

## ISSUES AND IMPACTS OF THE REPROMULGATION OF 40 CFR PART 191

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### ABSTRACT

Legislation in 1992 has resulted in the Environmental Protection Agency's (EPA) standards for disposal of high-level and transuranic radioactive waste, 40 CFR 191, being repromulgated with significant changes to some sections while revision of other sections was not considered. Concurrent legislation directed that separate standards with a different basis be developed for any repository at the Yucca Mountain site. There are many issues which are being addressed in the context of a compliance criteria rulemaking for 40 CFR 191, and, for the Yucca Mountain site, by a National Academy of Sciences Committee.

### BACKGROUND

The Nuclear Waste Policy Act of 1982 directed the EPA to issue standards for the management and disposal of high-level and transuranic (TRU) radioactive waste. These standards were promulgated in 1985. However, in 1987 a court vacated and remanded Subpart B of the rule (the disposal standards). *NRDC v. EPA*, 824 F.2d 1258 (1st Cir. 1987). The bases for this remand were a lack of opportunity for public comment on the groundwater protection requirements, lack of an adequate explanation for selecting a 1,000 year duration for the individual protection requirements, and a failure to consider the relationship of the disposal standards with Safe Drinking Water Act (SDWA) requirements.

Efforts to develop a standard which would respond to the concerns of the court and be supported by a consensus of the technical community were still underway in 1992. Because of legislative constraints, underground testing which was planned at that time at the Waste Isolation Pilot Plant (WIPP) would have been delayed by lack of a final standard. Congress considered and enacted two laws contemporaneously. In October, 1992 the Energy Policy Act of 1992 provided that 40 CFR 191 would not apply to any repository at the Yucca Mountain site and directed EPA to develop a new and different standard for Yucca Mountain. It established a committee of the National Academy of Sciences (NAS) to conduct a study to provide EPA with findings and recommendations on reasonable standards for protection of public health and safety from a geologic repository.

Also in October, 1992 the WIPP Land Withdrawal Act (LWA) was enacted, transferring control of the land from the Department of Interior to the Department of Energy. Section 8(a) of the act reinstated the 1985 disposal standard except the aspects of the individual and groundwater protection requirements at §§ 191.15 and 191.16 that were emphasized in the remand of the entire Subpart B ordered by the court. As part of this reinstatement, the Yucca Mountain site was exempted. In addition to the reinstatement of the standards, section 8 also required the EPA to 1) repromulgate individual and groundwater protection requirements; 2) develop criteria for the certification of compliance to 40 CFR 191; 3) certify WIPP's compliance to the standard; and 4) periodically recertify WIPP's compliance.

Many organizations are involved in activities related to the development of these two standards. DOE is responsible for characterizing the Yucca Mountain site to evaluate its suitability, and developing and operating a repository, subject to licensing by the NRC, if the site is suitable and the site recommendation is approved. DOE is similarly responsible for the development of the WIPP. DOE also is, or will be,

responsible for undertaking disposal of radioactive waste at other facilities which may be subject to the 40 CFR 191 standards, such as the Greater Confinement Disposal facilities at the Nevada Test Site, and, possibly, residuals in the HLW storage tanks at Hanford.

The U.S. Nuclear Regulatory Commission (NRC) is responsible for licensing repositories for the disposal of commercial HLW such as any repository at the Yucca Mountain site. It has promulgated regulations, 10 CFR 60, for such licensing and is required to issue conforming amendments to them if needed to be not inconsistent with the new EPA standards. The EPA is responsible for issuing the generally applicable standards for management and disposal of high-level and TRU waste and for issuing the standards for the Yucca Mountain site. Under the LWA they are now also responsible for certifying DOE's determination of compliance with 40 CFR 191 at the WIPP.

Organizations particularly related to the generally applicable standard include the EPA's National Advisory Council on Environmental Policy and Technology (NACEPT) WIPP Subcommittee. NACEPT is a Federal advisory committee that provides advice to EPA on issues associated with environmental problems. The WIPP Subcommittee provides independent advice to EPA on specific WIPP related issues. The NAS also has a WIPP Panel which provides oversight on WIPP related issues.

The NAS Committee on Technical Bases for Yucca Mountain Standards was formed in response to the Energy Policy Act and is separate from the WIPP Panel.

### 40 CFR 191 FOR WIPP AND OTHER NON-YUCCA MOUNTAIN FACILITIES

On December 20, 1993, the revised 40 CFR 191 was issued. Significant changes to the standard included increasing the regulatory time period for both the individual and groundwater from 1,000 years to 10,000 years. EPA changed the individual protection requirements from 25 mrem whole-body/75 mrem critical organ to 15 mrem annual committed effective dose. Additionally, EPA changed the groundwater protection requirements to the direct application of the maximum contaminant levels (MCLs) for drinking water specified at 40 CFR Part 141.

### Groundwater Protection Requirements in 40 CFR 191 Subpart C

The Department of Energy is concerned about the far-reaching impact of the application of the Safe Drinking Water Act (SDWA) MCLs to the many potential facilities regulated under 40 CFR 191. The EPA appears to have not evaluated

the impact of applying the SDWA MCLs for a number of facilities to which 40 CFR 191 would apply. Specifically, as DOE stated in its comments on EPA's proposed amendment, "DOE disagrees with the implication that EPA need consider only sites to which the rule currently applies. EPA must consider impacts on sites to which the rule will apply in the future."

Of particular concern is the application of a "post-treatment" standard to untreated groundwater. The DOE offered two options on how to deal with this inconsistency. First, DOE proposed to apply the MCLs to the predicted concentration after treatment. Secondly, DOE proposed that ambient (background) radionuclide/ activity should be excluded when applying the groundwater protection standard. The Department's justification for this proposal is described below:

#### **Discussion of Application of MCLs After Treatment**

Water is palatable only up to around 500 mg total dissolved solids (TDS) per liter. The justification for defining an underground source of drinking water as high as 10,000 mg TDS per liter is that the technology for treating water is advancing to the point that such sources could be used. It must be expected that a society with such technology would also monitor and treat for radioactive contamination as well. Therefore, it makes sense to impose less restrictive requirements for disposal facilities located over sources of groundwater that are high in TDS or otherwise cannot be used. Such an approach would encourage the siting of disposal facilities over such sources of groundwater. Because this water would require treatment before use in any case, the remote possibility of excess contamination in the water from the disposal facility would not cause an undue burden.

If water must be treated to be used, credit should be given for radionuclide removal via treatment as well (see 58 FR 7933). The inclusion of treatment in the application of MCLs is entirely appropriate given the definition of MCLs in 40 CFR 141.2 "Maximum contaminant levels means the maximum permissible level of a contaminant in water that is delivered to any user of a public water system." Operators of public water systems currently need to monitor water supplies for contaminants and treat the water to remove contaminants present.

Under the SDWA the radionuclide limits have been established using a method which differs from that traditionally used for establishing radiation exposure limits to individuals based on health effects. Under the SDWA process the EPA first establishes a Maximum Contaminant Level Goal (MCLG) - which for radionuclides is zero - and then must set the MCL as close to this level as is feasible, taking into account cost, availability of treatment technologies, and other practical considerations. 51 FR 34836. "Feasible" means feasible with the use of the best technology, treatment techniques, and other means which the administrator finds available (taking costs into consideration). 56 FR 33052. In issuing the drinking water regulations EPA concluded that treatment technologies for the removal of beta-gamma emitters would be feasible, available, and cost effective.

Thus, the potential future burden is not one of health impacts but is a matter of costs. The costs for repository design, construction, and demonstration of compliance are incurred now, while, in the unlikely event of a need for additional water treatment, the costs would not be incurred for hundreds or thousands of years.

The NRC expressed a similar view in its April 12, 1993 comments to the EPA on the proposed rule when it stated the following:

"EPA proposes to require that radionuclide levels in offsite underground sources of drinking water not exceed such MCLs as EPA might determine to be appropriate. EPA's past derivation of MCLs has been based on consideration of the technical capabilities of water treatment plants and of the cost-effectiveness of various types of water treatment. Specifically, EPA's MCLs have been derived to apply to public water supplies after treatment in a water treatment plant. EPA now proposes to apply the same MCL levels to groundwater supplies before treatment. In other words, EPA proposes to obviate use of the very water treatment technologies EPA has previously found to be technically practical and cost effective."

#### **Discussion on Exclusion of Ambient (Background) Radionuclide Concentrations**

§191.24(a) states that undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR 141.

For determining compliance with these limits, the rule requires inclusion of the background levels of radiation in underground sources of drinking water. According to EPA's National Inorganics and Radionuclide Survey (NIRS), considerable amounts of naturally occurring radioactivity are found in the public water systems of many states.

Therefore, while the levels of radioactive releases from the waste site might be in compliance with the limits specified in 40 CFR 141, these level, when combined with the background radioactivity levels, may significantly increase and result in unjustified noncompliance with the limits in 40 CFR 141. In addition, the EPA approach encourages siting of disposal systems in the area of pristine aquifers as opposed to locations where groundwater is already unfit for consumption without treatment.

By including background the EPA standard appears to contradict several proposed and final rules issued by EPA with regard to land disposal restriction "no migration" variances, including EPA provisions for no migration determinations at 55 FR 13072, as well as the following:

"Similarly, EPA does not believe ambient or background concentrations of constituents outside the unit boundary should be considered in evaluating migration out of the unit." 57 FR 35942.

"Petitioners for units in areas where background levels of a hazardous constituent exist should demonstrate that the *incremental contribution* from their unit will not, in and of itself, exceed health based levels. For example, if air inhalation health based levels for Substance X is 10 ppm, and background levels of the constituent are 5 ppm, 'no migration' could be successfully demonstrated by projecting and monitoring concentrations at the unit boundary not exceeding 15 ppm. ("No Migration" Variances to the Hazardous Waste Land Disposal Prohibitions: A Guidance Manual for Petitioners, Draft, U.S. Environmental

Protection Agency, Office of Solid Waste, Washington, DC, July 1992)

EPA offered limited rationale to explain this departure from previously established policy.

#### **40 CFR 194**

As stated above, the WIPP LWA required EPA to develop criteria that EPA would use in certifying WIPP's compliance with 40 CFR 191. On February 11, 1993, EPA issued an Advanced Notice of Proposed Rulemaking (ANPR) soliciting comments on several areas EPA proposed to evaluate as part of the certification process. EPA followed this ANPR with a meeting of the NACEPT WIPP Subcommittee.

Based on the NACEPT meeting and discussions with the Agency, the Department has identified issues concerning potential criteria in the standard. The WIPP Land Withdrawal Act spells out authority for the Agency, and this authority does not appear to be as broad as the Nuclear Regulatory Commission's authority under the Atomic Energy Act. However, it appears that the Agency has assumed that certification is synonymous with licensing.

The Department discourages the EPA from attempting to broaden the scope of the certification process. Section 8(c) of the WIPP Land Withdrawal Act (P.L. 102-579) clearly states that the Agency should develop criteria for compliance to the "disposal standard". The "disposal standards" are clearly defined as 40 CFR Part 191 Subpart B (now Subparts B&C) in the WIPP LWA. The EPA should avoid developing criteria regarding the management and storage of transuranic waste at WIPP.

With regard to the disposal standards, the EPA has an unprecedented opportunity to reconcile potential inconsistency between 40 CFR 191 and RCRA (particularly 40 CFR 268.6). The Department and the Agency have had several discussions on these issues and they will not be elaborated on in this paper.

Finally, the EPA has an obligation to insure consistency between 40 CFR 194, 40 CFR 191 Subparts B and C and the WIPP Land Withdrawal Act. If the criteria in 40 CFR 194 differ from the guidance in 40 CFR 191, the Agency should provide the rationale for the changes. Areas of particular concern include criteria on the rate of inadvertent human intrusions, engineered barriers, and future state assumptions.

The EPA asked the NACEPT for feedback regarding potential intrusions into the repository. This indicates that the EPA may propose a different rate for intrusion than specified in the Appendix C guidance. The EPA should justify any rate differing from the rate provided in Appendix C.

The EPA also asked the NACEPT to consider the benefits of engineered barriers in compliance assessments. The EPA's interest in application of engineered barriers concerns the Department. Section 8(g) of the WIPP Land Withdrawal Act clearly and unambiguously states "The Secretary shall use both natural and engineered barriers ... to the extent necessary to comply with final disposal regulations." Prescriptive criteria for the utilization of engineered barriers would be in direct conflict with the Act.

#### **DEVELOPMENT OF A NEW STANDARD FOR A REPOSITORY AT THE YUCCA MOUNTAIN SITE**

Section 801 of the Energy Policy Act of 1992 directs the EPA to promulgate new, health-based standards for protection of the public from releases from a repository at the Yucca

Mountain site. These new standards are to prescribe maximum annual radiation dose to individual members of the public. The EPA's existing general environmental standards for management and disposal of high-level wastes, 40 CFR 191, no longer apply to Yucca Mountain. These existing standards were not health based but were derived from consideration of technical achievability. They are also based on population doses over 10,000 years instead of annual individual doses.

The Act provides an opportunity to re-examine the bases for and implementation of standards for the protection of the public from radioactive materials stored or disposed of in a geologic repository. The goal appears to be development of "reasonable" standards for protection of public health and safety. Although the standards developed are to be the only such standards applicable to Yucca Mountain, the Act does not specify or preclude site-specific standards. The Act also does not specify the answers to the questions posed to the NAS, and the NAS believes that "everything is on the table" for consideration, except for policy-related issues.

#### **Actions Undertaken in Response to the Energy Policy Act**

In response to the Energy Policy Act, the NAS Committee on Technical Bases for Yucca Mountain Standards was formed in April 1993. Since that time the Committee has held four meetings with invited experts to discuss the various technical issues associated with development of health-based standards for a geologic repository. A fifth and final meeting is planned for April 1994, with a final report on the Committee's findings and recommendations scheduled to be sent to EPA in December 1994.

As the applicant for an NRC license, DOE will bear the burden of proof in showing compliance with the standards established by EPA and incorporated in the NRC's implementing rules. DOE has, therefore, been active in supporting the NAS Committee's activities and providing information to the Committee when requested to support the Committee's evaluations.

DOE is also developing its own recommendations on health-based standards for geologic disposal for presentation to the Committee at its final meeting in April 1994. In the process of developing these recommendations, DOE identified key issues associated with the development and implementation of such standards. This information was presented to the NAS Committee in August 1993.

#### **Preliminary DOE Recommendations on Standards for a Repository at the Yucca Mountain Site**

In DOE's view, standards for geologic disposal at any site should have the following characteristics:

- the technical basis should be sound and defensible;
- the standards should be consistent with other standards and regulations;
- the standards should be clear and understandable as a basis for protection of public health and safety; and
- a reasonable means for demonstration of compliance must be available to support implementation.

The following is a summary of the DOE's preliminary recommendations for development and implementation of standards for protection of the public from releases from radioactive wastes stored or disposed of in a repository at the Yucca Mountain site:

1. The standards should be reasonable and health-based.

The standards should be based on providing an appropriate level of public protection rather than on what is considered to be technically achievable by a geologic disposal system. Although the level of protection is a policy judgement, it should be commensurate with that for other radiation protection standards. Such standards are clearly the intent of the Energy Policy Act of 1992.

2. The standards should focus on protecting people in the vicinity of the potential repository at Yucca Mountain, or a repository at any other site.

People who will be living in the vicinity of a repository are those most likely to be at risk from releases from that repository and should be the focus for public protection. In particular, the Yucca Mountain site is both remote and essentially isolated from major aquifers and surface water bodies. The major risk is to people living in the vicinity of the site who may be exposed to radionuclides in the local source of ground water. Population protection and separate groundwater protection standards should not be necessary to provide adequate protection to the public from a repository located at the site, especially since consumption of ground water is a pathway that would be considered in estimating overall risk to people living in the vicinity of the repository. Standards incorporating a single overall performance measure (e.g., risk, or dose, or releases) focused on protection of people in the vicinity of a repository would make demonstration of compliance more straightforward in a licensing proceeding. Standards specifying multiple long-term performance measures would complicate the licensing process without providing significant benefit in terms of public health and safety since one measure would undoubtedly be more limiting than the others.

3. Standards expressed in terms of individual dose are acceptable provided that certain conditions are met and certain aspects related to implementation are specified in a regulation or associated guidance.

No matter how standards are expressed, protection of public health and safety should be the fundamental basis. The standards themselves may be expressed in terms of the underlying risk limit, or in other terms, such as limits on individual or population dose, or releases, based on the underlying risk limit. Standards expressed in terms of individual dose would be consistent with the formulation of other radiation protection standards and with the apparent intent of the Energy Policy Act. A dose limit can be directly related to the underlying risk basis and readily compared to other hazards. The following aspects characterize an acceptable dose standard:

- The individual dose limit is commensurate with allowable doses from other radiation hazards and consistent with the recommendations of national and international bodies.

- The assumptions related to the characteristics of the future biosphere that are necessary for compliance evaluations are specified in a regulation or guidance, since the state of future human society is unknowable. Such assumptions need to be specified prior to licensing in order to reduce uncertainty in the licensing process.

- The limit is applied to average dose, rather than to a maximum hypothetical dose. This will provide adequate protection without the need to evaluate hypothetical and highly *unlikely* circumstances over very long times.

4. The period of regulatory concern for quantitative standards should be no more than 10,000 years. Such standards should clearly be for hypothetical modeling results with inherent uncertainties.

10,000 years is much longer than the time of high hazard which is on the order of 1,000 years because of the decay of short-lived fission products. Uncertainty in quantitative performance calculations increases with the length of the time period of regulatory concern and, at very long times must rest on assumptions that are unprovable in the normal sense of the word, possibly precluding regulatory judgements about actual performance of the system. A precedent has already been established through EPA rulemaking (e.g., 40 CFR 191, 40 CFR 148) for the use of a 10,000 year period of regulatory concern. In the case of 40 CFR 191, the 10,000 year performance period was upheld by a federal court. The potential release peaks that may occur at times on the order of 100,000 years and beyond are characteristic of geologic disposal. Such potential releases have not and should not be the subject of standards because of the large uncertainties involved in estimating performance over such times and the questionable significance of the results in terms of regulatory decision making.

5. Qualitative rather than quantitative requirements should be established for human intrusion.

The risk of human intrusion is present for any geologic repository and can never be eliminated. Quantitative requirements for the treatment of human intrusion in evaluating risk to public health and safety require a prediction of future human behavior; something that is essentially unknowable. Such hypothetical predictions would be difficult to defend in a licensing arena since there are no "experts" in the prediction of human behavior over very long times. These predictions would also provide no real benefit in terms of increasing public health and safety. Qualitative requirements for passive institutional controls and design features provide a reasonable level of protection from hypothetical events and are currently relied on by the NRC for post-closure protection of both low-level (10 CFR 61) and high-level (10 CFR 60) radioactive waste disposal facilities.

6. The standards for a geologic repository should be stated in deterministic terms, with guidance for

appropriate use of probabilistic analyses to show compliance.

The demonstration of compliance for licensing should be based on the weight of the evidence presented including probabilistic analyses, but not solely on the results of uncertain quantitative analyses. In addition to performance analyses, such evidence could include use of robust, multiple barriers as required by 10 CFR 60 (defense-in-depth) and information from natural analogs. Probabilistic analyses are appropriate for the evaluation of the long-term performance of a geologic repository since they permit the examination of sensitivity to various assumptions and parameters, and they can be used to evaluate the significance of some uncertainties. Performance models also have value in communicating

the logic associated with arguments regarding the expected performance of the disposal system.

#### SUMMARY

DOE is concerned with the likelihood that EPA will use the repromulgated 40 CFR Part 191 as the basis for Yucca Mountain standards, including the specification of multiple performance measures (cumulative release limits, individual dose limits, and ground water protection limits) with both quantitative (probabilistic) and qualitative compliance criteria. DOE believes that specific recommendations are needed from the NAS Committee to provide the EPA with the justification needed to develop new standards for a repository at the Yucca Mountain site and prevent the carryover of some of the requirements set in 40 CFR 191 that would be inconsistent with the intent of the Energy Policy Act.