

April 10, 1995

MEMORANDUM TO: Claudia A. Sellig, Chief
 Program Analysis Branch, NMSS

FROM: John T. Greeves, Director
 Division of Waste Management, NMSS

SUBJECT: DIVISION OF WASTE MANAGEMENT INPUTS FOR NATIONAL PERFORMANCE
 REVIEW PHASE 2

The Division of Waste Management has completed the first part of the National Performance Review Phase 2, which consisted of reviewing 10 CFR Parts 40, 60, 61, and 62. I have attached the requested Regulation Review Report and Responses to Review Questions for each of the regulations we reviewed.

If you have any questions about our inputs please call me on 415-6708 or Robert Johnson of my staff on 415-7282.

Contact: Robert Johnson, NMSS
 415-7282

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REGULATION REVIEW REPORT

Regulation Reviewed: PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

Findings: Part 40 serves a useful function in the regulation of radioactive materials. Some aspects of Part 40 are well justified, while other portions are out of date and in need of improvement.

Recommendation: Part 40 could be revised in its entirety, to sort out the requirements for different types of licensees to make it more user friendly, to make the requirements for large processors more performance oriented and efficient, and to update the provisions for general licenses and for users of small amounts to more correctly reflect the current knowledge of the health hazards of the various forms of source material. However, while there is not sufficient demand to justify a general revision, Criteria 4 and 12 of Appendix A should be considered for revision.

Implementation: Revision of Appendix A of Part 40 should be accomplished within the next few years. Criterion 4 should be revised, with much of it eliminated. Criterion 12 should be revised to allow tailings reclamation plans to consider active maintenance. This would more closely conform Appendix A to EPA mill tailings standards, which are more flexible on this point. It would, however, result in mill tailings being the only radioactive waste disposal area in which the Commission would consider reliance on active maintenance.

Contact: Myron Fliegel, HLUR, Division of Waste Management, NMSS, 415-6629.

RESPONSES TO REVIEW QUESTIONS

Regulation: 10 CFR PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

1. Its purpose (what is it intended to accomplish; what is the improvement in safety?)

Part 40 provides procedures and requirements for licensing that authorizes the possession and use of source material such that it provides adequate protection of the public health and safety in a way that is not inimical to the common defense and security. Part 40 addresses licensing the use of source material (thorium and unenriched uranium) for a variety of purposes, for example, milling of uranium ores to recover uranium, use of depleted uranium metal in weights in aircraft, use of thorium to coat turbine blades. The NRC also has included in Part 40 its implementing regulations addressing the storage and disposal of uranium mill tailings.

2. Is it required for adequate protection of public health and safety? If not, for regulations that are procedural or otherwise statutorily required, offices should consider how the regulation(s) support NRC's primary safety mission and whether they enhance or detract from that mission. If they detract, suggested legislative reforms should be made.

Part 40 serves a useful function in the regulation of radioactive materials for the protection of the public health and safety, as part of NRC's primary safety mission. The rule as it now exists has become awkward and inefficient in some regards, and needs improvement. Much of Criterion 4 of Appendix A is not required in that other criteria contain required performance objectives. The prohibition in Criterion 12 on reliance on active maintenance is not necessary to protect health and safety.

3. Is it justified based upon cost/benefit (i.e., Statement of Considerations and Regulatory Analysis)?

Parts of Part 40 are judged well justified, for example, the regulation of the disposition of uranium mill tailings. Other portions of Part 40, for example, regarding general licensing of small quantities, are considered out of date and in need of improvement. Similarly, the requirements for certain facilities that process large amounts are viewed as needing revision to establish a more rigorous regulatory basis.

4. Does it state the solution (i.e., prescriptive) or does it state the objective (i.e., performance)?

Some of the requirements concerning the disposition of uranium mill tailings are performance oriented, but most of Part 40, including elements of Criterion 4, is prescriptive.

5. Have licensees identified it as an unnecessarily burdensome, overly prescriptive, or inefficient regulation?

Some licensees have argued that aspects of uranium mill tailings regulations, including the no maintenance requirement in Criterion 12, are unnecessarily burdensome, overly prescriptive, and are not warranted based on costs and benefits. Licensees have also complained of inefficiencies and ineffectiveness in the regulatory process. Some are primarily concerned about the time required for some licensing actions, and about the amounts they are billed for under our 100 % fee recovery, and the promptness of billing, rather than the regulation itself.

6. Is it an overly prescriptive regulation? Should it be revised to be more performance-oriented? Can performance be measured?

Much of Criterion 4 of Appendix A is overly prescriptive and should be revised or eliminated. Part 40 might be made more performance oriented for large operations that can support, for example, an effective safety committee. For the smaller operations and those for whom the radiation is an insignificant consideration, it is probably better to have prescriptive requirements. The NRC published October 28, 1992, a notice in the Federal Register about the agency's intention to revise Part 40 to modernize and improve regulation of general licenses and small applications of source material. The NRC also has been planning to update its regulation of large processors when it has completed, and learned from the experience of, doing that for large processors of special nuclear material.

7. What is the impact on safety if it is eliminated or made less prescriptive?

For certain users, relaxing the prescriptiveness of the requirements could lead to public health and safety consequences and environmental impacts. This is illustrated by the difficulty and costliness of cleanup of sites where less than adequate care was taken in the past.

8. Does it overlap with regulations of another Agency (Federal or State)?
If so, what should be done?

There are areas, primarily related to uranium mills, where NRC's jurisdiction overlaps that of EPA. To a lesser degree, it abuts the jurisdictions of other regulators, e.g., States, OSHA, and FDA. The NRC and EPA have been working for some time now on resolving the differences in their regulatory approaches to make a better working relationship.

REGULATION REVIEW REPORT

Regulation Reviewed: 10 CFR PART 60 - DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

Findings: The purpose of 10 CFR Part 60 is to prescribe rules governing the licensing and disposal of high-level radioactive waste by the U.S. Department of Energy. Prior to the passage of the NWPA and the promulgation of 10 CFR Part 60, there was no specific regulatory framework for the safe permanent disposal high-level radioactive waste. 10 CFR Part 60 states objectives in the form of performance objectives for the overall system and subsystems of a repository and therefore is not prescriptive. Since 10 CFR Part 60 is an untested regulation it would be difficult for the Department of Energy (the potential licensee) or other interested parties to determine whether they impose an unjustified burden. However, since promulgation of 10 CFR Part 60, concerns have been raised about the subsystem performance objectives and their implementation. The NRC believes these requirements are still necessary to support NRC's overall reasonable assurance finding by assuring both engineered and natural subsystems substantially contribute to waste isolation. This multiple barrier approach, successfully used by NRC in reactor licensing, builds confidence in the repository's compliance with the overall performance objective. Furthermore, the subsystem performance objectives are fairly broad and allow flexibility in their implementation. While the Department of Energy considers it can implement these requirements, NRC is preparing guidance in areas of concern and maintains an active dialogue with the Department of Energy and other parties to achieve resolution of these concerns. In a related action, NRC has also completed a systematic review of 10 CFR Part 60 to identify regulatory uncertainties where the regulation needs clarification in order to be most effectively implemented. Two rulemakings and regulatory guidance are being prepared to resolve these uncertainties. Finally, there is no overlap with regulations of any other Federal or State agency, and if 10 CFR Part 60 were to be eliminated, NRC would still be required to regulate the disposal of high-level radioactive waste, but without a standard in place.

Recommendation: No changes are recommended as a result of this review. However, 10 CFR Part 60 will likely need to be amended in the future either as required by the Energy Policy Act to conform to the revised EPA Standard, as directed by new legislation, or as a result of resolving regulatory uncertainties identified by NRC.

Action: None

Contact: Mark S. Delligatti, DWM NMSS 415 6620

RESPONSES TO REVIEW QUESTIONS

Regulation Reviewed: 10 CFR PART 60 DISPOSAL OF HIGH-LEVEL RADIOACTIVE

1. Its purpose (what is it intended to accomplish; what is the improvement in safety?)

The purpose of 10 CFR Part 60 is to prescribe rules governing the licensing of the U.S. Department of Energy to:

- 1) Construct a geologic repository (including site characterization) for the permanent disposal of high-level radioactive waste and,
- 2) Receive and possess: source, special nuclear, and byproduct material at a geologic repository operations area sited constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982, as amended (NWSA).

The improvement in safety is that prior to the passage of the NWSA and the promulgation of 10 CFR Part 60, there was no specific regulatory framework for the safe permanent disposal high-level radioactive waste.

2. Is it required for adequate protection of public health and safety? If not, for regulations that are procedural or otherwise statutorily required, offices should consider how the regulation(s) support NRC's primary safety mission and whether they enhance or detract from that mission. If they detract, suggested legislative reforms should be made.

In the NWSA, Section 111(a) Congress found that "radioactive waste creates potential risks and requires safe and environmentally acceptable methods of disposal." The staff believes that this finding is still correct. This regulation is still required for adequate protection of public health and safety insofar as high-level radioactive waste is extremely dangerous and remains so for a very long period of time.

3. Is it justified based upon cost/benefit (i.e., Statement of Considerations [sic] and Regulatory Analysis)?

The Statements of Consideration for the technical criteria in 10 CFR Part 60 clearly justify this regulation, in terms of issues considered and response to comments. The Statements of Consideration for the technical criteria in 10 CFR Part 60 specifically address: siting, design, and performance of a geologic repository. The Commission considered several options for developing final technical criteria for high-level waste disposal, before adopting the performance-oriented 10 CFR 60. The staff has continued to review 10 CFR Part 60 to ensure that it is clear and implementable.

In addition, NRC requires that a regulatory analysis, weighing the cost and benefit of each regulation, be undertaken before a regulation is finally promulgated. This has been done for each amendment to 10 CFR Part 60 which has been undertaken since the regulation was first drafted.

4. Does it state the solution (i.e., prescriptive) or does it state the objective (i.e., performance).

10 CFR Part 60 states objectives in the form of performance objectives for the overall system and subsystems of a repository. Siting and design criteria define the data needed to support demonstrations of compliance with the performance objectives.

5. Have licensees identified it as an unnecessarily burdensome, overly prescriptive, or inefficient regulation?

Since 10 CFR Part 60 is an untested regulation (i.e., no license application for a high-level waste repository has been submitted pursuant to the regulation yet), it would be difficult for the Department of Energy (the potential licensee) or other interested parties to determine whether they impose an unjustified burden. However, since the initial promulgation of 10 CFR Part 60, the Department of Energy, the National Academy of Sciences, the Nuclear Waste Technical Review Board, and others have raised concerns with the subsystem performance objectives and their implementation. Similar concerns were also contentious during the development of 10 CFR Part 60 and thus are not new. The NRC believes these requirements are still necessary to support NRC's overall reasonable assurance finding by assuring both engineered and natural subsystems substantially contribute to waste isolation. This multiple barrier approach, successfully used by NRC in reactor licensing, builds confidence in the repository's compliance with the overall performance objective. Furthermore, the subsystem performance objectives are fairly broad and allow flexibility in their implementation. While the Department of Energy considers that it can implement these requirements, NRC is preparing guidance in areas of concern and has an ongoing dialogue with the Department of Energy and other parties to achieve resolution of these concerns. In a related action, NRC has carried out a systematic regulatory analysis of 10 CFR Part 60 and identified potential regulatory and institutional uncertainties which the staff is currently resolving. One of these uncertainties related to design basis events was also the subject of a Department of Energy petition for rulemaking to clarify the requirements related to design basis events. This rulemaking effort is currently in the public comment stage. Another rulemaking, which is close to being finalized, will clarify the siting criteria and performance objectives, thereby making compliance with these requirements more efficient. Regulatory guidance will resolve other regulatory and institutional uncertainties.

6. Is it an overly prescriptive regulation? Should it be revised to be more performance-oriented? Can performance be measured?

10 CFR Part 60 is not overly prescriptive. The primary requirements with which compliance must be demonstrated are performance objectives. Although the performance objectives are stated in measurable values such as radionuclide releases, they are projections for future states which could not be measured.

7. What is the impact on safety if it is eliminated or made less prescriptive?

If this regulation is eliminated, disposal of high-level radioactive waste would by NRC would still be required under the Atomic Energy Act, as amended and the Energy Reorganization Act. However, there would no longer be an absolute standard against which to measure any potential impact on waste isolation and radiological health and safety.

8. Does it overlap with regulations of another Agency (Federal or State)? If so, what should be done?

No, there is no overlap with the regulations of another agency (Federal or State).

RESPONSES TO REVIEW QUESTIONS

Regulation Reviewed: 10 CFR PART 61, LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

1. Its purpose (what is it intended to accomplish; what is the improvement in safety?)

The purpose of Part 61 is to ensure protection of the public health and safety and the environment from commercial disposal facilities for low-level radioactive waste (LLW).

2. Is it required for adequate protection of public health and safety? If not, for regulations that are procedural or otherwise statutorily required, offices should consider how the regulation(s) support NRC's primary safety mission and whether they enhance or detract from that mission. If they detract, suggested legislative reforms should be made.

Yes. Specifically, the performance objective in §61.41 establishes the adequate protection standard for protecting members of the public from radiological emissions from disposal facilities. The performance objective in §61.43 cross-references the radiation protection standards in 10 CFR Part 20.

3. Is it justified based on cost/benefit (i.e., Statement of Considerations and Regulatory Analysis)?

No. However, the rulemaking established that compliance with the requirements was reasonably achievable using existing technology.

4. Does it state the solution (i.e., prescriptive) or does it state the objective (i.e., performance)?

Part 61 provides performance objectives and is a systems-based rule. The technical requirements, which are more prescriptive, are directed at ensuring that the performance objectives will be satisfied. However, the rule allows flexibility in departing from the technical requirements provided the performance objectives are satisfied.

5. Have licensees identified it as an unnecessarily burdensome, overly prescriptive, or inefficient regulation?

Some have, but the prevailing view of the States, LLW generators, and disposal site operators is that the rule is reasonable. In response to a specific request, NRC published (August 1994) an Advanced Notice of Proposed Rulemaking on potential revisions to the land ownership

REGULATION REVIEW REPORT

Regulation Reviewed: 10 CFR PART 61, LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

Findings: Requirements are necessary to ensure protection of the public health and safety and the environment from commercial disposal facilities for low-level radioactive waste (LLW). State regulatory programs for LLW are based largely on NRC requirements in Part 61. Modification of the requirements at this time could destabilize the regulatory framework for LLW disposal sufficiently to frustrate State and Compact progress in developing new disposal facilities as required by the Low-Level Radioactive Waste Policy Act, as amended. Although the requirements are not strictly justified on a cost-benefit basis, the technical evaluations that support the rule demonstrated that compliance was reasonably achievable. The requirements are performance-based and presented as a system of requirements directed at ensuring compliance with the performance objectives in Subpart C. Licensees have considerable flexibility in siting, designing, operating, and closing disposal facilities provided compliance with the performance objectives can be demonstrated. Elimination of the requirements in Part 61 could result in public doses well in excess of NRC's public dose limits in Part 20 (adequate protection threshold), which could cause radiation injuries and environmental contamination that would be costly to remediate. The Environmental Protection Agency is currently developing environmental standards for LLW management that would overlap with and partially duplicate NRC requirements in Part 61. NRC staff is opposing the EPA standards on the basis that they would be duplicative and unnecessarily burdensome, as well as be disruptive to the State and Compact development of new disposal facilities. For mixed waste, EPA regulations imposed under the Resource Conservation and Recovery Act also overlap with NRC requirements in Part 61. Industry (NEI and others) have consistently raised concerns about the large cost associated with joint regulation of mixed waste and favored sole regulation of mixed waste by NRC. In response to previous Congressional resistance to grant single agency jurisdiction, NRC and EPA continue to work together in seeking administrative solutions (e.g., joint guidance) to reduce the burden from joint regulation.

Recommendation: Maintain the present requirements in 10 CFR Part 61. Note, however, that the NRC staff is currently evaluating options for the streamlining of the NRC LLW program. If the program is terminated and responsibility for LLW regulation transferred to the States or another Federal agency (e.g., EPA), NRC would need to rescind 10 CFR Part 61.

Action: Submit the staff's evaluation of the LLW Program Streamlining Initiative for Commission consideration in March 1995.

Contact: Michael Weber, NMSS/DWM/LLDP, 415 7297

provisions in Part 61, which would consider private land ownership instead of requiring Federal or State ownership. Based on comments from States, industry, and members of the public, however, the staff intends to terminate this rulemaking and retain the current requirements for government ownership. As with all requirements, the regulatory agencies could entertain exemption requests to relax this requirement on a case-by-case basis.

6. Is it an overly prescriptive regulation? Should it be revised to be more performance oriented? Can performance be measured?

No. The rule is already performance oriented. Yes, performance can be measured for evaluating radionuclide releases and compliance with the dose limits.

7. What is the impact on safety if it is eliminated or made less prescriptive?

Doses to members of the public and workers could exceed the limits in Part 20. In addition, relaxation in the requirements could result in short-term and long-term environmental contamination that would be costly to remediate.

8. Does it overlap with the regulations of another Agency (Federal or State)? If so, what should be done?

Not presently for most types of radioactive waste. However, EPA is currently developing environmental standards for LLW management, which would overlap with Part 61 and establish new standards to which Part 61 would have to conform. NRC staff opposes the EPA standards on the basis that they would be duplicative and unnecessarily burdensome, as well as be disruptive to the State and Compact development of new disposal facilities. Existing technical and impact evaluations have not demonstrated that the large costs associated with implementation of a revised standard are justified by the slight improvement in human and environmental protection. The staff is developing an analysis and recommended comments for Commission consideration. The staff is also evaluating alternatives to responding to EPA's proposal to exclude NRC and Agreement State licensed LLW disposal facilities, if NRC amends Part 61 to incorporate explicit limits for groundwater protection. Although NRC believes that such limits cannot be justified, the staff is willing to make minor modifications to existing guidance documents to describe how groundwater protection would be provided at facilities licensed in accordance with Part 61.

For mixed waste, EPA regulations imposed under the Resource Conservation and Recovery Act (RCRA) also overlap with NRC requirements in Part 61. Industry (NEI and others) have consistently raised concerns about the large cost associated with joint regulation of mixed waste and favored

sole regulation of mixed waste by NRC. In response to previous Congressional resistance to grant single agency jurisdiction, NRC and EPA continue to work together in seeking administrative solutions (e.g., joint guidance) to reduce the burden from joint regulation.

REGULATION REVIEW REPORT

Regulation Reviewed: 10 CFR PART 62, CRITERIA AND PROCEDURES FOR EMERGENCY ACCESS TO NON-FEDERAL AND REGIONAL LOW-LEVEL WASTE DISPOSAL FACILITIES

Findings: Requirements are necessary in the event that emergency access to a low-level waste (LLW) disposal facility is required to ensure protection of the public health and safety and the environment. NRC developed the procedural requirements in Part 62 to ensure that the Commission was prepared to act on emergency petitions in a timely manner, in accordance with Section 6 of the Low-Level Radioactive Waste Policy Act, as amended (LLRWPA). The requirements have not been applied by NRC because there have not been any requests for emergency access. Consequently, there has not been sufficient experience with the requirements to determine whether they impose an unjustified burden. Although requests could be reviewed on a case-by-case basis, it is highly unlikely that the NRC would be able to make the necessary findings to grant or deny emergency access within the 45-days mandated by the LLRWPA without having such procedural requirements in place. In addition, the requirements make transparent NRC's decisionmaking process reducing the likelihood of State or generator objections that the process was unfair or biased. These requirements do not overlap or conflict with any other requirements with the same or related purpose.

Recommendation: Maintain the present requirements in 10 CFR Part 62.

Action: Retain Part 62 requirements.

Contact: Michael Weber, NMSS/DWM/LLDP, 415-7297

RESPONSES TO REVIEW QUESTIONS

Regulation Reviewed: 10 CFR PART 62, CRITERIA AND PROCEDURES FOR EMERGENCY ACCESS TO NON-FEDERAL AND REGIONAL LOW-LEVEL WASTE DISPOSAL FACILITIES

1. Its purpose (what is it intended to accomplish; what is the improvement in safety?)

The purpose of Part 61 is to provide procedures and criteria for reviewing requests for emergency access to non-Federal disposal facilities for low-level radioactive waste (LLW).

2. Is it required for adequate protection of public health and safety? If not, for regulations that are procedural or otherwise statutorily required, offices should consider how the regulation(s) support NRC's primary safety mission and whether they enhance or detract from that mission. If they detract, suggested legislative reforms should be made.

Yes. In passing the Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA). Congress recognized the potential need for NRC to grant emergency access to ensure continued protection of the public and environment.

3. Is it justified based on cost/benefit (i.e., Statement of Considerations and Regulatory Analysis)?

Not applicable. The requirements specifically implement the statutory mandate in Section 6 of the LLRWPA.

4. Does it state the solution (i.e., prescriptive) or does it state the objective (i.e., performance)?

The rule describes the procedures and criteria for making a decision on whether to grant or deny a request for emergency access.

5. Have licensees identified it as an unnecessarily burdensome, overly prescriptive, or inefficient regulation?

No.

6. Is it an overly prescriptive regulation? Should it be revised to be more performance oriented? Can performance be measured?

No. The rule only provides criteria and procedures for conducting emergency access requests.

7. What is the impact on safety if it is eliminated or made less prescriptive?

Changes to the rule to decrease its specificity could frustrate the Commission's intent to ensure timely and fair decisions on emergency access requests. Such changes could also be perceived as lowering the threshold for access requests, which, in turn, could require greater NRC and State resources to resolve in a timely manner without a commensurate enhancement for public protection.

8. Does it overlap with the regulations of another Agency (Federal or State)? If so, what should be done?

No.