

October 1, 1984

TO: FILE

FROM: F. R. COOK /5/

SUBJECT: COMMENTS ON ELD'S POSITION CONCERNING THE APPLICABILITY OF PARTS 19 AND 21 TO DOE AND THEIR CONTRACTORS (REFERENCE "F" BELOW)

REFERENCES:

- a. 10 CFR 60 with revisions through July 14, 1982
- b. Proposed technical criteria for 10 CFR 60 of July 8, 1981
- c. 10 CFR 60 with revisions through June 21, 1983.
- d. The Energy Reorganization Act of 1974
- e. Supplementary Information to 10 CFR 60, Federal Register, June 21, 1983 based on supporting document, Secy-83-59, of February 9, 1983.
- f. Memorandum for John G. Davis from Guy H. Cunningham, III, dated July 23, 1984
- g. 10 CFR 21 with revisions through September 28, 1983
- h. NUREG-0302, Rev. 1, October 1977, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting Defects and Noncompliance"

PURPOSE:

The purpose of this memorandum is to assess ELD's comments on the applicability of 10 CFR 19 and 21 to DOE and its contractors' activities to be licensed and currently otherwise regulated per 10 CFR 60 and other applicable NRC rules.

BACKGROUND:

Reference (a) contains a definition of "important to safety" which relates to the health and safety of the public, including issues concerning storage and disposal [1] of high level waste. The concept of public health and safety and NRC's role in assuring this health and safety has been discussed extensively in various staff documents leading up to issuance of references (a) and (b). One issue was whether or not NRC needs to issue criteria, separate from EPA's standards, pertinent to the health and safety of INDIVIDUALS of the public living at the boundary of the geologic repository in the accessible environment.

This issue was initially resolved along with the rationale for developing 10 CFR 60 when it was assumed that the future EPA standard for general environmental protection (40 CFR 191) would be based on scenarios analytically assessing the health and safety

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of INDIVIDUALS of the public. With this backup analysis the EPA's general environmental standards would serve two purposes:

1. They would constitute adequate criteria for protecting INDIVIDUALS.

2. They would provide general environmental standards to protect the current population as well as future generations.

In any case calculated repository releases compared to the standards could be correlated with INDIVIDUAL exposures assuming appropriate scenarios were used in setting the EPA standards in the first place.

In this respect NRC explicitly included a requirement in reference (b) that the engineered and natural barriers of the geologic repository perform so as to meet EPA standards and, thereby, proposed regulations intended to protect public health and safety as mandated in the law, reference (d), as well as meeting EPA's standard. (The issue of population vs individual dose is discussed in reference (e) on page 28204. This discussion obliquely addresses the difference between performance goals intended to assure (a) public health and safety and (b) general environmental standards, but does not make clear the respective responsibilities of NRC and EPA discussed above. It introduces a new concept, "an overall goal for safety performance"--an "overall safety goal" and suggests it is within the authority of EPA to establish this goal, but in the next sentences suggests some contingent NRC regulations may be established to assure the "overall safety goal" is achieved. It seems this reference (e) discussion borders on obscurantism.)

In early versions of 10 CFR 60 and the proposed technical revision "important to safety" (which was SPECIFICALLY defined) referred to structures, systems, and components in both the geologic repository (which includes NATURAL barriers in the overall barrier system) and ENGINEERED barriers. (See section 60.21(c)(3) and 60.21(c)(4) for usages in reference (a).

There appears throughout these early documents no attempt to limit applicability of the term "important to safety" to the operational phase of the repository or engineered structures. Associated with the early versions of 10CFR60 was the requirement for a quality assurance program applicable to structures, components and systems "important to safety" whether or not these were natural or engineered items and whether or not they functioned during the operational phase of the repository or after permanent closure to effect public health and safety.

Reference (c), as discussed in reference (e), clearly changes the definition "important to safety" to limit its applicability to ENGINEERED structures, systems and components and only those that are intended to function to protect public health and safety through the time of permanent closure. Hence, engineered barriers for long-term isolation are not covered by the wording

in 10CFR60 addressing quality assurance program requirements applicable to systems, structures and components important to safety except in so far as the barriers serve a dual purpose, i.e., providing safety during the operational phase. Packing is an example of an engineered barrier which would not likely be classified as important to safety, and, therefore, QA for its fabrication is not required by 10CFR60 considering the current definition of the term and QA program applicability specified in 10CFR60.151.

Reference (e)'s supporting document, Sect-83-59, page 26, identifies this change in the definition of "important to safety" and justifies it by indicating the uses and definition in references (a and b) were inappropriate and not traditional.

DISCUSSION:

1. Reference (f), page 3, second paragraph, seems to argue that since reference (c), recently written to redefine "important to safety", no longer includes the function of the barrier system for long-term isolation as substantially contributing to the health and safety of the public, its malfunctioning need not be considered a "substantial safety hazard". Hence, considering current usage, (not the usage when Part 21 was written nor when Part 60 applicability was added to part 21), reference (f) suggests that Part 21 would not apply. [This ELD rationale is closely consistent with the discussion in Secy-83-59, see reference (e), but is not supported by the rationale which was endorsed by the Commission in reference (e). A comparison of Secy 83-59 and reference (e) discussion of "important to safety" is recommended for the reader.] To be sure one might further reason to conclude, following the rationale in reference (f), that NRC has no business regulating DOE's HLW repository as to its long term isolation function, since health and safety is not a potential issue in this area.

I consider that it was intended that Part 21 apply to defects and noncompliances in barrier systems for long term waste isolation, since these systems are important to health and safety of the public, and that the rationale in reference (f) is faulted. This conclusion is supported by the final sentence of the reference (e) discussion, specifically: "Quality assurance requirements apply to STRUCTURES, SYSTEMS, AND COMPONENTS equally whether they be "important to safety" or "important to waste isolation."

2. Another statement in reference (f) is "...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." Reference (f) does not identify the regulations which are considered to be pertinent to this statement.

This statement appears unsupported and incorrect for the following reasons:

A. Section 206 of reference (d) indicates that facilities and activities which are licensed OR OTHERWISE REGULATED as well as basic components supplied to these facilities or activities are subject to the requirements of the law. The Purpose of reference (g) reflects, word for word, the text of the law in this regard.

B. Furthermore, the idea that the rule applies only to licensed entities after licensing is inconsistent with previous discussion of the applicability of Part 21 in reference (h) (see pages 21.2-3 and 21.2-4) by the NRC staff.

C. Since licensing to handle waste in a repository will not occur until 14 or more years hence and since construction and other critical activities are on going, it would make no sense to only apply the requirements at a late stage after most decisions affecting health and safety are made. (Note that the "Construction Authorization" required by reference (c) is not considered a license.) To be sure, it would appear the intent of the law and the rule is to keep the NRC aware of defects and noncompliances as they occur and to make all parties who may have knowledge of such problems responsible for notification. (Note that the term CONSTRUCTION in Part 21 includes DESIGN activities which are NOW ongoing relative to geologic repositories.)

3. Reference (f) also concludes that Part 19 has no present application to DOE or its contractors or subcontractors; see page 2, second paragraph.

What this conclusion seems to imply is that there are no licenses required for activities subject to Part 30 regulations--either for DOE or any other entity funded by DOE--if the activities are associated with the geologic repository work.

I would understand the rules of Part 30 together with 10CFR60.7 exempt DOE, including its duly authorized representatives (not necessarily its contractors and subcontractors), from the rules of Part 30 requiring a license to handle radioactive materials at a GEOLOGIC REPOSITORY. In any case the exemption of 10CFR60.7 does not appear to apply at locations away from the geologic repository. To be sure it would not appear to be NRC's intent to give blanket authorization to the large number of contractors and subcontractors doing work for DOE in the geologic repository arena to handle radioactive materials without license or Agreement State control at or away from the geologic repository.

I would conclude that Part 19 regulations could apply to most if not all of DOE's contractors, including those not duly representing DOE working at a future geologic repository. This includes Rockwell and Westinghouse currently handling radioactive materials in connection with commercial waste package construction at the 200 West area and the 300 area at Hanford, respectively, neither area being at a geologic repository or a prospective geologic repository.

It is also apparant on the surface that DOE and some of its chief

contractors and subcontractors are holders of general licenses described in 10CFR30 and issued under Parts 31 through 35. In this regard they would be subject to Part 19 rules even if they were not licensed yet under Part 60 to handle waste.

In summary I find no rules or laws which would appear to exempt DOE or its contractors or subcontractors from Part 30 and Part 19 rules which apply to repository construction activities (including design with its related R&D) except as provided in 10CFR60.7. (Even this exemption I question as it seems inappropriate for the NRC to allow self-regulation of any person otherwise subject to regulation under the law. This situation may be viewed as analogous to the EPA/DOE self-regulation practice associated with chemical wastes at ORNL, which I believe was found to be inappropriate in the Federal Court.

4. Reference (f) also suggests that DOE contractors may not be "contractually responsible" if they are so closely related to DOE that they may be viewed as "standing in the latter's [DOE's] shoes." This notion appears in the third paragraph of reference (f) and is in way of completing the argument that Part 21 does not apply to contractors who are "close" to DOE, supplying basic components, since DOE has no prelicensing obligations under Part 21.

I note that previous interpretations of Part 21 in reference (h) indicate it would apply any time, including "prelicensing", to defects and noncompliances in barrier systems for long term waste isolation, since this system is important to health and safety of the public. Therefore the rationale in reference (f) is faulted.

FOOTNOTES: (Numbers in [] indicate footnotes.)

1. Note the later revision of 10 CFR 60, reference (c) uses the term "storage" to include activities which are referred to as "disposal" of wastes. (See 60.102(3)) This usage appears to be inconsistent with definition of these terms in the National Waste Policy Act (NWPA) which distinguishes between "storage" and "disposal", primarily through existence of intent to recover or not recover the materials in question. NWPA makes the terms mutually exclusive when viewed logically, whereas NRC definitions appear to logically include disposal within the scope of the meaning of "storage", this being consistent with NRC's interpretation of the use of the term "storage" in Section 202 (3) and (4) of the Energy Reorganization Act of 1974, see FR 2/25/81, page 13971, footnote 1.
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