



Department of Energy
Washington, DC 20585

MAY 02 1995

Mr. Joseph J. Holonich, Chief
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Reference: Ltr, Holonich to Milner, dated 1/27/95

Dear Mr. Holonich:

During Audit YMP-94-10 at Lawrence Livermore National Laboratory, the U.S. Nuclear Regulatory Commission identified an inquiry related to electronic record keeping that was carried as an open item in the Commission's Observation Audit Report 94-12. This inquiry is answered in the enclosure provided. If this response is found to be satisfactory by the Commission, it is requested that this open item be closed.

For any further questions, please contact Fred Rodgers at (202) 586-9313.

Sincerely,

James H. Carlson, for

Ronald A. Milner, Director
Office of Program Management and
Integration
Office of Civilian Radioactive
Waste Management

Enclosure

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PDR WASTE PDR
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cc:

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**Lawrence Livermore National Laboratory****LLYMP9503036****March 8, 1995****QA:L**

**Tom Rodgers, Lead Auditor
U.S. Department of Energy
Yucca Mountain Site Characterization Project Office
P.O. Box 96808
Las Vegas, NV 89193-8608**

Subject: Audit Observer Inquiry 0003 from Audit YMP-94-10 (SCPB: NA)

The subject inquiry raised an issue about electronic scientific notebooks. It asked two questions. LLNL has changed its controlling procedure, TIP-YM-12, to address the two questions. The changed procedure is attached.

The first question was "what is to prevent editing of the text in the electronic record just before the hard copy revision is printed?" The answer is that procedural controls are the mechanism; if the author followed the procedure, the text would not be changed until after the prior version was printed. The procedure at the time of that audit (9/94) required an annual submission of a paper copy of the record and additional submissions if previous entries were to be changed. The procedure has been changed to require quarterly submissions. This is a trade-off. For bound scientific notebooks, with the higher level of physical control since they are bound and done in ink, an annual submission is accepted by the QA program. For current electronic scientific notebooks, which have a lower degree of physical control since they are not bound and entries can be easily changed on the computer, a more frequent submission is deemed appropriate.

The second question was "in this regard, is this TIP auditable?" The answer is that the paper submissions are objective evidence of the traceability of the work. If the controls in the procedure are followed, the traceability will be equivalent to that of a paper scientific notebook. The issue is whether the controls are followed. The more frequent submission of paper copies will decrease the vulnerability of traceability to non-compliance with the controls. In addition, each submission now requires incrementing the revision number and is also considered as a completed record (rather than a record segment that can be superseded). Therefore, the auditability of the procedure has been improved.

Concurrently, LLNL is developing software that will reduce the reliance on procedural controls. It is expected that this software will provide date stamps. It is possible that it might produce a log of dates that the record is changed, perhaps a listing of pages that were changed, or perhaps a listing of the actual changes. It may be able to automatically transfer a copy of the file to an archive location, such as the LRC, in a way that prevents the author from making subsequent changes to the copy. When the development of this software reaches the appropriate stage, it will be tested and procedures such as TIP-YM-12 will be

ENCLOSURE

revised. Two informal memos are attached which document the initial actions to develop the new software.

If you have any questions regarding this matter, please contact Conrad Wilgus at (510) 422-3755, Jim Blink at (702) 794-7157, or Ray Hamati at (510) 422-0537.

Sincerely,



Willis L. Clarke
Technical Project Officer
LLNL-YMP

WLC:JAB:jab
3 Attachments

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R. Hamati
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QA:95/048

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