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NUCLEAR REGULATORY COMMISSION
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MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

FROM: Guy H. Cunningham, III
Executive Legal Director

SUBJECT: APPLICABILITY OF 10 CFR PARTS 19 AND 21 TO THE
DEPARTMENT OF ENERGY'S HIGH-LEVEL RADIOACTIVE WASTE
PROGRAM

This is in response to your June 20, 1984 memorandum requesting a legal opinion on the applicability of 10 CFR Parts 19 and 21 to the Department of Energy's (DOE) high-level radioactive waste (HLW) program, specifically to the stage before DOE submits a license application to the Commission. In summary, we have concluded that 10 CFR Parts 19 and 21 do not apply to DOE before a license application is submitted. However, we believe that the quality assurance provisions of 10 CFR Part 60 may provide a basis for influencing DOE to adopt equivalent safeguards. The following discussion elaborates on these points.

1. 10 CFR Part 19 - Notice, Instructions, and Reports to Workers; Inspections

10 CFR Part 19 establishes requirements for Commission licensees to provide certain notices and instruction to their employees, particularly with respect to radiological working conditions. In addition, 10 CFR Part 19 recognizes a worker's right to report to the Commission possible violations of the Atomic Energy Act, Commission regulations or license conditions with regard to such working conditions, and to request an inspection. 10 CFR § 19.16. Any discrimination against an employee as a result of such an allegation is prohibited. 10 CFR § 19.20.

Part 19 is limited in its application to licensees (see § 19.1 "Purpose" and § 19.2 "Scope"). There is one provision, requiring the posting of Form NRC-3, that purports to apply to license applicants as well as licensees, but this is merely duplicative of provisions appearing elsewhere in NRC regulations^{1/} and sheds no light on the application of Part 19 generally. It is clear that all the other provisions only apply after a license is issued. Thus, the employee protection provision prohibits discrimination "by a licensee or a contractor or subcontractor of a licensee." 10 CFR § 19.20.

1/ See e.g., 10 CFR § 60.9(e).

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JUL 23 1984

Note also that the provisions of 10 CFR § 19.16 on the right of "workers" to report to the Commission and request inspection of potential violations related to radiological working conditions only applies to licensee employees. See 10 CFR § 19.3 ("Worker" means an individual engaged in activities licensed by the Commission).

In summary, Part 19 has no present application to DOE or its contractors or subcontractors.

2. 10 CFR Part 21 - Reporting of Defects and Noncompliance

10 CFR Part 21 establishes procedures and requirements for the implementation of section 206 of the Energy Reorganization Act, 42 U.S.C. 5846. That section requires notification of the Commission of information indicating the existence of certain defects or failure to comply with Commission requirements. In particular, notification is required when information reasonably indicates that a facility or activity licensed, or otherwise regulated, pursuant to the Atomic Energy Act of 1954 as amended or Energy Reorganization Act of 1974, or a basic component supplied to such a facility or activity, either:

- ° Fails to comply with the Atomic Energy Act of 1954 as amended or any applicable rule, regulation, order or license of the Commission relating to substantial safety hazards; or
- ° Contains a defect which could create a substantial safety hazard.

The reporting responsibility rests solely on a responsible officer or individual director of a partnership, corporation, or other entity that:

- ° is licensed to possess, use, or transfer source, byproduct, special nuclear material or spent fuel.
- ° is licensed to construct, manufacture, possess, own, operate, or transfer any production or utilization facility or independent spent fuel storage facility.
- ° constructs a production or utilization facility or an independent spent fuel storage installation.
- ° supplies basic components for a facility or activity licensed under 10 CFR Parts 30, 40, 50, 60, 61, 70, 71, or 72.^{2/}

^{2/} 10 CFR § 21.1

JUL 23 1984

Although Government agencies, such as DOE are presumed to fall within the coverage of 10 CFR Part 21,^{3/} under the terms of the existing regulations DOE would not be subject to Part 21 until DOE receives a license under 10 CFR Part 60. However, any firm that "supplies" basic components to DOE for the HLW repository would be subject 10 CFR Part 21 even during the period before a license application is submitted. This would be generally analogous to a similar application of Part 21 in the reactor licensing area and is keyed to the activity of supplying basic components rather than to the particular stage of the licensing process.

The applicability of Part 21 to repository characterization and construction activities is nevertheless far from clear. For one thing, the regulations only apply with respect to "basic components," which are components, structures, or systems in which a defect or failure to comply with NRC requirements could create a "substantial safety hazard." 10 CFR § 21.3(a)(2). Such a hazard exists where there is "a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety." 10 CFR § 21.3(b). A substantial reduction in waste isolation performance of a repository might still not constitute a "substantial safety hazard." It is pertinent in this connection to note the distinction between "systems, structures and components important to safety" and "barriers important to waste isolation" that appears in Part 60, e.g. 10 CFR 60.21(c)(1)(ii)(D),(E).

Even if a defect or failure to comply involves a basic component, the duties under Part 21 would only arise on the part of a firm that "supplies" the component. A firm "supplies" a basic component if it is "contractually responsible" for that component. The question here is whether a particular firm is "contractually responsible" if it is so closely related to DOE that it may be viewed as standing in the latter's shoes. DOE itself has no prelicensing obligations under Part 21, and it is reasonable to argue that those contractors operating with and for its account would similarly be beyond the reach of the regulations.

In short, Part 21 - at least as now constructed - does not provide a reliable basis for preventing design and construction errors for a geologic repository.

Although DOE is not subject to the regulations in 10 CFR Part 21 until the facility is actually licensed, DOE's license application must include information which will enable the Commission to consider whether its quality assurance program complies with Subpart G of Part 60. 10 CFR § 60.31(a)(3). Subpart G makes it clear that the QA program must be implemented during site


^{3/} See NUREG-0302 Rev. 1, Page 21.2-7.

JUL 23 1984

characterization and construction. 10 CFR § 60.151. Moreover, it expressly applies to design and characterization of barriers important to waste isolation as well as to structures, systems, and components important to safety.

The quality assurance program for a repository is to be based, generally, on the criteria of Appendix B of 10 CFR Part 50. 10 CFR § 60.152. It must therefore include "measures ... to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected." 10 CFR Part 50, Appendix B, XVI. While DOE has some leeway in developing its quality assurance program, one step that might be considered is the implementation of reporting responsibilities that conform to those set out in Part 21. This would seem to be a matter that could appropriately be explored under the Procedural Agreement between NRC and DOE. Alternatively, reasonable reporting procedures could be established, by rulemaking, in the form of more specific quality assurance requirements. Although such requirements would be directed at DOE, they could incorporate provisions which would obligate DOE's contractors and subcontractors to notify NRC with respect to substantial defects.^{4/}

In summary, it is our view that Part 21 has little, if any, applicability to near-term repository activities of DOE or its contractors or subcontractors, but that its objectives might be achieved pursuant to the quality assurance principles of Part 60.


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^{4/} Authority for such requirements is contained in the Atomic Energy Act, in Section 161i (regulations ... necessary ... to govern any activity authorized pursuant to this act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activity, in order to protect health and to minimize danger to life or property) and Section 161o. (require ... such reports, and the keeping of such records with respect to, and to provide for such inspections or activities under licensees issued ... as may be necessary to effectuate the purposes of this Act).