

Dr. Sigfried Hecker
[]
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EA 96-07

Subject: Preliminary Notice of Violation (NTS-ALO-LA-LANL-TSF-1996-0001)

Dear Dr. Hecker:

This refers to the Department of Energy's (DOE) evaluation of the circumstances surrounding two issues involving modifications associated with or affecting [a facility] at Los Alamos National Laboratory (LANL). These two issues included an unauthorized modification of [radiation] monitors in the TSFF and a sump modification in the basement of [a building], which contains some [facility] safety features. On July 16-17, 1996, the DOE Office of Enforcement and Investigation conducted an on-site review of these matters, the report of which was provided to you on September 19, 1996.

Based on DOE's evaluation of this matter, DOE concluded that potential violations of DOE's Quality Assurance Rule (QA Rule) (10 CFR 830.120) likely occurred. An enforcement conference was held with members of your staff on October 17, 1996, to discuss the facts and circumstances surrounding these incidents; the associated potential violations and weaknesses; the safety significance of these design control, work control, and quality improvement problems; and the status of corrective actions taken or planned to resolve the problems. An enforcement conference summary report is enclosed.

The first issue concerns the unauthorized modifications of three [radiation] monitors in [the facility]. The modifications to these monitors were identified by DOE in March 1996. The modifications were accomplished by using a blueberry can from a muffin mix as a filter housing, a styrofoam cup as a gasket, and a respirator cartridge as an air filter. The modifications had the potential to affect operability of the monitors during [] operations. However, these modifications were made without any formal design review or approval, procedures to control installation of the modification, or calibration testing to demonstrate accurate operability of the modified monitors. These monitors are required to be operable during [] operations by facility Operating Safety Requirements (OSR's). The purpose of these monitors is to alert workers to a [radioactive material] release to minimize potential exposures to workers. In addition to the OSR operability requirement, these monitors are listed as a safety feature in the facility Safety Assessment and the Basis for Interim Operation.

Although the radiological control technician (RCT) who performed the modification was alerted by DOE of the need to conduct a formal review of the planned design change prior to installation, no design review/approval of the modification to determine its potential impact on facility safety was performed. When LANL management was informed of the unauthorized modification by DOE, an informal critique was held; however, management did not sufficiently recognize the problems with lack of a formal design review, the lack of work controls for the modification, or the issue of operability of the monitors. Further, LANL management did not ensure that formal corrective action

documentation, as required by your Quality Management Plan (QMP) and procedures, to assure the requisite evaluation and resolution of the unauthorized modification was initiated. As a result, the unauthorized modification was not corrected for 77 days after the problem was initially identified by DOE, at which time the modified monitors were removed from the facility.

As described in the enclosed Preliminary Notice of Violation (PNOV), the violations associated with the modification to the [radiation] monitors involve requirements of 10 CFR 830.120 (Quality Assurance Requirements) pertaining to Design, Work Processes and Quality Improvement. Specifically, the failure to adhere to these requirements, your QMP and your implementing procedures developed for maintaining the requisite level of quality for features intended to protect the safety of workers, the public and the environment resulted in a potential reduction in the safety margin for the facility if an accidental release of [radioactivity] had occurred during this period.

DOE recognizes that the actual safety significance associated with the unauthorized modification to the [radiation] monitors was low because other [] monitors that were not modified were available, and may have provided an alarm for a [radioactive material] release in sufficient time for personnel evacuation. However, the violations associated with this matter are of more than minor concern to DOE in that the unauthorized modifications were not identified and properly evaluated by your management control systems in accordance with your QMP despite a number of opportunities to do so. DOE is particularly concerned that the failure to adhere to your established processes in this case is reflective of a broader programmatic issue. For example, the DOE Office of Independent Oversight's assessment of LANL operations, the report of which was issued on November 8, 1996, identified weaknesses in conduct of operations and a sitewide culture problem with respect to adherence to the procedures, programs and policies established by you to assure safe operation. Therefore, in accordance with the "General Statement of Enforcement Policy" (Enforcement Policy), 10 CFR 820, Appendix A, the violations associated with this incident have been classified in the aggregate as a Severity Level III problem.

The second issue occurred on January 17, 1996, and involved a modification to install a sump in the basement of [a building]. During this modification, a power supply line was accidentally cut resulting in a loss of power to certain [facility] safety features and causing the automated diesel generator backup power systems to be energized. You indicated that this modification was not being performed in an area designated by the LANL QMP for 10 CFR 830.120 because your practice had been to apply the QMP only to activities taking place within the physical boundaries of the nuclear facility. However, the basement of [the building] contains certain electrical cabling and controls associated with design features for the [] nuclear facility which is also located in [the building]. For example, controls and electrical cabling associated with the [facility] ventilation system are located in [the building]. The DOE approved QMP Implementation Plan specifies that work performed outside of nuclear facilities that could impact safety of a nuclear facility would be controlled under the QMP. However, no such review was performed for the sump modification to determine whether there was a potential impact on facility safety, nor was there a procedure to conduct such a review. During the enforcement conference, you indicated that you believed the QA Rule requirements and the provisions of your Implementation Plan were not applicable because the power line and its location had not been identified as part of the "nuclear facility."

DOE has concluded that the issue rests not on whether the power line was a part of a formally designated "nuclear facility," but rather, as described in your QMP, on the need to review and control work on systems and components that have the potential to impact on the safety of a nuclear facility. DOE believes that under the facts of this case, the sump modification activity should have been controlled in accordance with your QMP, to determine whether the modifications would have had an impact on the safety of the nuclear facility.

DOE recognizes that at the time of this incident, there was relatively short experience in the DOE complex, including LANL, with the QA Rule. Additionally, DOE has considered your current initiatives to identify equipment and systems

that may be part of the nuclear facility based on their potential impact on facility safety. DOE also believes this process should continue in a logical fashion and can lead to improved implementation of your QMP. Additionally, the potential safety significance of this noncompliance is low in that, although some safety features were activated when the power supply was cut, no failures of safety features or substantial reduction in the facility's safety margin occurred. Therefore, in accordance with the discretionary criteria set forth in the DOE Enforcement Policy, no enforcement action is considered appropriate with respect to this second issue at this time.

However, you are required to respond to the PNOV and should follow the instructions specified in the Notice in preparing your response. In your response you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, DOE will determine whether further action is necessary to ensure compliance with the applicable nuclear safety requirements.

Additionally, due to the incorrect determinations made on the applicability of your QMP to review this work for impact on nuclear safety and to better understand how compliance with the QMP will be maintained in the future, you should also provide the following:

- (a) A description of how the Facility Manager (FM) reviews and controls activities performed by Johnson Controls, Inc., including turnover and training requirements for any acting personnel;
- (b) A description of the process and identification of the procedure used to determine the potential impact of activities on the safety of the nuclear facility; and
- (c) A description of the process and procedure(s) the FM uses to control modifications in the non-nuclear portion of the facility to assure these do not impact the safety of the nuclear facility.

This additional information should be provided directly to Mr. G. Thomas Todd, Area Manager, DOE Los Alamos Area Office and a copy to the Office of the Docket Clerk.

Sincerely,

T. O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Enclosures:
Preliminary Notice of Violation
Enforcement Conference Summary Report

PRELIMINARY NOTICE OF VIOLATION

Los Alamos National Laboratory
[Facility]
EA 96-07

As a result of a Department of Energy (DOE) evaluation of activities associated with DOE's identification on March 6, 1996, of unauthorized modifications to [radiation] monitors in the [facility], violations of DOE nuclear safety requirements were identified. In accordance with the "General Statement of Enforcement Policy," 10 CFR 820, Appendix A, DOE proposes to issue a Notice of Violation pursuant to Section 234A of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2282a., and 10 CFR 820. The particular violations are set forth below.

- A. 10 CFR 830.120 (c)(2)(ii) requires the adequacy of design products to be verified and validated before approval and implementation of the design.

The LANL Quality Management Plan (QMP) requires that verification and validation of design changes be performed prior to approval and implementation of the design.

Contrary to the above, three [radiation] monitors in the [facility] were modified at some unrecorded date prior to March 6, 1996, by utilizing a blueberry can as a filter housing, a styrofoam cup as a gasket, and a respirator cartridge as an air filter, without any formal design review, verification or validation prior to installation of the modification.

- B. 10 CFR 830.120(c)(2)(i) requires work to be performed to establish administrative controls using approved procedures.

The LANL QMP requires that work activities be planned in advance and that written procedures be developed to provide an auditable trail for critical items procured or fabricated.

Contrary to the above, the unauthorized modification of the [radiation] monitors prior to March 1996 was not performed to established administrative controls using approved procedures in that:

1. No formal management review and approval of the modification was conducted.
2. No review of potential impact on nuclear safety through use of formal LANL review procedures was conducted.

3. No auditable trail or formal pre-planning of the work took place.
 4. No formal installation procedure or work package was prepared or used.
- C. 10 CFR 830.120(c)(1)(iii) requires that processes to detect and prevent quality problems be established and implemented. Items, services and processes that do not meet established requirements shall be identified, controlled and corrected, according to the importance of the problem and the work affected. Correction shall include identifying the causes and working to prevent recurrence.

The LANL QMP requires that methods be established to identify, report and trend conditions adverse to quality.

Contrary to the above, after notification of the unauthorized modification of the [radiation] monitors in March 1996 formal identification, control and corrective processes to correct quality problems as required by LANL Procedure ESA-3 "Nonconformance and Corrective Action Reporting" were not implemented. Specifically, a Nonconformance Report was not developed to report and document materials identified that did not conform to established requirements.

Collectively, these violations constitute a Severity Level III problem.

Pursuant to 10 CFR 820.24, LANL is hereby required within 30 days of the date of this Notice, to submit a written statement or explanation to the Director, Office of Enforcement and Investigation, Office of the Assistant Secretary for Environment, Safety and Health, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290, Attention: Office of the Docketing Clerk, CXXI, Suite 305, with copies to the Manager, DOE Los Alamos Area Office, and to the cognizant DOE Secretarial Office for the facilities that are the subject of this Notice. This reply should be clearly marked as a "Reply to a Preliminary Notice of Violation" and should include for each violation: (1) admission or denial of the alleged violations, (2) the facts set forth above which are not correct and the reasons for the violations if admitted, and if denied, the reasons they are not correct, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

This Preliminary Notice of Violation will become a Final Notice of Violation if the violation is not denied within 30 days and sufficiently justified.

T. O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety, and Health

Dated at Washington, D.C.
this 18th day of December, 1996