geological information and analytical tools -- to pretend to be able to make very accurate predictions of long-term site behavior -- is scientificly unsound." Similar discussion is provided elsewhere --e.g., pages 51-52.

recovered, albeit at extra costs and risks to radiation workers and the public.

If the purpose of the question is to consider a prohibition on disposal of liquid low-level wastes, then we don't believe that such an outright and blanket prohibition can be justified. If EPA can develop a justification, it must balance possible health and safety and environmental gains against costs. In so doing, EPA must consider the extent of the practices that would be affected by the ban, and consider alternatives for managing liquid wastes. As a few examples of practices:

- o Discharge of liquids into soils and aquifers. Although this practice is generally not a preferred option, it is still a viable option for the treatment of large quantities of liquid wastes containing low concentrations of short-lived radionuclides such as tritium. It is very difficult to remove tritium from waste liquids, but because tritium has a half-life of only 12.3 years, techniques have evolved where tritium is allowed to decay to safe levels while moving through soils and groundwaters under the administrative control of the Department. This approach permits the decay of the tritium before exposure of memebers of the public. The principal alternative to this practice is evaporation, which releases tritium directly into the air, hence resulting in a greater likelihood of human exposure.

- o Discharge of liquids into surface water bodies. Discharge of small quantities of radionuclides in effluents to surface waters is normal operational practice for most nuclear fuel cycle facilities. Would EPA prohibit this practice? If so, what alternatives would EPA suggest, and at what cost and net gain in public health and safety and environmental quality?

- o Discharge of liquids into sanitary sewers. Discharge of small quantities of radionuclides into sanitary sewers is allowable pursuant to DOE directives and NRC regulations. If EPA proposes to prohibit this practice, then EPA must consider the costs and risks of disposing the liquids by alternative methods, and balance these costs and risks against any net gains in public health and safety and environmental quality. Most persons authorized to discharge liquids and other dispersible materials into sanitary sewers are probably small entities within the context of the Regulatory Flexibility Act.

6. Which of two methods discussed previously should be used in applying the radionuclide MCLs for the management, storage, and disposal of LLW in a situation where the contamination in a USDW is near, at, or above the MCLs prior to operation of a facility?

Neither of the two options proposed by EPA is appropriate. A preferred option would be a multi-media standard of general applicability that did not set forth separate limits for particular media such as water or air.

7. **Is the EPA position that none of the methods analyzed in the development of 40 CFR Part 193 for disposal of LLW constitutes underground injection appropriate?**

Yes. Disposal methods for LLW considered by EPA do not constitute underground injection. Disposal methods that can be considered to be underground injection are adequately regulated under the requirements of Resource Conservation and Recovery Act and the Safe Drinking Water Act.

Additional issues

1. **Are the individual dose limits and USDW protection standards appropriate to protect the environment and public health?**

No. EPA has presented no health, risk, or cost-benefit basis for the cited individual dose limits and USDW protection standards. As noted above, a more appropriate standard would be one that truly established a generally-applicable environmental standard that, rather than setting forth separate requirements for particular media such as water or air, permited the optimization of protection based on a generally acceptable dose or risk limit.

In addition, given the acknowledged impossibility of predicting quantitatively actual doses to people in the distant future, dose limits should not be applied beyond a few hundred years at the most. If quantitative standards are to be specified beyond that time, it is essential that any such standards should clearly apply only to the results of hypothetical analytical calculations, and not be a requirement to limit actual doses to actual individuals in the future. However, DOE does not recommend that EPA specify the constraints on requirements for any such predictive analytical calculations. These should be left to the implementing agency.

2. **How should EPA deal with intruder scenarios in this rulemaking?**

EPA should not address intruder scenarios. EPA has no authority under the Atomic Energy Act of 1954 and Energy Reorganization Act No. 3 to promulgate requirements for protection of an inadvertent intruder. EPA's authority is limited to standards that apply "outside the boundaries of locations under the control of persons possessing or using radioactive material." After disposal, DOE or other government entities will continue to possess the disposed radioactive material.

There has been a long history of government ownership of LLW disposal facilities. NRC's 10 CFR Part 61 requires State or Federal ownership of commercial LLW disposal facilities. If State owned, the Nuclear Waste Policy Act sets forth conditions under which ownership can be transferred to the federal government. DOE certainly intends to own the land used for disposal of DOE LLW, and to maintain ownership of LLW disposal facilities indefinitely.

There is no intent for unrestricted release of a LLW disposal following the end of an active institutional control period. Government ownership is intended to continue. Nonetheless, bureaucratic accidents happen. Because of this possibility of accidents, the notion of inadvertent intrusion is used as a hypothetical construction to reduce the possibilty that excessively large doses might occur because of such accidents. Intrusion calculations are used to set forth radionuclide concentration limits in waste acceptance criteria and to establish certain design and construction parameters for the disposal facility. An intruder is not a "real person" to be protected. (And indeed, a real person cannot be protected because there is no way to predict what a real person may or may not do.)[3]

EPA must acknowledge this point and clarify its intentions. As the preamble is written, EPA leaves the reader with the impression that EPA might develop and promulgate future standards for protection of an inadvertent intruder. This uncertainty cannot help but have a deleterious effect on the process of siting and licensing new LLW disposal capacity. Progress will be slowed indefinitely by the uncertainty of a possible future EPA standard.

If EPA **did** attempt to promulgate standards for protection of an inadvertent intruder, it would have to do so in a manner consistent with the requirements of the Low-Level Radioactive Waste Policy Amendments Act of 1985. This Act defines commercial GTCC waste according to existing NRC's Class C limits. These Class C limits were established based on analyses involving hypothetical doses to a potential inadvertent intruder.

3. Would it be preferable to use a fraction of the SDWA MCLs as a limit rather than one of the approaches discussed earlier for the USDW protection requirements?

No. Neither SDWA MCLs, nor any fraction thereof, should be used

[3]NRC does not require intrusion analyses in applications for LLW disposal facilities because requirements for protection of an inadvertent intruder are established generically in 10 CFR 61.55 and elsewhere. Because of DOE's different situation (known disposal sites and fewer generators), DOE performs intruder analyses on a site-specific basis.

as a basis for a LLW management standard. See our above comments.

Department of Energy
Washington, DC 20585

September 9, 1991

J. William Gunter, Director
Criteria and Standards Division
Office of Radiation Programs
U.S. Environmental Protection Agency
Washington, DC 20460 (ANR-460)

Dear Mr. Gunter:

The Environmental Protection Agency (EPA) has sent to the Office of Management and Budget (OMB) for approval to publish as a proposed rule, an April 1989 version of a Federal Register Notice (FRN) describing its draft Environmental Standards for the Management, Storage, and Land Disposal of Low-Level Radioactive Waste (LLW) (40 CFR Part 193) and Naturally Occurring and Accelerator-Produced Radioactive Waste (NARM) (40 CFR Part 764).

We have grave concerns about the draft standards, particularly about draft Subpart C of Part 193, which would impose a zero-degradation limit for Class I aquifers and a 4-millirem/year (mrem/yr) limit for protection of Class II aquifers. We have expressed our preliminary concerns verbally to your staff and in a November 16, 1989, letter to OMB. Subsequent to our November 16 letter, OMB suspended its review of the draft standard, and instructed EPA to work out the concerns of the Department as well as those of the Nuclear Regulatory Commission (NRC).

We have conducted a more complete review of the draft standards, and their accompanying technical support, and have concluded that the draft standards should not be published in their present form. Our review indicates that (1) the technical support for the draft standards is faulty; (2) the requirements in draft 40 CFR Part 193 could be implemented only at very large costs, with very little benefit, and could as likely increase overall risks to humans as decrease overall risks; (3) the draft standards lack, but need, both a Regulatory Flexibility Analysis (RFA) and a Regulatory Impact Analysis (RIA); (4) the draft no-degradation standard for Class I aquifers lacks justification and contradicts other EPA requirements and guidance; and (5) the draft NARM waste requirements lack justification and would likely result in a new "orphan" class of waste. These points are expanded below.

A detailed review of the draft FRN is attached, along with a preliminary review of EPA's draft Background Information Document (BID). These reviews indicate a very large number of problems in addition to those discussed here. Along with the Economic Impact Assessment (EIA), EPA relies on the BID as the primary support document for the draft standards. The BID discusses the sources of LLW and NARM, pathways of exposure, assessment methods, and

individual doses and population health effects. The EIA discusses the cost-effectiveness of the regulatory options. EPA has published the BID but not the EIA. (We did not review EPA's analysis of possible radiation doses and health effects from disposal of below regulatory concern (BRC) waste.)

Lack of Technical Support. The draft Part 193 standard lacks technical support. The BID analysis, upon which EPA justifies the achievability of the draft standard, is based on a faulty radionuclide leaching and release model that underestimates releases from disposed wastes by at least an order of magnitude. (Also see the attached reviews by Brookhaven National Laboratory.) This means that no disposal method analyzed by EPA, having the radionuclide inventories assumed by EPA, would meet the draft 4 mrem/yr limit at EPA's model humid site having permeable soils. Thus, it will be much more difficult to comply with the 4 mrem/yr limit than supposed by EPA. The result will likely be a proliferation of small disposal facilities sited in pristine environments, putting more groundwaters at risk than if EPA proposed a higher limit than 4 mrem/yr.

As another problem, values for critical analysis parameters, such as leaching from wastes in different disposal methods or the degree to which trench caps fail, are chosen based not on hard technical evidence, but on preconceived notions of "better" and "worse" disposal methods. Thus, the results of the BID analysis, both actual and comparative, are largely artifacts of the assumptions that went into the analysis.

There are several other problems with the BID analysis. EPA's assumed source term for LLW contradicts available data for both commercial and DOE wastes. For example, uranium and thorium isotopes are present in LLW in quantities over a hundred times that assumed by EPA. The BID greatly underestimates the volume and activity of both commercial and DOE LLW that will be generated in the near future. The BID (and EIA) also fails to consider the size and complexity of DOE sites, which are very dissimilar to the simple commercial disposal facility analyzed in the BID. Some alternative disposal methods considered in the BID appear to violate federal regulations and Orders, and could not operate as depicted in the BID. EPA hasn't assessed the application of the standard to either mixed or greater-than-Class C (GTCC) wastes. Both types of LLW would be subject to the standard, yet neither may be disposed by the disposal methods analyzed in the BID. Also, EPA hasn't assessed the application of the standard to the above-grade engineered disposal methods proposed by most state compacts attempting to establish new LLW disposal capacity under the Low-Level Radioactive Waste Policy Amendments Act of 1985. At least one study suggests that such above-grade disposal methods may lead to releases that exceed those for shallow land burial.

Costs vs. Benefits. Very large costs would be associated with Subpart C, costs that would result in few or no corresponding benefits. As part of its justification of the draft 4-mrem/yr

limit for Class II aquifers, EPA refers to the BID and EIA analyses of health effects that could be avoided by use of improved disposal technologies. (EPA refers to similar analyses for the draft 25-mrem/yr limit in Subpart B of draft Part 193.) But these documents neglect to consider the risks that use of the improved disposal technologies would cause -- e.g., risks to workers solidifying wastes. Considering risks both avoided and caused, we calculate a net benefit for the draft 4-mrem/yr limit as roughly three health effects avoided over 10,000 years, at a cost of over $800 million per health effect avoided (or more than $300,000 per man-rem avoided).

These calculations are uncertain, and were made using EPA's estimates of LLW generation and characteristics, health effects avoided, and implementation costs. All of these estimates are unrealistic. Thus, we believe that draft Subpart C could as likely increase overall risks to humans as decrease overall risks.

Need for RIA and RFA. The draft standards could have a significant economic impact on DOE and on small businesses or other entities. (Preliminary studies indicate that costs to DOE could run to several billion dollars.) Thus, EPA needs to prepare a Regulatory Impact Analysis pursuant to Executive Order 12291, and a Regulatory Flexibility Analysis pursuant to the Regulatory Flexibility Act of 1980.

No-Degradation Standard. There is no radiological safety precedent for the draft no-degradation standard for Class I aquifers. Neither does EPA offer a radiological safety justification for it. Although the standard would avoid no risks to future populations, it could cause risks to existing individuals and populations. It could cause premature closure of some DOE and commercial facilities. EPA has neither evaluated the consequences of such closures nor justified their necessity. Last, the standard is arbitrary in that EPA would impose a zero-degradation limit for management and disposal of LLW over Class I aquifers, but would allow a limit larger than zero (4 mrem) for management and disposal of BRC waste above Class I aquifers.

NARM Waste. EPA would establish requirements and radionuclide concentration limits for near-surface disposal of NARM waste without any risk-based analyses of alternative requirements, classification limits, or lower cutoff limits. Although the draft standard would prohibit near-surface disposal of "GTCC" NARM wastes, EPA hasn't addressed how such wastes would be disposed or who would be responsible for doing so. A new "orphan" class of waste will probably be created. EPA has underestimated the range

and quantities of NARM wastes that would be subject to the standard, as well as the costs of complying with it. Those subject to these costs will include small businesses and other entities.

Conclusion. Because there is no statutory or judicial directive requiring issuance of the draft standards, the most workable and least disruptive solution may be to abandon their development. If EPA does decide to continue development of the draft standards, EPA should base the standards on a realistic risk-based analysis that considers and balances impacts both caused and avoided by alternative standards. In so doing, EPA should concentrate on development of Subparts A and B of draft 40 CFR Part 193, and draft 40 CFR Part 764.

We believe that Subparts A and B could be implemented by EPA in a reasonable time because of the general similarity of these Subparts to existing DOE and NRC requirements in DOE Order 5820.2A and 10 CFR Part 61. Regarding EPA's concerns about groundwater protection, we believe that NRC's existing regulations and DOE Order 5820.2A already provide adequate protection.

We would be pleased to discuss these comments and conclusions with you. Your contact is Mr. G. Roles (586-0289).

Sincerely,

/S/

Raymond Pelletier, Director
Office of Environmental Guidance

Enclosures:
1. Comments on draft FRN
2. Preliminary comments on BID
3. BNL Reports

cc w/enclosures:
Dr. Arthur G. Fraas,
Office of Management and Budget

DOE F 1325.8
(8-89)

United States Government **Department of Energy**

memorandum

DATE: May 4, 1995

REPLY TO
ATTN OF: EH-412

SUBJECT: 19 April 1995 Meeting with EPA Staff about 30 November 1994 Preproposal Draft LLW Standard, 40 CFR Part 193

TO: Through: Raymond Pelletier, Director, Office of Environmental
Policy and Assistance

To: Raymond Berube, Director, Office of Environment

On 19 April 1995, EM-412 staff met with staff from the Environmental Protection Agency (EPA) to discuss the Department's draft comments on EPA's 30 November 1994 preproposal draft of 40 CFR Part 193, Environmental Standards for the Management, Storage and Disposal of Low-Level Radioactive Waste (LLW). The EPA staff delegation was headed by Mr. L. Weinstock, Acting Director of the Criteria and Standards Division. Representatives from EM-30, EM-40, OGC, and the Nuclear Regulatory Commission (NRC) also attended (see attached attendance list). At the meeting, EH-412 provided the participants with a set of talking notes (attached), as well as the Department's draft consolidated comments on the preproposal draft standard. By copy of this memorandum we are providing a revised set of draft comments (attached) to EPA. DOE staff indicated that they expected to provide the comments to EPA by the end of the month.

Department staff pointed out that largely similar issues had been discussed in previous versions of the draft standard, and indicated that, in their opinion, with some exceptions (e.g., NARM, BRC), the current draft was very similar in its essentials to the previous versions. Department staff stated that in its present form, the standard would provide very few benefits, if any, at very large costs and disruptions to the Department and to commercial entities. Department staff nonetheless noted that solely from DOE's perspective, a different EPA LLW standard would be useful to DOE. DOE suggested revising the standard using a performance-based multi-media approach as recommended by the National Performance Review. Other criteria include:

- Generally-applicable standard;
- Non-disruptive to commercial LLW programs;
- Cost-beneficial consistent with Executive Order 12866 and the spirit of regulatory reform; and
- Address alternative disposal options for very low levels of radioactive material in waste.

As the Department's concerns were discussed, EPA staff made a number of statements about EPA's intent regarding the standard. These include:

- Subpart A would not apply to Department away-from-generator processing and storage facilities. Subpart A would be applicable only to Department LLW disposal facilities, to commercial away-from-generator processing and storage facilities, and to commercial LLW disposal facilities.

- Persons demonstrating compliance with Subpart A must consider the possible doses to the public from transport vehicles brought within the facility and emitting radiation in compliance with Department of Transportation regulations.

- After the standard is promulgated, EPA does not plan to issue followup guidance on interpreting and implementing the standard. Necessary guidance would be prepared by the implementing agency.

- Modifications to the draft definition of LLW could be considered. The current draft definition considers as LLW, 11(e)(2) byproduct material not addressed under 40 CFR 192.

- For compliance with Subpart C, the same point and time of compliance would be assumed as those applicable for compliance with Subpart B. The intent for Subpart C is that the maximum concentration limits (MCLs) that are in effect at the time of promulgation of Part 193 would apply to concentrations of radionuclides as they are projected to occur in groundwater itself rather than concentrations of radionuclides as they might exist in water as it is withdrawn from the ground for use. (Mr. Weinstock, however, indicated that EPA could consider adopting the latter interpretation for the standard.)

There was considerable discussion about groundwater protection requirements. EPA staff stated that the position that existing or potential sources of drinking water must be protected to drinking water standards was an EPA policy that ORIA could not change. Their goal was to assure that nobody in the future should have to treat drinking water because of current LLW management activities. (A second goal, not discussed in the meeting but stated in the preproposal draft, was to minimize the need for future generations to institute cleanup of closed disposal sites.)

DOE's position was that a policy statement represented

insufficient justification. The need for separate groundwater protection requirements should be justified on a cost-benefit basis. The recommendations of the National Performance Review should be considered. DOE staff felt that drinking water MCLs had been inappropriately applied as a waste management objective, and that the language of the Safe Drinking Water Act precluded EPA from assuring the realization of its stated goals.
DOE staff felt that neither groundwater protection option proposed by EPA in the preproposal draft was workable, and that both had the effect of driving LLW management facilities toward sites having pristine groundwater conditions. The difficulties with option 1 (MCL's including background) were discussed in previous DOE comments. DOE staff felt that option 2 was also problematic: it provided little if any relief over option 1, was physically unrealistic, and acted to discourage groundwater remediation.

There was some discussion about the potential for alternative forms of a groundwater protection requiremement: Possible alternatives include (1) publish an all-pathways standard without setting forth separate groundwater limits (EPA staff did not favor this alternative.), (2) address groundwater protection at a local level, (3) apply the requirement to much shorter time frames or at a local drinking water system, and (4) set forth a design and monitoring standard for LLW disposal similar to the approach used for disposal of hazardous waste (rather than long- term modeling of hypothetical risks.

As miscellaneous matters, Mr. Weinstock indicated that (1) the response from States was mixed, and (2) drinking water MCLs for radionuclides were not likely to change soon.

Finally, there was a brief discussion of the meeting to be held the following week between Ramona Trovato and Jill Lytle.

/S/

Andrew Wallo III
Director
Air, Water and Radiation Division

Attachments

Copies for: Ramona Trovato, EPA
L. Weinstock, EPA
J. Lytle, EM-30
J. Baublitz, EM-40
J. Greeves, NRC

EPA LOW-LEVEL RADIOACTIVE WASTE STANDARD,

40 CFR PART 193

30 NOVEMBER 1994 PREPROPOSAL DRAFT

SUMMARY OF CONSOLIDATED DOE COMMENTS

APRIL 19, 1995

AGENDA

1. **Abbreviated History.**

2. **Preproposal Draft Standard.**

3. **Concerns by States, Compacts, and NRC.**

4. **Selected DOE Concerns.**

5. **Response to EPA.**

ABBREVIATED HISTORY

8/31/83: EPA issues an ANPR for a LLW standard.

Over time, EPA prepares multiple draft versions of standard:

Example: April 1989 draft standard.
(Support: July 1988 Background Information Document)

Review by DOE, NRC, and Others:

Examples: 1987 note from Carl Welty, DOE, to EPA.

1991 letter from Pelletier, DOE, to EPA.

Major Issues Include:

Groundwater protection provisions -- e.g., inclusion of background in limit.

Unclear requirements -- e.g., point of compliance unspecified.

No risk-based rationale for use of MCLs.

Few benefits, if any, at high costs.

Unclear need for standard.

30 NOVEMBER 1994 PREPROPOSAL DRAFT STANDARD

SUBPART A: STANDARDS FOR MANAGEMENT AND STORAGE.

Annual 15 mrem/yr limit from operations at a LLW disposal facility and an away-from-generator management or storage facility. All pathways.

SUBPART B: STANDARDS FOR DISPOSAL.

Annual 15 mrem/yr limit from disposal of LLW. All pathways.

Point of compliance outside permanent markers. Options for time of compliance.

SUBPART C: STANDARDS FOR UNDERGROUND SOURCES OF DRINKING WATER.

Applies MCLs to USDWs under facilities covered by Subparts A and B. Water pathway only.

Option 1: MCLs not exceeded regardless of existing contamination.

Option 2: Up to MCLs if existing contamination < MCL.

MCL delta if existing contamination > MCL.

Point and time of compliance not mentioned.

Language of standard cites activity in water rather than as it may be used.

DRAFT STANDARD IS SIMILAR IN ESSENTIALS TO PREVIOUS DRAFTS:

Missing -- e.g.: BRC limits, NARM requirements.

CONCERNS BY STATES, COMPACTS, AND NRC

STATES AND COMPACTS:

- The standard is unnecessary; no cost justification.
- Rulemaking disruptive to siting and licensing activities.
- Rulemaking creates regulatory uncertainty and undermines public confidence.
- Need for BID and EIA before proceeding with the rulemaking.

NRC:

- Unnecessary regulation.
- Difficulty in demonstrating compliance.
- Impact on siting and licensing activities.
- Questionable applicability of drinking water standards to ground water.
- Unavailability of BID and EIA.
- Misunderstanding of 10 CFR Part 61.

DOE CONCERNS

OVERALL:

- Likely very small benefits, if any, at large costs. Annual additional costs may exceed $200 million (DOE estimate), not including disruptions. Hence, an RIA is needed.

- Disrupt DOE LLW management programs. Likely close LLW sites. Of concern: Hanford, Savannah River Site, Idaho National Engineering Laboratory, maybe others. Costs perhaps $ billions (Costs: new sites, storage, transportation).

- Disrupt environmental restoration programs, such as FUSRAP.

- Standard lacks clarity and creates uncertainties.

- Radon isotopes not considered separately, but should be.

- No technical justification published. Previous technical justification questionable.

- Definition of LLW includes some 11(e)(2) byproduct material.

- Inconsistencies:

  - Executive Order 12866, Regulatory Planning and Review.

  - Regulatory Flexibility Act.

  - Vice President's Report of the National Performance Review, which recommends other mechanisms than a media-specific approach for complex, multi-media problems.

SUBPART A:

- o Weak justification for standard.

- o Unclear applicability. May be extensive.

- o Compliance may be difficult:
  - 15 mrem/yr standard (equivalent 1.7 urem/hr limit against larger natural variations).
  - Groundwater protection requirements.
  - Sanitary sewer disposal.
  - Inconsistency with DOT regulations.

SUBPART B:

- o Weak justification for standard.
- o Need to clarify compliance requirements.
- o Need to clarify point of compliance.

SUBPART C:

- **Problems with Option 1:**

* Existing and uncertain future levels of contamination at many DOE sites.
* Large and variable concentrations of naturally-occurring radionuclides at SRS.
* U.S. Ecology facility at Hanford.
* Lack of clarity for about timing of multiple plumes and multiple radionuclides.

- **Problems with Option 2:**

* No relief over Option 1. Similar problems.
* Option is not physically realistic (contamination levels vary with three dimensions and time).
* Severity of standard varies with contamination levels.
* Discourages groundwater remediation in some situations.

- **Drives LLW management facilities toward pristine groundwaters.**

- **Other problems -- e.g.:**

* Unspecified point of compliance.
* Unspecified time of compliance.
* Cites concentrations in groundwater rather than as used.

- **Insufficient justification:**

* Stated goal undermined by Safe Drinking Water Act.
* Linkage to MCLs ensures uncertainty in LLW requirements.
* MCLs used in a manner inconsistent with derivation, justification, and use.

RESPONSE TO EPA

EXPECT DOE COMMENTS ABOUT END OF MONTH.

Summary:
In general, there is no overriding health-based need for this standard in its present form for the commercial sector or, for that matter, the Federal sector. However, solely from DOE's perspective an EPA LLW standard (external standard) would be useful to DOE. However, in its present form the standard will be disruptive and costly but have little benefit.

EPA should revise the standard. Criteria for the new standard should include:

- Performance-based multi-media approach as recommended by the National Performance Review.

- Generally applicable standard consistent with EPA's Federal Radiation Council-based authority.

- Non-disruptive to commercial LLW programs.

- Cost beneficial consistent with E.O. 12866 and regulatory reform.

- Address alternate disposal options for very low levels of radioactive material in waste.

Recommend EPA consider:

- A generally applicable standard like 40 CFR Part 190 using a general dose limit that will permit the implementing agencies to develop standards that on balance will be most protective across all pathways, or

- Append waste management to 40 CFR Part 190, increasing the allowable dose limit from 25/75/25 mrem/year to 30 or 40 mrem/year (ede) to account for waste management.

- Ground water is adequately protected by an all-pathways standard but if EPA must address ground water it should be on a local level (e.g., each facility shall develop a site-specific groundwater protection plan in cooperation with the affected states).