



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 28, 1997

Mr. Alan Brownstein, Director
Regulatory Coordination Division
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW 30
1000 Independence Avenue, S.W.
Washington, DC 20585

**SUBJECT: OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ADMINISTRATIVE PROCEDURE AP 32.6, REPORTING OF DEFECTS AND
NONCOMPLIANCE TO MEET THE INTENT OF 10 CFR PART 21"**

Dear Mr. Brownstein:

In a letter dated March 18, 1997, the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM) provided the U.S. Nuclear Regulatory Commission with an information copy of the subject document. In its letter, OCRWM stated its position that although 10 CFR Part 21 would not formally apply to its programs until DOE receives a construction authorization for a potential geologic repository at Yucca Mountain, Nevada, or a centralized interim storage facility, OCRWM has elected to voluntarily apply Part 21's evaluation and reporting requirements to its programs.

As stated during a May 18, 1997, DOE/NRC meeting on quality assurance (QA), the NRC staff notes DOE's commitment to *voluntarily* apply Part 21 to its programs. The staff also notes DOE's position that Part 21 will not formally apply to its programs until NRC issues a construction authorization to DOE for a geologic repository or storage facility, or a certificate of compliance for a storage or transportation cask. The staff does not dispute DOE's position. However, in light of DOE's decision to voluntarily apply Part 21, the staff may choose to audit DOE's implementation of the Part 21 evaluation and reporting requirements. Since DOE has voluntarily committed to evaluate and report in accordance with Part 21, its failure to do so would be the basis for a notice of non-compliance by the NRC staff. In the event of a DOE decision to modify or terminate its voluntary commitment to apply Part 21, the staff requests that OCRWM inform the staff of its decision before implementing such a decision.

At the May 1997 DOE/NRC QA meeting, the staff noted that it would review the subject procedure, to the extent that resources permit, and provide DOE with any comments it might have. In response to a request by the Division of Waste Management, the Office of Nuclear Reactor Regulation, and the Office of the General Counsel reviewed AP 32.6, and their comments (enclosed) are provided for your consideration.

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If you have any questions regarding the enclosed comments, please contact either William L. Belke (702/794-5047) or Ted H. Carter (301/415-6684) of my staff. My staff and I would be pleased to meet with you to discuss and clarify the attached comments, if you would find it helpful.

Sincerely,
[Original signed by:]
Michael J. Bell, Acting Chief
Performance Assessment and High-Level
Waste Integration Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

- cc: R. Milner, OCRWM
- S. Frishman, State of Nevada
- B. Price, Nevada Legislative Committee
- J. Meder, Nevada Legislative Counsel Bureau
- W. Barnes, YMPO
- C. Einberg, DOE/Wash., DC
- M. Murphy, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- D. Weigel, GAO
- P. Niedzielski-Eichner, Nye County, NV
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- R. Holden, NCAI
- T. Burton, NIEC
- S. Brocoum, YMPO
- R. Arnold, Pahrump, NV
- N. Stellavato, Nye County, NV
- J. Lyznicky, AMA
- B. Russo, EPA
- A. Gil, YMPO
- R. Anderson, NEI

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NAME	MLee/cgj	WBelke	SWastler	WReamer	TCarter	MBell
DATE	9/29/97	09/29/97	09/29/97	10/07/97	11/25/97	11/28/97

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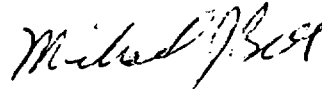
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**U.S. NUCLEAR REGULATORY COMMISSION STAFF COMMENTS ON
U.S. DEPARTMENT OF ENERGY ADMINISTRATIVE PROCEDURE AP-32.6
(REVISION 0)**

1. In the last sentence of the first paragraph of Section 1.0, "PURPOSE" (page 2 of 19), it is indicated that implementation of this procedure is "voluntary." The next paragraph notes that implementation of the procedure is not legally required prior to issuance of a construction authorization for a facility or a certificate of compliance for casks. The last sentence of the second paragraph seems to contradict these statements. In the last sentence, it is suggested that the words "Prior to" be changed to "Upon."
2. Contrary to the provisions of 10 CFR Part 21, AP-32.6 establishes the position of a *Responsible Individual* (RI) whose primary functions are to receive notices of deviations and failures to comply from all organizations involved in the design, construction and operation of the high-level nuclear waste facility, oversee their evaluation to determine whether they rise to the level of defects that are reportable to the NRC, and provide interim reports of deviation evaluations and reports of defects to the NRC. The procedure further authorizes the RI to seek assistance from suppliers and other contractors to perform the evaluations, as necessary. The proposed procedure is different from that described in Part 21, and it would require modification to the current Part 21 regulation to permit its use. A key provision of the adopted approach is the authorization of any affected organization in the procurement process to notify the RI in the event of discovery of a deviation or failure to comply, rather than the NRC directly as is required by Part 21.
3. In the "NOTE" at the top of page 3 of 19, it is recommended that the phrase "...as determined by the RI..." be added.
4. At the end of the third paragraph on p. 3 of 19, it is recommended that the phrase "unless that defect affects a prior delivery as noted above" be added.
5. Under Section 2.0 ("APPLICABILITY"), third paragraph, first sentence, it could be construed that the phrase "...except for commercial-grade items..." infers that commercial grade items (CGI) are a subset of basic components. This is not the case and the phrase should be deleted. The reportability requirements for CGIs, however, should be addressed. Once a CGI is dedicated, it becomes a basic component and all the reportability requirements for a basic component are now applicable [See §21.61(c)]. Further, the dedication process itself, including all activities, equipment, and procedures, is subject to Part 21 reporting. The requirements for performing CGI dedication should be addressed in a separate procedure (See NRC guidance in *Generic Letters 89-02 and 91-05 and NRC Inspection Procedure 38703*).
6. It would be useful and informative to the user of this procedure to include examples of failures to comply that, upon evaluation, would be reportable.

Enclosure

7. Activities that could be added include: dedication of CGIs, selection and verification of critical characteristics, calibration, testing, inspection, auditing, heat treatment, seismic and environmental testing and qualification, etc. These are all considered to be basic components [See §21.3, Basic component(3)], and deviations associated with these activities are potentially reportable.
8. Under Section 3.0, Item 3.8 (definition of "Discovery"), it is not clear that the 60-day period for reporting a defect is maintained due to the requirement for subtier suppliers to report to the RI within 5 days rather than directly to the NRC. It needs to be made clear that the definition of "Discovery" remains identical to that given in Part 21 and that the sixty day reporting requirement is retained.
9. In Section 5.1.2 b) and c), it is indicated that suppliers subject to Part 21 reporting requirements will be informed that the RI is the project point-of-contact for Part 21 issues. A memorandum will be issued identifying the RI and include definition of the interface between the RI and contractors and affected organizations. The procedure should state that *all* suppliers, subject to Part 21 requirements, including subtier and low-subtier suppliers, will be so informed.
10. In Section 5.2.4 a), reference to the criteria given should be generalized to state that the listing of potential sources of deviations are examples and the listing may not be complete. As an example, if it is determined that a certain testing instrument to verify a critical parameter was found to be out of calibration after delivery of the product, this could be a deviation subject to evaluation. It is not clear that this example is included in the listing of criteria.
11. In Section 5.2.4 a), it is recommended that a criterion be added that addresses deviations that may arise due to deficiencies in the dedication process.
12. The last sentence in Section 3.2 is potentially confusing. It is recommended that it be replaced with the following: "...a commercial list-grade item is a basic component after it is dedicated...."
13. To preclude potential conflicts between the note near the top of page 3 of 19 and the last paragraph on the preceding page (Section 2.0), it is suggested that the following be added to the initial sentence of that paragraph: "...unless the deviation or failure to comply affects a component previously delivered to facilities or activities subject to Part 21...." The cited note may then be deleted.



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