

Subject: LANL EVENT NOTIFICATION

Title: LANL receives a DNA sample potentially contaminated with live organisms

Facility: Health Research Laboratory, TA-43-1 (HRL)

Significance Level: High

Facility Manager Designee: Julie Wilson, 505-667-3448; Jill Trehwella, 505-667-2690

(X) **Synopsis:** On November 20, 2001, Los Alamos National Laboratory issued a press release in response to an inquiry from the Washington Post. The inquiry was regarding the receipt on October 26, 2001, by researchers in B Division of a DNA sample potentially contaminated with viable *Bacillus anthracis*. The shipment was from NNSA-funded researchers at Northern Arizona University, Flagstaff, AZ. The press release follows:

Los Alamos National Laboratory and the National Nuclear Security Administration are reviewing administrative procedures associated with shipment of extracted DNA samples. The review was prompted by receipt at Los Alamos of a sample identified as "virulent" on the accompanying shipping document.

"This incident did not at any point involve any safety risk to Laboratory workers, the public or the environment," said Jill Trehwella, Bioscience Division Leader at Los Alamos. "The issue is one of procedural compliance related to shipping documentation."

Los Alamos has been providing technical DNA analysis support to the federal agencies investigating the anthrax incidents, and the sample was sent as part of that effort. As soon as it was received at Los Alamos, standard safety handling procedures were employed to ensure complete destruction of any potential live organisms. All extracted DNA samples received at Los Alamos are handled on the presumption that they are infectious. "Our policy in this regard is to assure protection of workers, the public and the environment," Trehwella said.

The standard safety handling procedures include filter sterilization and thermal destruction of packaging and filtrate material. These procedures all were employed with the sample in question. Tests after these procedures confirmed there were no residual organisms.

The review is being handled by the Laboratory in conjunction with NNSA and is expected to be completed within 30 days.

For more information, please refer to ORPS report ALO-LA-LANL-HRL-2001-0003



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NOV 20 2001

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Laboratory Registration and Select Agent Transfer Program
Etiologic Agent Import Permit Program
Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Rd. MS A-13
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Mr. Hemphill:

I left you a voice mail message a few minutes ago regarding this subject and spoke to David Bressler in addition.

This is to notify you that an issue involving possible discrepancies of a Form EA-101 involving our contractor, Los Alamos National Laboratory (Requestor) and Northern Arizona University (Transferor) was brought to the attention of the Department of Energy, National Nuclear Security Administration (NNSA), Albuquerque Operations Office yesterday November 19, 2001. The select agent involved was Bacillus anthracis. A review of events and circumstances surrounding this possible discrepancy has been initiated and additional meetings are occurring today. Los Alamos National Laboratory self-reported this possible discrepancy both to the NNSA/Albuquerque Operations Office and to the Centers for Disease Control and immediately took action to establish the factual basis of the concerns; these actions are continuing. Further action on this matter will be based on the results of the review and your office will be notified immediately upon a determination.

If you have any questions or require additional information, please contact me at (505) 845-4827 (desk), 1(888) 540-3681 (pager), or by email at jjohnsen@doe.gov.


John-Olav Johnsen
Acting Senior Technical Advisor
for Bioscience

cc:
John Arthur, OOM
Larry Kirkman, OEOS
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David Gurule, LAAO
Tracy Loughhead, OPA

ALO-LA-LANL-HRL-2001-0003

Notification Report

Occurrence Report

Health Research Laboratory

(Name of Facility)

Balance-of-Plant

(Facility Function)

Los Alamos National Laboratory

Los Alamos National Laboratory

(Laboratory, Site, or Organization)

Name: Julie Wilson
Title: Facility Manager

Telephone No.: (505) 667-3448

(Facility Manager/Designee)

Name: BRAKE, RICK
Title:

Telephone No.: (505) 667-0598

(Originator/Transmitter)

Name: Roger Kruse

Date: 1/21/2001

(Authorized Classifier (AC))

1. Occurrence Report Number: ALO-LA-LANL-HRL-2001-0003

Receipt of DNA Sample Potentially Contaminated with Live Organisms

2. Report Type and Date: Notification

	Date	Time
Notification:	11/21/2001	18:39 (MTZ)
Initial Update:		
Latest Update:		
Final:		

3. Occurrence Category: Off-Normal

4. Number of Occurrences: Original OR:

5. Division or Project: Bioscience Division

6. Secretarial Office: DP - Defense Programs

7. System, Bldg., or Equipment: Health Research Laboratory, BSI.-2 Facilities

8. UCNI?: No

9. Plant Area: TA-43-

10. Date and Time Discovered: 11/20/2001 15:00 (MTZ)

11. Date and Time Categorized: 1/20/2001 16:00 (MTZ)

12. DOE Notification:

13. Other Notifications:

Date	Time	Person Notified	Organization
11/20/2001	15:00 (MTZ)	Herman Ledoux	DOE/LAAO
11/20/2001	15:00 (MTZ)	Fred Bell	DOE/LAAO
11/20/2001	15:00 (MTZ)	John Olav-Johnson	DOE/AL

14. Subject or Title of Occurrence:

Receipt of DNA Sample Potentially Contaminated with Live Organisms

15. Nature of Occurrence:

- 10) Cross-Category Items
- C. Potential Concerns/Issues

16. Description of Occurrence:

MANAGEMENT SYNOPSIS: On November 20, 2001, Los Alamos National Laboratory (LANL) issued a press release in response to an inquiry from the Washington Post regarding the receipt on October 26, 2001, by researchers in Bioscience Division of a DNA sample potentially contaminated with viable *Bacillus anthracis*. LANL is not currently registered with the Centers for Disease Control and Prevention (CDC) to receive viable *B. anthracis* for routine work. The shipment was from NNSA-funded researchers at Northern Arizona University (NAU), Flagstaff, AZ, and was in direct support of law enforcement efforts related to recent anthrax incidents. The media inquiry and press release are reported here based on the potential for adverse publicity. CDC has rendered a preliminary ruling that, because the work was direct support of law enforcement, the shipment was exempt from the registration limitation, and was in full regulatory compliance. This incident did not at any point involve any safety risk to Laboratory workers, the public, or the environment.



BACKGROUND:

Under sponsorship of NNSA, the LANL Bioscience Division has been providing DNA analysis support to the federal agencies investigating anthrax incidents. The work is in collaboration with NNSA-funded researchers at NAU. NAU personnel extract DNA from viable *B. anthracis*, sterilize the DNA sample, confirm the sterilization by culture, then ship the sterile DNA samples to LANL for further analysis in B Division's Biosafety Level-2 (BSL-2) facilities. The work is performed under CDC regulations and registrations of the participating laboratories. Shipments between laboratories are processed using CDC Form EA 101: Transfer of Select Agent. At the time of the incident LANL was registered to receive only sterile (non-virulent) DNA samples using Form EA 101. LANL was in transition through internal processes to implement procedures to operate under an exemption of 42 CFR 72.6 that allows transfer of select agent materials in support of law enforcement activities.

Between October 23 and October 25, 2001, one of three DNA samples being prepared for shipment at NAU failed a sterility test. On October 25, NAU shipped this sample to LANL. The sample was packaged and labeled compliant with DOT regulations for shipment of infectious agents, and the accompanying form EA 101 identified the contents as "virulent." NAU telephoned LANL to ensure LANL personnel were aware of the potential contamination of the shipped sample prior to receiving it. Upon receipt at Los Alamos, standard safety handling procedures were employed to ensure complete destruction of any potential live organisms. As a precaution, all extracted DNA samples received at Los Alamos are handled as though they were infectious. The standard safety handling procedures include filter sterilization and thermal destruction of packaging and filtration apparatus. These procedures all were employed with the sample in question. Tests after these procedures confirmed there were no residual viable organisms.

17. Operating Conditions of Facility at Time of Occurrence:

Normal

18. Activity Category

03 - Normal Operations

19. Immediate Actions Taken and Results:

On November 17, the Bioscience Division Leader and the Bioscience Safety Officer reviewed the shipment of virulent material using Form EA 101 and the possible violation of work controls by B Division personnel, and as a precaution the B Division Leader suspended all BSL-2 operations until a review with the BSL-2 workforce could be completed.

B-DO convened critiques of the events on November 18, 19, and 20, attended by B-DO, HRL Facility Management, ESH, DOE LAAO, and DOE AL representatives.

On November 19, B-DO held an informational meeting with all BSL-2 workers, reviewed safety requirements, announced additional interim requirements, and solicited BSL-2 workers' concerns. Following the meeting, all BSL-2 work was resumed except the receipt of select agent DNA, which, as of November 21, remains in review.

On November 19, the LANL Responsible Facility Official reported in writing to CDC the discrepant use

of Form EA 101 for the October 26 transfer of virulent material. On November 21, CDC provided a verbal response that because there is an exemption in 42 CFR 72.6 for work in support of law enforcement, the transfer was compliant with all regulations, and no regulatory action was anticipated. A written confirmation of this CDC position is expected to follow.

As of November 21, 2001, no adverse publicity has been noted.

Recognizing that, though all LANL safety procedures were followed, certain internal administrative procedures were not followed in the shipping and tracking documentation, the LANL Director's Office chartered a review of administrative procedures associated with the work. The review is being performed by the Laboratory in conjunction with NNSA and is expected to be completed within 30 days.

20. Direct Cause:

21. Contributing Cause(s)

22. Root Cause:

23. Description of Cause:

24. Evaluation (by Facility Manager/Designee):

25. Is Further Evaluation Required?: Yes

If YES - Before Further Operation? No

By whom? HRL FM

By when? (Not given)

26. Corrective Actions

(* = Date added/revised since final report was approved.)

27. Impact on Environment, Safety and Health:

There was no adverse impact on the environment or to the safety and health of workers or the public as result of this incident.

28. Programmatic Impact:

BSL-2 operations were suspended four normal working hours the morning of November 19, 2001, with minimal impact on programs. Receipt of select agent DNA was suspended beyond three working days,

but as no receipts were anticipated this was of no impact as of November 21, 2001

29. Impact on Codes and Standards:

None

30. Lessons Learned:

31. Similar Occurrence Report Numbers:

None

32. User-defined Field #1:

33. User-defined Field #2:
