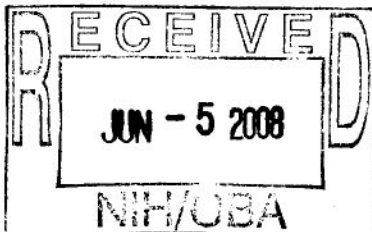




The University of Texas at San Antonio

Environmental Health, Safety and Risk Management



June 2, 2008

Amy P. Patterson, M.D.
Director
NIH Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Patterson,

In your letter dated May 13, 2008 you requested that the University of Texas at San Antonio develop a policy on reporting of incidents in laboratories working with recombinant DNA to the OBA. Attached is the policy which has been drafted.

This policy will be disseminated to the pertinent personnel through the Dean of the College of Sciences, as soon as your approval of the policy has been received. It will be added to our Biosafety Training course which all personnel working with recombinant DNA are required to take. It will also be added to the training course provided to our research personnel working with select agents.

If you have any questions, feel free to contact me at (210) 458-5250.

Sincerely,

J. Brian Moroney
Director
Environmental Health, Safety and Risk Management

UTSA Policy for Reporting Incidents to NIH

UTSA receives NIH funding and, therefore, must comply with the mandatory *NIH Guidelines for Research Involving Recombinant DNA Molecules*. A portion of these guidelines relates to reporting requirements for incidents in research laboratory working with rDNA. This policy provides guidance for what types of incidents must be reported to NIH and how this reporting should be done.

Types of Incidents to be reported: Incidents involving significant problems, violations of NIH Guidelines, significant research-related accidents and illnesses, spills in BSL-2 laboratories resulting in an overt exposure or breach of containment, spills or accidents in BSL-3 laboratories resulting in an overt or potential exposure or breach of containment. When in doubt about whether an accident needs to be reported, contact UTSA's Biological Safety Officer (BSO) or NIH's Office of Biotechnology Activities (OBA).

Reports of Incidents at UTSA will be made by the Institutional Biosafety Committee (IBC) or the BSO. All incidents must first be reported to the BSO or the chair of the IBC. Further information can be found at: <http://vpr.utsa.edu/oric/ibc/>. The BSO can be reached through Environmental Health, Safety and Risk Management at X5250. If the IBC and BSO fail to report an incident to NIH, it is ultimately the principle investigator's responsibility to send in the report.

NIH has a specific timeframe for reporting incidents. Most incidents must be reported within 30 days to the OBA. Some incidents must be reported immediately to OBA. These include accidents or spills in BSL-2 laboratories resulting in an overt exposure or spills or accidents occurring in BSL-3 laboratories resulting in an overt or potential exposure.

A complete copy of the NIH Guidelines can be found at:
http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm .

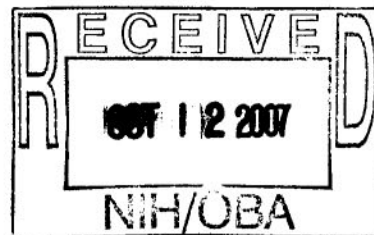
Guidance on reporting incidents can be found at:
<http://www4.od.nih.gov/oba/IBC/Incidents.htm>.



The University of Texas at San Antonio

Environmental Health, Safety and Risk Management

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist (contractor)
NIH Office of Biotechnologies Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Tel: (301) 435-2149
Fax: (301) 496-9839



Dr. Whitney:

Attached to this letter are the documents that were submitted to CDC in regards to the occurrence CDC asked us to file in the form of an "incident" report with regards to our BSL-3 lab on April 12, 2007. While this lab does work with recombinant DNA, no lab work was in progress during this time. The agent was secured and the working surfaces had been decontaminated. Several hours of air changes had been allowed prior to the entry into the lab as per our entry / exit procedure for maintenance. Under CDC regulations this is not an incident. Under University regulations this was considered an incident that occurred (occurrence) due to a failure of a trained and authorized Facilities maintenance supervisor to follow posted protocol in regards to using respiratory protection in the lab.

While no exposure is believed to have been possible in this incident, and federal regulations do not require respiratory protection for the procedure being performed, it is our policy to allow anyone who enters the BSL-3 lab without respiratory protection to consult with a licensed healthcare professional. All three people involved in this occurrence chose medical consultation with physicians who are not on staff at our institution. The decision to take a prophylactic round of antibiotics was made by the personnel and the physician. None of the individuals involved in the occurrence have ever shown any signs or symptoms of an exposure to the *F. tularensis* agent used in the BSL-3 lab.

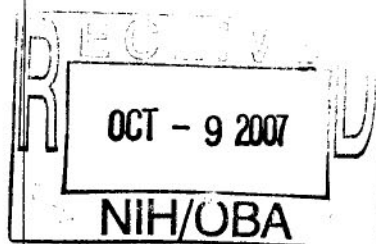
Our office did not feel that this occurrence was reportable to either NIH or CDC. Initially CDC agreed with this assessment. Later we were contacted and asked to submit a Form 3. We therefore submitted the Form 3 and other follow-up documentation. A review of the OBA's frequently asked questions website on whether or not to report an incident seems in our opinion to indicate that more serious incidents need to be reported. In our case there was no spill or accident, containment was not breached, and no injury or illness resulted from the incident.

Respectfully,

J. Brian Moroney
Director of Environmental Health, Safety & Risk Management
Responsible Official for the UTSA Select Agent Program

Pages 7 through 16 redacted for the following reasons:

Other Agency Document

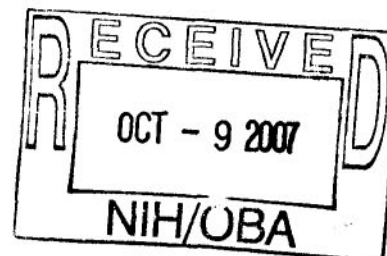
FAX**Date** 10/08/2007**Number of pages including cover sheet** 12**TO:** Dr. Bruce Whitney**Phone** 301-435-2149**Fax Phone** 301-496-9839**FROM:** J. Brian Moroney
Environmental Health, Safety
& Risk Management
University of Texas at San
Antonio
One UTSA Circle
San Antonio, Texas 78249-
0672**Phone** (210) 458-5250**Fax Phone** (210) 458-5813**CC:****REMARKS:**☐ Urgent☒ For your review☐ Reply ASAP☐ Please Comment



The University of Texas at San Antonio

Environmental Health, Safety and Risk Management

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist (contractor)
NIH Office of Biotechnologies Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Tel: (301) 435-2149
Fax: (301) 496-9839



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Our office did not feel that this occurrence was reportable to either NIH or CDC. Initially CDC agreed with this assessment. Later we were contacted and asked to submit a Form 3. We therefore submitted the Form 3 and other follow-up documentation. A review of the OBA's frequently asked questions website on whether or not to report an incident seems in our opinion to indicate that more serious incidents need to be reported. In our case there was no spill or accident, containment was not breached, and no injury or illness resulted from the incident.

Respectfully,

J. Brian Moroney
Director of Environmental Health, Safety & Risk Management
Responsible Official for the UTSA Select Agent Program

Pages 19 through 28 redacted for the following reasons:

Other Agency Document

Whitney, Bruce (NIH/OD) [C]

From: Whitney, Bruce (NIH/OD) [C]
Sent: Thursday, September 20, 2007 9:53 AM
To: 'Wendy McCoy'
Subject: RE: Reporting Requirement

Dear Ms McCoy,

Thank you for the information you provided to me in response to my call concerning the April 11, 2007 incident at The University of Texas at San Antonio. So that we can better understand what occurred, the NIH Office of Biotechnology Activities (OBA) requests that you provide us with a written report of the incident.

For information regarding the reporting of incidents to OBA, please see our FAQ, "Incident Reports to the NIH Office of Biotechnology Activities (OBA), at <http://www4.od.nih.gov/oba/IBC/Incidents.htm>. In addition, if you have any additional questions, please don't hesitate to call or email us.

Regards,

Bruce

Bruce Whitney, Ph.D.
Senior Biosafety and Outreach Specialist (contractor)
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Tel: (301) 435-2149
Fax: (301) 496-9839

-----Original Message-----

From: Wendy McCoy [mailto:Wendy.McCoy@utsa.edu]
Sent: Wednesday, September 19, 2007 11:49 AM
To: Whitney, Bruce (NIH/OD) [C]
Cc: Brian Moroney
Subject: Reporting Requirement

Mr. Whitney,

As per our phone conversation yesterday afternoon, I have spoken with the PI and recombinant DNA work is done in the lab in question. No work was being done at the time of the incident, all agents were secured and the surfaces had been decontaminated. The incident did not involve an accident or spill, but was a failure to follow procedure.

I reviewed the website and was not able to find reporting guidance other than for adverse events. I would appreciate any further guidance you can provide us on this matter.

Sincerely,

10/15/2007

Wendy McCoy

Laboratory Safety Officer

The University of Texas at San Antonio

210-458-6101 (office)

210-458-5250 (main office)

Whitney, Bruce (NIH/OD) [C]

From: Wendy McCoy [Wendy.McCoy@utsa.edu]
Sent: Wednesday, September 19, 2007 11:49 AM
To: Whitney, Bruce (NIH/OD) [C]
Cc: Brian Moroney
Subject: Reporting Requirement

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Sincerely,

Wendy McCoy










Laboratory Safety Officer

The University of Texas at San Antonio

210-458-6101 (office)

210-458-5250 (main office)

SAFETY
Risk Management

 Workplace |
  Laboratory |
  Radiation |
  Environmental |
  Construction |
  Waste |
  Recycling |
  Risk Mgmt |
  Emergencies |

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Laboratory Safety

- Lab Safety Home
- Manuals
- Training
- IBC Home
- MSDS
- Controlled Substances
- New P.I. Information
- Important Links
- UTSA Plans
- Laboratory Evaluations
- Children in Labs
- Contact Information

 Printable Format
Weekly Safety Tip**Tough Lifting Jobs**

Oversized loads: do not try to carry a big load alone; ask for help. Work as a team by lifting, walking and lowering the load together. Let one person call the shots and direct the lift. Use proper mechanical devices for heavy loads.

**UTSA Laboratory Safety Contact Information****Lab Safety Officer**

Put descriptive text as to why you should contact the Laboratory Safety Officer here

Wendy McCoy, MS, CHMM, CBSP
(210) 458-6101

E-MAIL WENDY

Laboratory Specialist I

Put descriptive text as to why you should contact the Laboratory Safety Specialist I here

Jessica Moshfeghian-Prado
(210) 458-6697

E-MAIL JESSICA

Environmental Safety Manager

Put descriptive text as to why you should contact the Environmental Safety Manager for Laboratory Safety issues here

Richard Garza, REM
(210) 458-5808

E-MAIL RICHARD

Hazardous Waste Specialist

Put descriptive text as to why you should contact the Hazardous Waste Specialist for Laboratory Safety issues here

Israel Falcon
(210) 458-6698

E-MAIL ISRAEL

Biological Waste Technician

Put descriptive text as to why you should contact the Hazardous Waste Specialist for Laboratory Safety issues here

Rudy Hernandez Jr



The University of Texas at San Antonio

Environmental Health, Safety and Risk Management

TO: Robert W. Gracy – Vice President for Research

FROM: J. Brian Moroney – Director of EHSRM

THROUGH: Pamela Bacon – AVP – Administration
Julie Olson – Administrative Services Officer III

DATE: September 4, 2007

SUBJECT: Clarification of UTSA EHSRM Incident Report dated 04/12/2007

On page 2 of the Environmental Health, Safety and Risk Management internal Incident Report dated 04/12/2007, regarding the BSL-3 facility (copy attached); the question was raised as to why the "INJURY" box was checked, when in fact, there was no actual injury to any employee? This box was checked to alert my office to follow-up as a potential reportable Worker's Compensation incident and is a shortcoming of the form itself as this was an unusual case and it was unclear which boxes best to check. My office will update the current form to better reflect possible choices for future incidents.

INCIDENT REPORT

UTSA Environmental Health, Safety and Risk Management

Date: 04/12/2007
M D Y

Time: 1355
(24 Hr)

Campus: X1604

Location: Bldg: BSB Room [REDACTED]

☐ DT

☐ ITC

Other Location:

Person Reporting: Dr. Karl Klose

Phone/ Ext: 6140

Assigned to: Person Wendy McCoy

Division: LSD

Short description of incident as reported: Persons noted in BSL-3 without respiratory protection.

Nature of Incident: (Choose one)

<input type="checkbox"/> Accident	<input type="checkbox"/> Recycle	<input type="checkbox"/> Egress/Life Safety
<input type="checkbox"/> Fire Alarm	<input type="checkbox"/> Fire Suppression	<input type="checkbox"/> Water Intrusion
<input type="checkbox"/> Odor	<input type="checkbox"/> Mold (visible/suspect)	X Other : Lack of required safety equipment
SPILL	EXPOSURE	SELECT AGENT
<input type="checkbox"/> Biological	<input type="checkbox"/> Biological	<input type="checkbox"/> Theft
<input type="checkbox"/> Chemical	<input type="checkbox"/> Chemical	<input type="checkbox"/> Spill
<input type="checkbox"/> Radioactive	<input type="checkbox"/> Radioactive	X Potential Exposure

Result of Investigation: Dr. Klose, Dr. Arul, and Dr. Yu had all observed persons in the BSL-3 lab without respiratory protection. I knew [REDACTED] had been in the lab today so I attempted to call him and the lab, but did not get an answer. Jessica and I went over to see if the persons were still in the lab. We entered the BSL-3 and found [REDACTED] and Dr. Yu in the changing room. [REDACTED] was not wearing any protective equipment, but had not entered the main lab room. [REDACTED] and Dr. Yu were wearing appropriate PPE. Dr. Yu had just arrived and gotten them the PPE. [REDACTED] and [REDACTED] had entered the lab without respiratory PPE. [REDACTED] had touched HEPA filters without gloves.

Corrective Action: I met with [REDACTED] and discussed the symptoms of tularemia. We discussed that the lab had been routinely cleaned the previous night and exposure was unlikely, but they were offered (on the advice of Drs Arul, Klose, and Guentzel) prophylactic antibiotics. They were given paperwork from WCI as well as information on treatments for tularemia and contact phone numbers. Each indicated that they would get the antibiotics.

Injury: ☒ Yes ☐ No ☐ N/A

Near Miss: ☒ Yes ☐ No

Employee: X Yes ☐ No

Injured Name: _____

If yes, WCI Claim #: [REDACTED] 0730114 ; [REDACTED] 0730115 ; [REDACTED] 0730116

If no, Tort Claim Notification: ☐ Yes ☐ No

Report prepared by: Wendy McCoy

Date: 4/12/07

Assigned: 0045

Database entry: YMW 4/13/07

Wendy McCoy

From: Wendy McCoy
Sent: Thursday, April 19, 2007 3:14 PM
To: 'McClee, Vondguraus (CDC/COTPER/DSAT) (CTR)'
Cc: Brian Moroney
Subject: Incident in BSL-3 Laboratory

Good afternoon Von,

As per our conversation this morning, I am sending you information on an incident that occurred in our BSL-3 lab in the BSB building. On April 11, 2007 high negative pressure was reported in the lab after work hours. On April 12, 2007 Facilities workers, who have been trained on BSL-3 procedures, under the direction of a Facilities supervisor with approved access to the lab entered the lab. The supervisor and one of the workers were unable to locate PAPRs and the two of them entered the lab without respiratory protection. The third worker remained behind in the changing room to pass through tools as necessary. The researchers noted the lack of respiratory equipment on the workers while viewing the lab cameras. One researcher went to the lab and got the Facilities workers into the proper PPE while another reported the incident to me as ARO. I followed up on the issue with a visit to the lab, meetings with the three workers to discuss proper procedures, which they were aware of, and symptoms of tularemia. Active lab work had last been carried out in the lab the previous night after which the surfaces were decontaminated. During this incident, no active research was in progress, the pressure remained negative and no release of agent occurred. While the PI's and I felt that it was highly unlikely that the three workers had contacted any *F. tularensis* while in the laboratory, we followed our procedures and recommended that the workers get prophylactic antibiotic treatments. All three agreed and went to different medical providers for treatment paid for by the university. Two workers were asked to return for follow-ups. If the follow-up visits or other information shows that an infection or infections occurred, the CDC will be informed immediately. An incident report will be kept on file in our office.

Thank you,

Wendy McCoy

ARO

UTSA

Tracking:

Recipient

'McClee, Vondguraus (CDC/COTPER/DSAT) (CTR)'

Brian Moroney

Delivery

Delivered: 4/19/2007 3:14 PM

Pages 37 through 40 redacted for the following reasons:

Other Agency Document



The University of Texas at San Antonio

Environmental Health, Safety and Risk Management

TO: Carlos Alonso – Acting Facilities Director of Operations
Dave Riker - AVP Facilities

FROM: J. Brian Moroney – Director of EHS&RM and Responsible Official for
UTSA Select Agent Program

DATE: April 23, 2007

SUBJECT: Facilities Incident: BSB BSL-3 on April 12, 2007

On April 12, 2007 at approximately 1:55 pm, Wendy McCoy was notified by Dr. Karl Klose, Principal Investigator for the *Francisella tularensis* vaccine research program, that Facilities personnel had been observed via CCT monitors entering the BSB BSL-3 suite 3.03.22T, past the anteroom, and into the lab area without donning appropriate personal protective equipment (PPE). This is a serious breach of BSL-3 protocol and instructions for entering the lab area from the anteroom are clearly posted on the entry door. No research was ongoing in the lab at the time of entry, however minimum PPE of an N-95 respirator, body suit and booties is required to enter at any time for maintenance.

██████████ – PM Supervisor, who is a CDC/FBI authorized and BSL-3 trained employee, used his magnetic swipe card to enter the facility and ██████████ Operator accompanied him through the door. A third operator, ██████████ remained in the anteroom to pass through tools as needed. ██████████ and his Facilities crew were entering to change out problematic supply air HEPA filters.

Dr. Klose immediately sent over Dr. Yu, who got the Facilities personnel out of the lab area and into appropriate PPE. Wendy also arrived on the scene at this time and after consultation with the research staff (Drs. Klose, Arul, and Guentzel) and myself, the decision was made to offer the 3 affected employees a medical consultation and prophylactic antibiotic even though no research was ongoing and the lab had been surface disinfected the previous shift. Marty Contreras, Occupational Safety Specialist with EHSRM, will continue to work with the medical providers to monitor the employees over the next 2 weeks for any signs of tularemia infection, however remote the chance.

As Responsible Official for the UTSA Select Agent Program, I have instructed Wendy McCoy to do an immediate review of BSL-3 entry procedures with all appropriate Facilities staff (annual training is required). Additionally, I am notifying you that if ██████████ enters any BSL-3 facility again without following proper procedures, I will immediately remove his access privileges. Again, I consider this a serious breach of protocol and his lapse in judgment also placed other employees at potential risk. Please contact myself or Wendy McCoy, Laboratory Safety Officer and Alternate Responsible Official if you have any further questions.

Cc: SAP file

BSL-3 & Select Agent Policy and Procedures (including Entry/Exit) Training – Rev 11/11/05

Discussed routes of exposure and precautions necessary (including Personal Protective Equipment) for the agents *F. tularensis* and *C. immitis* / *posadasii*. Discussed Select Agent & Toxin security and emergency response requirements as listed in 42 CFR §73. Also discussed proper entry and exit procedures for the BSB and MBT ABSL/BSL-3 facility.

[illegible]

Trainer(s) Wendy McCarty Title: Lab Safety Officer Date: 12-17-06
 Title: _____

**University of Texas at San Antonio (UTSA)
SELECT AGENTS & TOXINS TRAINING FORM
Biosafety, Security and Incident Response Plans BSB & MBT BSL-3 Laboratories**

The following topics were covered during this training session:

1. Definitions: Select Agent & Toxin; Biosafety Level 3
2. Regulatory background: 1989 Bio-weapons Act; 1996 Act—Created Select Agents; 2001 USA PATRIOT Act; 2002 Bio-terror Act
3. 42 CFR 73, Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule—Covered new requirements to include: Registration; Security Risk Assessments; Responsible Official & Alternate; Safety & Security Plans; Emergency Response Plans
4. Training Requirements under 42 CFR 73; special requirements for BSL-3 Facility
5. Agent inventory, transfer, shipping, and record keeping requirements
6. Notification of theft, loss, or release of a select agent or toxin
7. Civil & criminal penalties for non-compliance
8. Agents / toxins used at UTSA

Question & Answer Session

All my initial questions pertaining to the above listed topics were answered to my satisfaction and I understand I may contact my supervisor, or the Environmental Health Safety & Risk Management Office for further questions or clarification.

I understand the information presented in this training session and I further understand that it is my responsibility to comply with the safety requirements listed in the *UTSA Tularemia BSL-3 (BSB 3.03.22T1) – Site Specific Biosafety & Good Laboratory Practices Manual* and/or the *UTSA Coccidioides/Francisella BSL-3 (Tobin 1.304) – Biosafety and Laboratory Practices Manual* as well as the *UTSA Bloodborne Pathogen Exposure Control Plan* as they apply to my job function, including the wearing of appropriate Personal Protective Equipment. I also understand that my failure to do so may subject me to disciplinary action and removal from access to the BSL-3 laboratory (ies).

NAME (PRINT): _____

DATE: 10-17-06

SIGNATURE: _____

SUPERVISOR: CARLOS ALONSO

EMPLOYEE ID: 000523841

DEPARTMENT: FACILITIES

JOB TITLE: MAINTENANCE LEADER

TRAINER (Please check box):

☒ Wendy R. McCoy

☐ OTHER: _____

TRAINER TITLE:

Laboratory Safety Officer

RETURN ORIGINAL FORM TO SAFETY OFFICE – BSA 1.01.18

[Retain on file a minimum of 3 years]

REVISION 11/1/05

Pages 44 through 48 redacted for the following reasons:

Other Agency Document