On 4/13/06 6:41 AM, "David N. McMurray" <mcmurray@medicine.tamhsc.edu> wrote:

> Dear Tom:
> We have used the chamber several times for TB infections since
> last October. I could put a complete calendar of those exposures
> together for you, if you think that would be helpful. Since March 1, we
> have used the chamber at least three times that I can recall. I was
> present at most of those infection procedures and all three procedures
> in March, along with various other members of my research team. I am
> virtually certain that was not involved in any of the
> exposures which took place in March. I know of no evidence of
> cross-contamination of our guinea pigs exposed to TB during the interval
> since you began using the chamber, based upon bacterial culture of lungs
> and spleens. A large number of animals have been necropsied in the past
> 6 months, and I feel that any significant cross-infection would have
> been apparent.
> I agree that chamber interior surface or animal basket
> contamination is the most likely source of a contact infection involving
> the conjunctiva. Safe decontamination is certainly an important aspect
> of chamber use. I am ready to work with you to insure the safety of
> future experiments.
>
> Take care,
>
> David
>
>>>> Tom Ficht <tficht@cvm.tamu.edu> 4/12/2006 7:33 PM >>>
> Dave,
>
> I was working on this time line for our experiments and it raised a
> couple
> questions.
>
> 10/5/05 Initial trials
>
> 2/9/06 Second set of vaccine trials
>
> 3/1/06 Knockout mouse infections
>
>
> Now I know was there for the first two, but I do not think
> was
> there for the last one. I was also only there for the first trial.
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> My question is whether used the chamber since March 1st?
> Although
> it would seem more likely that was infected when Brucella was
> actively

> used, the possibility exists that was infected during a subsequent
> visit. I have no reason to suspect that the chamber and room were not
> cleaned properly, but the time to onset of illness would fit for
> either
> date, i.e., 3-8 weeks. But if a latter exposure is a possibility, I
> also
> wondered if there was any evidence of brucellosis in your experimental
> animals.
>
> The one certainty in my mind is that in order to enhance the safety of
> lab
> personnel, I have to be present during any use of the equipment to
> make
> certain it and the room are cared for and properly cleaned.
>
> Tom
>
>
>
>
>
> Thomas A. Ficht, Ph.D.
> Professor
> Veterinary Pathobiology
> Texas A&M University
> 4467 TAMU
> College Station, TX 77843-4467
> 979-845-4118 ph
> 979-862-1088 fax
>
>

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

ID: 79
DATE: 2006-04-13 09:28:45
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: Melissa Kahl-McDonagh <mkahl@cvm.tamu.edu>, Jianwu Pei <jpei@cvm.tamu.edu>
SUBJECT: FW: Madison Chamber
MAILBOX: Exposures.mbox

This message seems to pinpoint exposure to 2/9/06 or earlier.

Taqf

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

------ Forwarded Message
> From: "David N. McMurray" <mcmurray@medicine.tamhsc.edu>
> Date: Thu, 13 Apr 2006 06:41:53 -0500
> To: <tficht@cvm.tamu.edu>
> Subject: Re: Madison Chamber
>
> Dear Tom:
> We have used the chamber several times for TB infections since
> last October. I could put a complete calendar of those exposures
> together for you, if you think that would be helpful. Since March 1, we
> have used the chamber at least three times that I can recall. I was
> present at most of those infection procedures and all three procedures
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> cleaned properly, but the time to onset of illness would fit for
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> Professor
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> Texas A&M University
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>
>

------ End of Forwarded Message

ID: 78
DATE: 2006-04-20 18:56:31
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: <cmcfarland@medicine.tamhsc.edu>
SUBJECT: Workmen's Compensation

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used, the possibility exists that [redacted] was infected during a subsequent visit. I have no reason to suspect that the chamber and room were not cleaned properly, but the time to onset of illness would fit for either
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4467 TAMU
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979-845-4118 ph
979-862-1088 fax

ID: 80
DATE: 2006-04-13 08:08:06
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: David N. McMurray <mcmurray@medicine.tamhsc.edu>
SUBJECT: Re: Madison Chamber
MAILBOX: Exposures.mbox

Dave,

Thanks for your continued support and assistance.

I was told yesterday that anyone concerned about potential exposure are welcome to go to Scott & White desk E (Occupational Health) to have blood drawn for testing anytime this week. Just mention that you are their as part of the TAMU occupational health program. If you have not been to Scott & White before they will require some simple information (name, address, SS#, etc).

tom

ID: 153
DATE: 2006-04-13 06:43:38
FROM: David N. McMurray <mcmurray@medicine.tamhsc.edu>
TO: <tficht@cvm.tamu.edu>
SUBJECT: Re: Madison Chamber
MAILBOX: Exposures.mbox

Dear Tom:

We have used the chamber several times for TB infections since last October. I could put a complete calendar of those exposures together for you, if you think that would be helpful. Since March 1, we have used the chamber at least three times that I can recall. I was present at most of those infection procedures and all three procedures in March, along with various other members of my research team. I am virtually certain that ' was not involved in any of the exposures which took place in March. I know of no evidence of cross-contamination of our guinea pigs exposed to TB during the interval since you began using the chamber, based upon bacterial culture of lungs and spleens. A large number of animals have been necropsied in the past 6 months, and I feel that any significant cross-infection would have been apparent.

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Take care,

David

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Now I know was there for the first two, but I do not think was
there for the last one. I was also only there for the first trial.

My question is whether used the chamber since March 1st? Although

MAILBOX: Exposures.mbox

Here is a draft of my incident report.

Tom

I wanted to let you know that has been diagnosed with brucellosis. apparently contracted the disease during an experimental challenge at on the ninth of February 2006. At that time along with Dr. McMurray were training us in the use of the Madison chamber for aerosol inoculations.

has been home sick for several weeks being treated by personal physician and was only recently diagnosed. I heard about this last week (Mon or Tues) and instructed other personnel present at that challenge to have an an immediate blood draw for testing. The results should be available in another week or two.

We do not know the exact cause of ' exposure, although we assume it may have occurred as a result of cleaning out the Madison chamber after an aerosol run. In the future we plan to flush the chamber with disinfectant rather than using manual cleaning methods. The chamber will be wiped out after running disinfectant through the chamber, but this will involve the use of a long-handled applicator or mop. In addition, we will not rely on the use of N95 face masks and will instead use positive air displacement respirators.

In the initial aerosol trials we relied on the experience of the TB researchers for the level of precaution typically employed in such experiments. It is my fault for not recognizing the differences between Brucella and Mycobacteria in regard to routes of infection. It is suspected that a conjunctival route of infection is responsible for infection, perhaps as a result of manually cleaning the Madison chamber.

An isolate was made from a culture of blood and has been sent to TDH for confirmation. It would be helpful if EHSD could requested a sample of this isolate for culture confirmation here.

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph

979-862-1088 fax

ID: 77
DATE: 2006-04-21 13:27:24
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: Mattox, Brent S <bsmattox@tamu.edu>, Angelia Raines <ARaines@vprmail.tamu.edu>,
Tiffany Agnew <tmagnew@tamu.edu>,L. Garry Adams <gadams@cvm.tamu.edu>,
David N. McMurray <mcmurray@medicine.tamhsc.edu>, <njones@medicine.tamhsc.edu>
Jeanine Malazzo <jmalazzo@cvm.tamu.edu>, Betty Suehs <BSUEHS@cvm.tamu.edu>,
John Park <john-park@tamu.edu>
SUBJECT: FW: Workmen's Compensation
MAILBOX: Exposures.mbox

> Brent
>
> I wanted to let you know that . has been diagnosed with
> brucellosis. apparently contracted the disease during an
> experimental challenge at LARR (CMP) on the ninth of February 2006. At that
> time ' along with Dr. McMurray were training us in the use of the
> Madison chamber for aerosol inoculations.
>
> nas been home sick for several weeks being treated by personal
> physician and was only recently diagnosed. I heard about this last week
> (Mon or Tues) and instructed other personnel present at that challenge to
> have an an immediate blood draw for testing. The results should be
> available in another week or two.
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> it may have occurred as a result of cleaning out the Madison chamber after
> an aerosol run. In the future we plan to flush the chamber with
> disinfectant rather than using manual cleaning methods. The chamber will be
> wiped out after running disinfectant through the chamber, but this will
> involve the use of a long-handled applicator or mop. In addition, we will
> not rely on the use of N95 face masks and will instead use positive air
> displacement respirators.
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> researchers for the level of precaution typically employed in such
> experiments. It is suspected
> that a conjunctival route of infection is responsible for
> infection, perhaps as a result of manually cleaning the Madison chamber.
> It is my fault for not recognizing the differences between Brucella and
> Mycobacteria in regard to routes of infection.
>
> An isolation was made from a blood culture by physician and
> sent to TDH for confirmation. It would be helpful if EHSD could requested
> a sample of this isolate for culture confirmation here.
>
>
>
> Thomas A. Ficht, Ph.D.

> Professor
> Veterinary Pathobiology
> Texas A&M University
> 4467 TAMU
> College Station, TX 77843-4467
> 979-845-4118 ph
> 979-862-1088 fax

ATTACHMENTS:

ID: 76
DATE: 2006-04-25 11:46:13
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: @medicine.tamhsc.edu>
SUBJECT: Re: <no subject>
MAILBOX: Exposures.mbox

I have not heard back from Brent and I think anything will work. But according to the select agent guidelines we are required to report any laboratory exposures to the CDC. So I guess he will need to have some record. I do not know how this impacts on your personal files??? Since this has been done through a personal physician you may be within your rights to deny any of these requests. Having said that I don¹t know either way how this would impact me or the university, but that should not be your concern.

I guess as PI I can¹t help but be involved, but it does seem like something that is best handled between you and Brent Mattox (as representative of EHSD).

I am glad to help (as a non-physician), and would like to suggest that you take part in our blood testing so that we can carefully watch your titer. Perhaps you could ask your personal doctor his thoughts?

Another thought is for you to go to Scott and White and get a blood draw immediately (desk E is Occupational Health) . I can meet you there if you like.

tom

On 4/25/06 11:30 AM, @medicine.tamhsc.edu>
wrote:

> Tom,

>
> All I have is a preliminary report on the blood cultures done at St. Jose=
ph's
> as well as the earlier report from CPL on the first blood culture. Serol=
ogy
> was never done on me. Is this what Brent needs to see? I can copy both
> sheets and campus mail them to you tomorrow as I don't have them here at =
work.
>
>
>
>>>> >>> Tom Ficht <tficht@cvm.tamu.edu> 04/24/06 4:56 PM >>>
> Oddly, they asked me to find out about Dr. Ding's number.
>
> I will ask if we can get this info through I was consider=
ing
> asking to take part in our blood testing program which we were going =
to
> schedule in May. Unless you think we need it sooner.
>
>
> On 4/24/06 4:03 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:
>
>> > By the way, I heard from Scott & White today: all titers were negative=
. I
>> do
>> > need a copy of the Lab results on though. I can g=
o the
>> > long route or would perfer getting a copy through , if possib=
le.
>> Did
>> > you have her retested at S&W?
>> >
>> > As to the Ding subject, I don't understand why you had to contact Virg=
inia
>> > Tech instead of our illustrious Office of Compliance. Isn't that their=
 job?
>> >
>> > Brent
>> >
>> > -----Original Message-----
>> > From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
>> > Sent: Monday, April 24, 2006 1:51 PM
>> > To: Charlotte Waggoner
>> > Cc: Raines, Angelia; Tiffany Agnew; Mattox, Brent S
>> > Subject: Re: <no subject>
>> >
>> > Thanks. CDC's approval process doesn't seem to be getting any faster.=
 I
>> will
>> > pass this on to my compliance office.

>> >
>> > Taf
>> >
>> >
>> >
>> >
>> > On 4/24/06 1:09 PM, "Charlotte Waggoner" <ren@vt.edu> wrote:
>> >
>>> >> Hi Dr. Ficht....
>>> >>
>>> >> Xicheng's DOJ ID number at Virginia Tech was C-XD-012047. Hope this
>>> helps...
>>> >>
>>> >> At 10:53 AM 4/24/2006, you wrote:
>>>> >>> Dear Ms. Waggoner
>>>> >>>
>>>> >>> We are aware of the need to renew Dr. Ding¹s CDC approval. We wer=
e
>>>> >>> asked by our compliance office to obtain his previous number to
>>>> >>> expedite this request.
>>>> >>>
>>>> >>> If you prefer I will ask that the compliance office contact you
>>>> >>> directly for this info.
>>>> >>>
>>>> >>>
>>>> >>> Charlotte M. Waggoner, RBP
>>>> >>> University Biosafety Officer/Responsible Official Environmental,
>>>> >>> Health and Safety Services (MS 0423) Virginia Tech
>>>> >>> 459 Tech Center Drive
>>>> >>> Blacksburg, Virginia 24061
>>>> >>> http://www.ehss.vt.edu/
>>>> >>>
>>>> >>> ren@vt.edu
>>>> >>> (540) 231-5864
>>>> >>> (540) 231-3944 FAX
>>>> >>>
>>>> >>>
>>>> >>>
>>>> >>>
>>>> >>> Sincerely,
>>>> >>>
>>>> >>> Thomas A. Ficht, Ph.D.
>>>> >>> Professor
>>>> >>> Veterinary Pathobiology
>>>> >>> Texas A&M University
>>>> >>> 4467 TAMU
>>>> >>> College Station, TX 77843-4467
>>>> >>> 979-845-4118 ph
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>>> >>
>>> >> Charlotte M. Waggoner, RBP

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ATTACHMENTS:

ID: 134
DATE: 2007-04-11 12:20:42
FROM: Edward Hammond <hammond@sunshine-project.org>
TO: Kelly, Scott <S-Kelly@tamu.edu>, tficht@cvm.tamu.edu, bsmaddox@tamu.edu, mcmui
Callcott, Diane <D-Callcott@tamu.edu>
SUBJECT: Fwd: RE: Public Information Request
MAILBOX: Exposures.mbox

<!doctype html public "-//W3C//DTD W3 HTML//EN">
<html><head><style type="text/css"><!--
blockquote, dl, ul, ol, li { padding-top: 0 ; padding-bottom: 0 }
--></style><title>Fwd: RE: Public Information
Request</title></head><body>

Mr Scott Kelly
Legal Counsel

Dr Thomas Ficht
Professor

Mr Brent Maddox
Biosafety/Lab Safety Director
Texas A&M Universty

Dr David McMurray
Professor
Texas A&M University Health Science Center

Gentlemen:

My patience is at its end in this matter. As you are
well-aware, the Texas Public Information Act sets forth clear
deadlines for public officials to produce and/or seek Attorney General
ruling on records requested by the public. I requested accident
records involving RG2 or higher agents at Texas A&M in October
2006. You have yet to produce a complete set of responsive records,
and you are unquestionably in violation of Texas law.

You initially only acknolweged one occupational exposure to
brucella, noted in a curious piece of paper that obviously did not
consititute anything close to the complete set of records for that
incident. You still acknowledge no other records on other possible or
actual occupational exposures to RG2 or higher agents at Texas A&M
since 2000, an assertion that I frankly find hard to believe.

Having failed to provide anything resembling the responsive
records in the first instance, in reply to my complaint, TAMU at first
stalled. Then, when I threatened to go to the Attorney General, lo and
behold, you produced some rather shocking records about the brucella
incident, apparently only in order to forestall the Attorney General's

attention. These records still do not form a complete set of those that should have been handed over last year, not even for that single incident.

For example, you have produced no TAMU accident report(s) or recordkeeping by your environmental health department nor the Vet school nor LARR for the brucella incident or any other. You have produced no APHIS/CDC Form 3 for the brucella incident, a form that Mr. Maddox, who I believe is your select agent RO, was required to submit by federal law.

I also note that TAMUHSC, employer of the owner and inventor of the "foolproof" Madison Aerosol Chamber used when the brucella incident occurred, initially did not reply to my PIA request and now denies having any records regarding the incident, another assertion that I frankly find hard to believe.

Therefore, if I do not recieve a complete set of records from TAMU and TAMUHSC for the brucella incident and any others by the end of this day, I will take action including any or all of teh following:

1) Lodging a formal complaint with the Attorney General of Texas for TAMU and/or TAMUHSC violation of the Public Information Act;

2) Reporting to the Federal Bureau of Investigation apparent violation of the implementing regulations for the Bioterrorism Act of 2002 by officials of TAMU, and possibly TAMUHSC.

3) Reporting to the Centers for Disease Control and/or USDA APHIS apparent violation of the Select Agent Rule by TAMU and possibly TAMUHSC.

4) A news release explaining this situation and drawing public and media attention to a possible illegal coverup of violation of federal law and lab-acquired infection by TAMU.

I insist that you reply fully and completely by 5:00PM.

Sincerely,

Edward Hammond

Date: Tue, 10 Apr 2007 22:08:08 -0700
To: "Kelly, Scott" <S-Kelly@tamu.edu>
From: Edward Hammond <hammond@sunshine-project.org>
Subject: RE: Public Information Request
Cc: "Yeager, Susan" <s-yeager@tamu.edu>,
"Raines, Angelia" <araines@vpr-mailsrv1.tamu.edu>,
"Dr. Alicia Dorsey" <dorsey@tamhsc.edu>,
"Callcott, Diane" <D-Callcott@tamu.edu>
Bcc:
X-Attachments:

Mr Kelly:

The issue is not your clarity, it is TAMU (non)compliance with
the Texas Public Information Act and TAMU's failure to produce or seek
AG ruling on records responsive to a request filed in October,
2006.

You represent TAMU. Where is the APHIS/CDC Form 3, plus any other
responsive documents? It is incumbent upon TAMU to produce them.
It was many months ago.

Sincerely,

Edward Hammond

At 11:43 PM -0500 4/10/07, Kelly, Scott wrote:
<blockquote type="cite" cite>Mr. Hammond,

I thought my previous email was clear. I have provided you with
the documents that have been identified, provided to me and been found
responsive to your request. If other documents are identified,
provided to me and found to be responsive to your request those
documents will also be provided to you.

Scott Kelly

_____

From: Edward Hammond [mailto:hammond@sunshine-project.org]
Sent: Tue 4/10/2007 11:31 PM
To: Kelly, Scott
Cc: Yeager, Susan; Raines, Angelia; Dr. Alicia Dorsey; Callcott,
Diane
Subject: RE: Public Information Request

Dear Mr. Kelly:

That is not an acceptable response, nor one that
I believe is legal under Texas law. A select
agent accident resulting in an infection is far
from a trivial event, nor could TAMU possibly be
ignorant of the reporting requirements of federal
law, particularly after the prosecution of Thomas
Butler.

Has TAMU replied completely, or not? Has TAMU
replied in accordance with the Texas Public
Information Act, or have one or more of its
officials failed to produce documents as required
by law?

Sincerely,

Edward Hammond

At 11:10 PM -0500 4/10/07, Kelly, Scott wrote:
>Mr. Hammond,
>
>You have all of the documents that have been
>located and found responsive to your request.
>If there are other responsive documents that are
>identified those documents will also be provided
>to you.
>
>Scott Kelly
>
>_____
>
>From: Edward Hammond [mailto:hammond@sunshine-project.org]
>Sent: Tue 4/10/2007 6:24 PM
>To: Kelly, Scott
>Cc: Yeager, Susan; Raines, Angelia; Dr. Alicia Dorsey; Callcott,
Diane
>Subject: Re: Public Information Request
>
>
>
>Dear Mr. Kelly:
>
>Thank you for your belated reply, however, it remains
incomplete.
>

>TAMU is required by federal regulation to contact
>APHIS or CDC immediately upon discovery of a
>theft, loss, or a release (occupational exposure
>or release of an agent or toxin outside of the
>primary barriers of the biocontainment area) of a
>select agent. After the initial report, APHIS/CDC
>Form 3 must be sent to APHIS or CDC within 7
>calendar days. The RO or facility director must
>complete, sign and date the form.
>
>I have no record of an intial report to CDC or
>APHIS, nor have you provided a completed
>APHIS/CDC Form 3 for the confirmed brucella LAI
>of February 2006.
>
>My request, filed on 24 October 2006, included:
>
>>2. All records on possible or actual occupational exposures
and/or
>>laboratory-acquired infections with risk group 2 (RG2) or
higher
>>agents at TAMU, from 1 January 2000 through the present. You
may omit
>>the name(s) of exposed persons.
>
>The APHIS/CDC Form 3 is clearly responsive, and
>the time allowed under the Texas Public
>Information Act to produce this record is long
>since past.
>
>I insist that you immediately provide this record
>and all other responsive records that you have
>yet to produce.
>
>I am very disturbed by TAMU's response to this request.
>
>Sincerely,
>
>Edward Hammond
>
>
>
>
>
>At 5:04 PM -0500 4/10/07, Kelly, Scott wrote:
>>Attached are additional records that our
>>office received today related to the record
>>previously provided to you regarding an incident</blockquote>
<blockquote type="cite" cite>>>of occupational exposure to
brucella. We have
>>redacted personally identifiable information

>>about the patient as well as information related
>>to the exact location of toxins.
>>
>>We are also advised by Dr. Alicia Dorsey of
>>the Texas A&M System Health Science Center that
>>the HSC does not have any records responsive to
>>your request.
>>
>>Mr. Scott A. Kelly
>>Deputy General Counsel
>>The Texas A&M University System
>>Office of General Counsel
>>A&M System Bldg., Ste. 2079
>>200 Technology Way
>>College Station, Texas 77845
>>(979) 458-6125
>>(979) 458-6150 - facsimile
>>
>>
>>Content-Type: application/octet-stream;
>>   name="Hammond
Response.pdf"</blockquote>
<blockquote type="cite" cite>>>Content-Description: Hammond
Response.pdf
>>Content-Disposition: attachment;
>>
>>
>>Attachment converted: Red Fish:Hammond Response.pdf (PDF
/«IC») (00D24885)</blockquote>

</body>
</html>

ATTACHMENTS:

ID: 132
DATE: 2007-04-12 15:20:06
FROM: Callcott, Diane <D-Callcott@tamu.edu>
TO: Dr. Alicia Dorsey <dorsey@tamhsc.edu>, Raines, Angelia <araines@vprmail.tamu.edu>,
Mattox, Brent S <bsmattox@tamu.edu>, Salsman, John M <jmsalsman@tamu.edu>,
McClendon, Rodney P <rpm@tamu.edu>, Meyer, Chris <c-m-meyer@tamu.edu>,
<tficht@cvm.TAMU.edu>, <mcmurray@medicine.tamhsc.edu>,
Moore, Steve <steve.moore@tamu.edu>, <gadams@cvm.tamu.edu>,
Stephenson, Lane B <l-stephenson@tamu.edu>, Wolf, Cherry Kay <CKWolf@tamu.edu:
Faber, Jan <Jan-Faber@tamu.edu>,Godfrey, Mike <MGodfrey@tamu.edu>,
Lawson, Caroline <Caroline-Lawson@tamu.edu>
SUBJECT: Edward Hammond ABSA News Release
MAILBOX: Exposures.mbox

The attached news release was sent to the ABSA (American Biological
Safety Association)email listserve today by Edward Hammond of the

Sunshine Project. Brent Mattox forwarded it to our office and Scott Kelly has asked me to forward it on to you. We look forward to seeing you at tomorrow's meeting at 2 p.m. in our offices. Please contact Scott (8-6125), his secretary Caroline (8-6129) or me if you have any questions.

Scott also asks that you bring all documents or records related to this matter to tomorrow's meeting.

Diane Callcott
Legal Assistant II / Public Information
Office of General Counsel
The Texas A&M University System
A&M System Bldg. Suite 2079
200 Technology Way
College Station, TX 77845-3424
(979) 458-6149
(979) 458-6150 - facsimilie

ATTACHMENTS:

ID: 147
DATE: 2007-04-12 15:36:12
FROM: Don Davis <ddavis@cvm.tamu.edu>
TO: Tom Ficht <tficht@cvm.tamu.edu>
SUBJECT: Fwd: Texas A&M Violates Law in Biodefense Lab Infection
MAILBOX: Exposures.mbox

For your info

Begin forwarded message:

> From: "Elzer, Philip H." <PElzer@agcenter.lsu.edu>
> Date: April 12, 2007 1:45:06 PM CDT
> To: <ddavis@cvm.tamu.edu>
> Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
>
> What happened???
> This is a bad thing.
>
>
> From: Hagius, Sue D.
> Sent: Thu 4/12/2007 1:39 PM
> To: Elzer, Philip H.
> Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
>

> Did you hear about this and who got infected?
>
>
> From: ABSA biosafety forum [mailto:Biosafety@BIOSAFETY.ABSA.ORG] On
> Behalf OfEdward Hammond
> Sent: Thursday, April 12, 2007 1:29 PM
> To: Biosafety@BIOSAFETY.ABSA.ORG
> Subject: Texas A&M Violates Law in Biodefense Lab Infection
>
>
> The Sunshine Project
>
> News Release - 12 April 2007
>
> http://www.sunshine-project.org
>
>
>
> Texas A&M University Violates Federal
>
> Law in Biodefense Lab Infection
>
>
> - Student climbs into dirty bioaerosol chamber and contracts
> brucellosis
>
> - A&M failed to report the incident to federal authorities
>
> - May lose federal funding and owe $750,000 or more in fines.
>
>
> - Urgent need for mandatory federal accident and near-miss
>
> reporting system that publishes institution-level data on
>
> mishaps to provide missing lab public accountability.
>
>
>
> 12 April 2007 - An aerosol chamber mishap at Texas A&M University
> in February 2006 caused a researcher to be infected with the
> bioweapons agent brucella. Texas A&M University then violated
> federal law by not reporting the brucellosis case to the Centers
> for Disease Control (CDC) and now faces severe penalties. This
> information has only come to light as a result of persistent Texas
> Public Information Act requests by the Sunshine Project.
>
>
> Overdue records obtained by the Sunshine Project in the last two
> days confirm that A&M officials discussed the fact that the federal
> Select Agent Rule required reporting the brucella infection; but

> they chose not to do so. A&M is still holding back additional
> documentation of crime. The scandal points to the urgent need for a
> mandatory federal accident and near-miss reporting system that
> publishes institution-level data on mishaps and creates public
> accountability for biodefense lab accidents.
>
>
> For federal violations, Texas A&M may be fined $500,000, plus up to
> $250,000 for individual(s) that failed to report the incident. In
> refusing to produce information about the infection, A&M officials
> also flouted the Texas Public Information Act. The Sunshine Project
> is filing a complaint with Texas Attorney General Greg Abbott that
> may result in other fines and/or jail sentences if A&M officials
> are found guilty of hiding documents.
>
>
> What Happened: The infection incident occurred on 9 February 2006.
> Several A&M researchers, including Principal Investigator Thomas
> Ficht, were in a BSL-3 lab training in the use of the Madison
> Aerosol Chamber. Supervising was David McMurray, an A&M professor
> and self-described inventor of the chamber, who has characterized
> it as "foolproof".
>
>
> Following a "hot" run that blew aerosolized brucella into the
> chamber to expose mice, researchers began clean up procedures.
> Using what Texas A&M now admits were inappropriate protocols, a
> researcher "cleaned the unit by climbing partially into the chamber
> to disinfect it." A&M officials later concluded that the brucella
> bacteria likely entered body via eyes as a result of this
> improper procedure. (This is the third instance of lab-acquired
> infections related to the Madison chamber that the Sunshine Project
> has uncovered. The others were in Seattle and New York City.)
>
>
> By April 2006, the researcher had "been home sick for several
> weeks." Nobody apparently suspected brucellosis, despite the
> occupational exposure and, presumably, familiarity with its
> symptoms. Eventually, the researcher's personal physician ordered
> blood tests and made the diagnosis on about April 10. On 15 April,
> the infected researcher began a heavy treatment course reflecting
> the severity of the situation. received a week of intravenous
> antibiotics followed by a 45-day course of two additional
> antibiotic drugs. Just over a month later, new blood tests
> indicated that the infection had passed.
>
>
> Failure to Report: E-mails that Texas A&M finally released to the
> Sunshine Project late on Tuesday night reveal that the University
> broke federal law by not reporting the infection. The Select Agent
> Rule required A&M to report the infection immediately upon its

> discovery and for the school to file a formal report, called APHIS/
> CDC Form 3, within 7 days.
>
>
> According to A&M records, the sick researcher told Thomas Ficht of
> the diagnosis on Monday or Tuesday, April 10 or 11, 2006. Based on
> the records A&M has released, Ficht does not appear to have told
> A&M administrators until ten days later. On 21 April, a Friday
> afternoon, Ficht informed other A&M officials, including Angela
> Raines, the Responsible Official under the Select Agent Rule and
> Brent Maddox, the A&M biosafety director, in an e-mail titled
> "Workmen's Compensation".
>
>
> Texas A&M has also released a partial e-mail sequence involving
> discussions during the following week between Ficht, the sick
> researcher, and Maddox (the safety director). On Tuesday April 25,
> Ficht noted "according to the select agent guidelines [sic] we are
> required to report any laboratory exposures to the CDC." Yet no
> report was filed.
>
>
> Ficht is the Research Standards Officer of Texas A&M University, a
> member of the NIH bacterial biodefense and bacterial pathogenesis
> study groups, and is funded to study bioweapons agents by the
> Department of Homeland Security and National Institutes of Health.
> Notably, Ficht is one of only a few US researchers who were
> studying Brucella before the post-9/11 biodefense boom.
>
> A&M has yet to release any of Maddox or Raines' records about the
> incident, despite having been obligated to do so by Texas law for
> almost six months. These undoubtedly would shed more light on A&M's
> violation of the Select Agent Rule.
>
>
> A Year Too Late: There is no reason to suspect that A&M would have
> admitted the truth without pressure. It has taken six months for
> the Sunshine Project to convince A&M to reveal this incident to the
> limited extent known today. This week, as the Project was closing
> in on details in a series of tense e-mails with the Texas A&M
> General Counsel (including a threat to take the matter to law
> enforcement), A&M officials apparently decided that they could no
> longer stonewall.
>
>
> While A&M was refusing to answer Sunshine Project requests, on
> Tuesday (10 April), A&M e-mailed CDC to inform it of the incident -
> a full year after the infection should have been reported.
> Yesterday (11 April), A&M's Angela Raines filed the required APHIS/
> CDC Form 3 document, 51 weeks after A&M was required to submit it.
>

>
> Penalties: The Sunshine Project is calling for maximum penalties to
> be levied. Says Sunshine Project Director Edward Hammond, "The
> evidence released to us indicates that Texas A&M officials
> discussed the federal requirement to report the incident, yet they
> did not do so. They chose to ignore the law, and that irresponsible
> decision to endanger public health and security should be swiftly
> and severely punished with maximum fines and loss of federal
> research funding."
>
>
> An Ongoing Problem: For years, watchdogs have pointed to the lack
> of effective regulation of BSL-3 and BSL-4 labs in the United
> States, and particularly the need for improved (and transparent)
> accident reporting. Those calls have grown louder after a series of
> accidents in recent years that labs tried to hide from the public,
> including tularemia infections at Boston University, a plague
> problem in Newark, New Jersey, and a genetically-engineered bird
> flu incident in Austin, Texas.
>
>
> The Sunshine Project has gathered data (in press) documenting
> nearly a score more BSL-3 and BSL-4 accidents, including select
> agent incidents, almost none of which have been reported to the
> public. Due to the absence of effective federal regulation, there
> are, undoubtedly, many more accidents that have been successfully
> buried, like the Texas A&M brucella incident almost was.
>
> "It is common knowledge in the biodefense business that lab
> accidents with bioweapons agents are routinely buried in order to
> avoid negative publicity and endangering funding," says Hammond,
> "It is only through the power of the Texas Public Information Act
> that Texas A&M's criminal failures have been revealed."
>
>
> The Sunshine Project is calling for a mandatory national accident
> and near-miss reporting system to be established. "When accidents
> are buried, nobody learns from past mistakes, and communities are
> kept in the dark about accidents and sloppy labs in their midst."
> says Hammond, "It's time for biodefense labs to stop talking down
> to the public with false safety claims and to start being
> transparent. All BSL-3 and BSL-4 labs should be required to report
> all significant accidents and near-accidents, and that information
> should be published by the federal government, with details of
> every incident, including the name of the lab and the agent involved."
>
>
> - END -
>
>
> Note: Look for original A&M documents to be posted online with this

> news release at the Sunshine Project website.
>
>
>
> The views expressed in this forum are those of the individual
> poster and do not reflect the views of ABSA or the List Owner.
>

ATTACHMENTS:

ID: 131
DATE: 2007-04-12 15:49:31
FROM: Angelia Raines <ARaines@vprmail.tamu.edu>
TO: Thomas Ficht <t-ficht@tamu.edu>,Tiffany Agnew <tmagnew@tamu.edu>
SUBJECT: Fwd: NIH Biotechnology Group
MAILBOX: Exposures.mbox

This is a MIME message. If you are reading this text, you may want to consider changing to a mail reader or gateway that understands how to properly handle MIME multipart messages.

Per the attached document, please review your funding application to ensure all reporting requirments have been met. You may also want to share this with your department.

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

I spoke twice today with Dr. Bruce Whitney of the NIH, concerning the Sunshine Report. Dr. Whitney was checking to determine if rDNA was involved in the exposure. It was not. This was verified by contacting Dr. Ficht's Lab, who verified that a wild strain (not rDNA) was used in the aerosol chamber. According to Dr. Whitney, exposures to rDNA in BL3 Labs requires reporting to NIH. However, that was not the case with this incident. No further contact is expected. Dr. Whitney's number is 301-435-2149, if anyone wants to follow up. It was Dr. Whitney who initiated the contact.

Brent

ATTACHMENTS:

ID: 130
DATE: 2007-04-12 16:08:48
FROM: Angelia Raines <ARaines@vprmail.tamu.edu>
TO: Brent S Mattox <bsmattox@tamu.edu>, Thomas Ficht <t-ficht@tamu.edu>,John Salsman
Tiffany Agnew <tmagnew@tamu.edu>
SUBJECT: Fwd: Form 3
MAILBOX: Exposures.mbox

This is a MIME message. If you are reading this text, you may want to consider changing to a mail reader or gateway that understands how to properly handle MIME multipart messages.

Per the attached, please ensure that your records are updated to include form 3.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

Hi Jim,

Thanks for following up with me regarding the Brucella exposure. I also briefly spoke with Paul Mehta. Attached is an electronic copy of the report that was faxed to you. Per my conversation with Dr. Mehta, I will be prepared to send additional information about changes in our safety plan after we get the official response from your office.

To recap our conversation about the exposure:

- It most likely occurred in February 2006.
- The employee was tested, and treated.
- Other lab personnel were tested and found to be negative for exposure.
- The Lab Director reviewed his Biosafety Plan to determine if changes were needed.
- The Biosafety Plan was modified as a result of the incident.
- Lab personnel were updated and retrained on the changes.

- Form 3 was not submitted at the time of the event, as required; however a process is now in place to ensure immediate notification. We have also submitted the required report.

Thanks for sharing with me that many institutions have been unclear as to whether they needed to report some exposures based on the information contained in the Form-3 instructions. While I fully understand the regulatory requirements, clarity in these instructions could indeed assist the reporting process.

Thanks again for your insight and assistance!

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
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Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

ATTACHMENTS:

ID: 128
DATE: 2007-04-13 14:01:33
FROM: Shannon Davis <s.davis@tamu.edu>
TO: <ddavis@cvm.tamu.edu>,Fuller Bazer <fbazer@cvm.tamu.edu>,<gadams@cvm.tamu.edu>
James Samuel <jsamuel@medicine.tamhsc.edu>, Vernon Tesh <tesh@medicine.tamhsc
<mihrig@tamu.edu>, Richard Ewing <richard-ewing@tamu.edu>,
Thomas Ficht <tficht@tamu.edu>,Betsy Browder <BBrowder@vprmail.tamu.edu>,Van Wil
Angelia Raines <ARaines@vprmail.tamu.edu>, Dianne Cornett <DCornett@vprmail.ta
SUBJECT: Notification of CDC Site Visit 4/16/07
MAILBOX: Exposures.mbox

This is a MIME message. If you are reading this text, you may want to consider changing to a mail reader or gateway that understands how to properly handle MIME multipart messages.

** High Priority **

I just got a call from CDC in response to our report of Brucella exposure. =
They are planning on conducting a site visit beginning Monday morning. =
Further information is attached.

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

ATTACHMENTS:

ID: 144
DATE: 2007-04-15 19:30:12
FROM: Richard Ewing <richard-ewing@tamu.edu>
TO: <ddavis@cvm.tamu.edu>,Fuller Bazer <fbazer@cvm.tamu.edu>,<gadams@cvm.tamu.edu>
James Samuel <jsamuel@medicine.tamhsc.edu>, Vernon Tesh <tesh@medicine.tamhsc
<mihrig@tamu.edu>, Shannon Davis <s.davis@tamu.edu>, Thomas Ficht <tficht@tam
Betsy Browder <BBrowder@vprmail.tamu.edu>,Van Wilson <v-wilson@tamu.edu>,
Angelia Raines <ARaines@vprmail.tamu.edu>, Dianne Cornett <DCornett@vprmail.ta
SUBJECT: Re: Notification of CDC Site Visit 4/16/07
MAILBOX: Exposures.mbox

All,
I had meetings from when this was sent through close of business on Friday. I have read through what was sent to me on the incident from Angie's staff on Friday, but probably before they received this request. The review team will be here tomorrow, Monday, April 16. I do not have access to the information that they are requesting. I hope that you received this on Friday in time to begin to put this information together. I will cancel any or all of the appointments that I have tomorrow to try to address these concerns. Please let me know if anyone has already put some of this information together for the audit team. Please be reminded that articles in the Chronicle suggest fines up to $500K and reduction of funding overall, so we need to seriously address these problems.

Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585

FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> Shannon Davis 4/13/2007 2:01:09 pm >>>
I just got a call from CDC in response to our report of Brucella exposure. They are planning on conducting a site visit beginning Monday morning. Further information is attached.

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

ID: 143
DATE: 2007-04-16 05:12:26
FROM: Angelia Raines <araines@vprmail.tamu.edu>
TO: <ddavis@cvm.tamu.edu>,Fuller Bazer <fbazer@cvm.tamu.edu>,<gadams@cvm.tamu.edu>
<tesh@medicine.tamhsc.edu>, <bsmattox@tamu.edu>, <mihrig@tamu.edu>, Richard E\
Shannon Davis <s.davis@tamu.edu>, <tficht@tamu.edu>, Betsy Browder <BBrowder(
Dianne Cornett <DCornett@vprmail.tamu.edu>
SUBJECT: Re: Notification of CDC Site Visit 4/16/07
MAILBOX: Exposures.mbox

This is a MIME message. If you are reading this text, you may want to consider changing to a mail reader or gateway that understands how to properly handle MIME multipart messages.

Brent and/or John,

Please review the attached draft response (from Tom Ficht) and let us know if there are any remaining safety questions. I also need a copy of the lab inspection that was performed as a result of the incident as well as any other inspections of the chamber. Our office will resond to question 7 as well as format the response to RO signature after final review/input.

I have not heard from CDC yet so I still do not know when to expect them. I will update you as I learn more. In the mean time, please prepare to see them anytime after 8:00 a.m. should they come come directly to the lab.

Thank you,
Angie

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
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College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

>>> Richard Ewing 04/15/07 7:30 PM >>>
All,
I had meetings from when this was sent through close of business on Friday. I have read through what was sent to me on the incident from Angie's staff on Friday, but probably before they received this request. The review team will be here tomorrow, Monday, April 16. I do not have access to the information that they are requesting. I hope that you received this on Friday in time to begin to put this information together. I will cancel any or all of the appointments that I have tomorrow to try to address these concerns. Please let me know if anyone has already put some of this information together for the audit team. Please be reminded that articles in the Chronicle suggest fines up to $500K and reduction of funding overall, so we need to seriously address these problems.

Dick

Dr. Richard E. Ewing
Vice President for Research
Texas A&M University
1112 TAMU
College Station, TX 77843-1112
Phone: (979) 845-8585
FAX: (979) 845-1855
E-mail: richard-ewing@tamu.edu

>>> Shannon Davis 4/13/2007 2:01:09 pm >>>
I just got a call from CDC in response to our report of Brucella exposure. They are planning on conducting a site visit beginning Monday morning. Further information is attached.

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance
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1500 Research Parkway
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(770) 789-3456 Cell

ATTACHMENTS:

ID: 142
DATE: 2007-04-16 06:49:56
FROM: Angelia Raines <araines@vprmail.tamu.edu>
TO: <ddavis@cvm.tamu.edu>,<gadams@cvm.tamu.edu>, <tficht@cvm.tamu.edu>,
<TESH@medicine.tamhsc.edu>, <wilson@medicine.tamhsc.edu>,
<a-wallis@tamu.edu>, <bertvk@tamu.edu>, <bsmattox@tamu.edu>,
<c-m-meyer@tamu.edu>, <cbc@tamu.edu>, <d-callcott@tamu.edu>,
<Jan-Faber@tamu.edu>, <jmsalsman@tamu.edu>, <jsamuel@tamu.edu>,
<mihrig@tamu.edu>, Richard Ewing <richard-ewing@tamu.edu>,
<rpm@tamu.edu>, <S-Kelly@tamu.edu>, <steve.moore@tamu.edu>,
Tiffany Agnew <tmagnew@tamu.edu>, Fuller Bazer <Bazer@vprmail.tamu.edu>,
Betsy Browder <BBrowder@vprmail.tamu.edu>,Shannon Davis <s.davis@tamu.edu>
SUBJECT: Re: CDC Visit- No Update
MAILBOX: Exposures.mbox

Good Morning,

I just spoke with Diane Martin, one of the inspectors from the CDC. They will arrive this morning at 9:00 a.m. Per Diane, they wish to focus solely on the exposure incident and are not inspecting our entire registration, therefore they DO NOT want to have an entrance briefing. They do want everyone involved to be available but have not yet decided how they are going to approach the inspection. Per Diane, they will most likely want to start off by meeting with Dr. Ewing and myself. Following that meeting, they will let us know how they want to proceed.

My office will contact you as quickly as possible to provide additional updates.

Thank you,
Angelia

Angelia Raines
Director, VPR Office of Research Compliance
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(979) 862-3176 fax
(770) 789-3456 Cell

>>> Tiffany Agnew 04/15/07 7:43 PM >>>
Greetings All!

Angelia has asked that I inform you all that as of 7:30 pm, our office has not received any new information in regards to the arrival time of the CDC inspection team. The only information that has been confirmed is that the inspection is scheduled to take place on Monday, April 16, 2007. At this time, our office is unable to provide any times or locations; however, we will inform you as soon as information becomes available.

In addition, our office has begun compiling information based upon the questions submitted by the CDC on Friday. Dr. Ficht has been very instrumental in providing extremely detailed answers to all 13 questions.

Thank you!

Regards,

Tiffany

Tiffany M. Agnew
Program Coordinator (Office of Research Compliance)
Texas A&M
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
(979) 458-3624
(979) 862-3176 - fax
tagnew@vprmail.tamu.edu

ID: 39
DATE: 2007-04-20 02:29:24
FROM: Tom Ficht <tficht@cvm.tamu.edu>
TO: Angelia Raines <ARaines@vprmail.tamu.edu>
SUBJECT: FW: TAMU Human Brucellosis Case
MAILBOX: Exposures.mbox

Angie

Care to address this question?

Taf

Thomas A. Ficht, Ph.D.
Professor

Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

> ------ Forwarded Message
> From: <Terry.H.Conger@aphis.usda.gov>
> Date: Thu, 19 Apr 2007 15:40:22 -0500
> To: <tficht@cvm.tamu.edu>
> Subject: RE: TAMU Human Brucellosis Case
>

>
> Hello Tom,
>
> With reference to the human brucellosis case that has been reported, the
> pathogen has been identified as Brucella melitensis. The Madison Aerosol
> Chamber was being used to infect small laboratory animals (mice?), correct?
> Do you attribute the human exposure to a leaking chamber, or just to the
> residual B. melitensis pathogen in the chamber that affected the technician
> during cleaning (i.e., have you identified the break in biosecurity that
> resulted in the infection). I've had several questions posed to me about the
> incident, so I'm relaying them on to you.
>
> Thanks for your help!
>
> Terry H. Conger, DVM, PhD
> Louisiana Area Epidemiology Officer
> Area Aquacultural Coordinator
> USDA, APHIS, Veterinary Services
> 5825 Florida Blvd., Suite 1140
> Baton Rouge, LA 70806
> Office: (225) 389-0436
> Direct Line; (225) 935-2174
> FAX: (225) 925-4103
> E-Mail: Terry.H.Conger@aphis.usda.gov
>

------ End of Forwarded Message

ATTACHMENTS:

ID: 115
DATE: 2007-05-11 10:01:55
FROM: Angelia Raines <araines@vprmail.tamu.edu>
TO: Brent S Mattox <bsmattox@tamu.edu>,<jsamuel@medicine.tamhsc.edu>,

Vernon Tesh <TESH@medicine.tamhsc.edu>, David S. Carlson <carlson@tamhsc.edu>,<I
Chris Meyer <c-m-meyer@tamu.edu>, <ibc@tamu.edu>, John M Salsman <jmsalsm
Richard Ewing <richard-ewing@tamu.edu>, Thomas Ficht <t-ficht@tamu.edu>,
Fuller Bazer <Bazer@vprmail.tamu.edu>
SUBJECT: Re: Elevated Titer for Q Fever
MAILBOX: Exposures.mbox

Brent,

Thank you for letting me know. I have notified the RO as well as CDC and others on our contact list. Please keep me updated as you investigate the incident. We will need the results of the investigation within 5 days. Also, please let me know if the IBC needs to convene a meeting to immediately review this incident.

Finally, please let me know if this incident involves work with rDNA so we can inform NIH.

Thank you,
Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/11/2007 9:00 AM >>>
Angelia/Dr. Samuel:

Scott and White informed me that a high titer (Phase II 1:1024) was received on a new addition (baseline titer) to the Occupational Health Surveillance Program yesterday afternoon (5/11/07). Due to issues with obtaining a copy of the titer results, our response was delayed until this morning. According to the Texas Department of State Health Services, a titer of greater than 1:256 is evidence of a prior infection, but, it DOES NOT confirm that the infection was recent. EHSD
will be conducting an investigation concerning this issue, and will need
the date of hire and the work history of the individual, including any possible exposures, since employment at Texas A&M Health Sciences Center. If any other individuals have been potentially exposed, please

notify our office. A detailed occupational history of past possible exposures prior to employment is also requested from the employee.

According to recent statements from CDC, it is EHSD's opinion that this
constitutes a reportable condition to CDC. It is also our understanding
that this reporting is to be done by the Office of Research Compliance.
We will provide a summary of our findings to the Office of Research upon
completion of the investigation. The employee will continue to be monitored by the Occupational Health Program as directed by the occupational health physician at Scott & White.

If you have any further questions, please let me know. A copy of the titer result is attached.

ID: 113
DATE: 2007-05-18 11:39:39
FROM: Mattox, Brent S <bsmattox@tamu.edu>
TO: Raines, Angelia <araines@vprmail.tamu.edu>,Vernon Tesh <TESH@medicine.tamhsc.edu>
Kretzschmar, Bert <bertvk@tamu.edu>, Meyer, Chris <c-m-meyer@tamu.edu>,
Salsman, John M <jmsalsman@tamu.edu>, Thomas Ficht <t-ficht@tamu.edu>,
Tiffany Agnew <tmagnew@tamu.edu>, Fuller Bazer <Bazer@vprmail.tamu.edu>
SUBJECT: RE: Investigative Report on Q Fever
MAILBOX: Exposures.mbox

Below are responses to your three questions concerning the high titer issue. Please note that the employee has not shown signs or symptoms of any illness, so this is an investigation of a high Q fever titer, not an investigation of Q fever.

1. The first visit to was to draw blood from pre-exposed varmints (in other words, no potential exposure to the agent). The remaining three were to draw blood that would have potentially contained the AGENT, not antigen. These three trips would constitute documented risk of exposure due to the proximity of the agent (in rodent and blood). The first exposure is more remote, with the agent not being present in the same room as the employee. Further, I recommend that all work with select agents involve pre-exposure screening, including all visitors. I recommend (for example) that all individuals entering the BL3 suite at be required to have titers drawn for Q fever and Brucella, in addition to TB testing. Obviously, this recommendation needs to go to the IBC.

2. The researcher's own protocols require pre-exposure monitoring

and were apparently disregarded. However, we may want to look at the facility plan to require not just TB screening for access, but baseline serum titers for anyone entering the facility (BL3 rooms) regardless of planned exposure. That is what we are doing with the contractor, but his risk is obviously higher (cutting into contaminated ductwork linking all the rooms).

3. The SOP regarding pre-screening was not followed, according to the PI. I do not know if re-training is necessary, but clearly the PIs should be informed that pre-screening is a necessity for their employees, and that they must strictly adhere to their written SOPs.

Hope this helps,

Brent S. Mattox
Biological Safety Officer

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 18, 2007 11:06 AM
To: Mattox, Brent S
Cc: Vernon Tesh; Kretzschmar, Bert; Meyer, Chris; Salsman, John M; Thomas Ficht; Tiffany Agnew; Fuller Bazer
Subject: Re: Investigative Report on Q Fever

Hi Brent,

Thanks for sending the report. I am preparing form-3 to send to CDC and want to make sure I have the correct information. I will send it to you, Jim and Bert to review before I send it. However before completing it, I have a few questions:

1. During the 4 times the employee accessed the Lab, was exposed to the antigen only?
was not DSAT approved until 1/07 and the facility access logs were completed prior to that approval. I want to make sure we include the correct information in the report.

2. Do the plans (security, safety, incident or surveillance) need to be changed as a result of this incident? If so, what changes are needed.

3. In reviewing the report, it appears that the SOP that required screening prior to work in the lab was not followed. If this is the case, when will refresher training be conducted? Since your report will be presented to the IBC at the next meeting, we will need to be sure the follow up letter from the comittee indicates what type of training documentation is required.

Thanks again for the report.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/17/2007 10:05:52 AM >>>
Angelia:

Please find attached another pdf of the investigative report on the Q fever titer. I inadvertently left off copies of the entry logs for

Thanks,

Brent

ID: 138
DATE: 2007-05-18 12:22:31
FROM: Angelia Raines <araines@vprmail.tamu.edu>
TO: Richard Ewing <richard-ewing@tamu.edu>,Vernon Tesh <TESH@medicine.tamhsc.edu>,
Bert Kretzschmar <bertvk@tamu.edu>, Brent S Mattox <bsmattox@tamu.edu>,
Chris Meyer <c-m-meyer@tamu.edu>, John M Salsman <jmsalsman@tamu.edu>,
Scott Kelly <S-Kelly@tamu.edu>, Thomas Ficht <t-ficht@tamu.edu>,
Tiffany Agnew <tmagnew@tamu.edu>, Fuller Bazer <Bazer@vprmail.tamu.edu>
SUBJECT: Draft - RE: Investigative Report on Q Fever
MAILBOX: Exposures.mbox

Dr. Ewing,

I am trying to draft our report to CDC and need input regarding how the =
institution is going to handle this issue of non-compliance.

Per the response from Brent below, it appears that an employee who was not =
approved for access to a select agent was allowed to use it. I am very =
concerned and think that immediate action is needed in order to prevent =
future occurrence. We are planning training for all Select Agent =

personnel and it will be conducted by June 30th, but in the mean time I =
would like to suggest some type of immediate action be taken.

I have to submit the report to CDC today. With your input on the action =
required, I will include it in the documentation. I will send a draft of =
the of the report to you as well as the PI, BSO, IBC and Departmental =
contacts for review as quickly as possible.

Thanks,
Angie

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/18/2007 11:39:33 AM >>>
Below are responses to your three questions concerning the high titer issue. Please note that the employee has not shown signs or symptoms of any illness, so this is an investigation of a high Q fever titer, not an investigation of Q fever.

1. The first visit to was to draw blood from pre-exposed varmints (in other words, no potential exposure to the agent). The remaining three were to draw blood that would have potentially contained the AGENT, not antigen. These three trips would constitute documented risk of exposure due to the proximity of the agent (in rodent and blood). The first exposure is more remote, with the agent not being present in the same room as the employee. Further, I recommend that all work with select agents involve pre-exposure screening, including all visitors. I recommend (for example) that all individuals entering the BL3 suite at be required to have titers drawn for Q fever and Brucella, in addition to TB testing. Obviously, this recommendation needs to go to the IBC.

2. The researcher's own protocols require pre-exposure monitoring and were apparently disregarded. However, we may want to look at the facility plan to require not just TB screening for access, but baseline serum titers for anyone entering the facility (BL3 rooms) regardless of planned exposure. That is what we are doing with the contractor, but his risk is obviously higher (cutting into contaminated ductwork linking all the rooms).

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Hope this helps,

Brent S. Mattox
Biological Safety Officer

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 18, 2007 11:06 AM

To: Mattox, Brent S
Cc: Vernon Tesh; Kretzschmar, Bert; Meyer, Chris; Salsman, John M; Thomas Ficht; Tiffany Agnew; Fuller Bazer
Subject: Re: Investigative Report on Q Fever

Hi Brent,

Thanks for sending the report. I am preparing form-3 to send to CDC and want to make sure I have the correct information. I will send it to you, Jim and Bert to review before I send it. However before completing it, I have a few questions:

1. During the 4 times the employee accessed the Lab, was exposed to the antigen only?
was not DSAT approved until 1/07 and the facility access logs were completed prior to that approval. I want to make sure we include the correct information in the report.

2. Do the plans (security, safety, incident or surveillance) need to be changed as a result of this incident? If so, what changes are needed.

3. In reviewing the report, it appears that the SOP that required screening prior to work in the lab was not followed. If this is the case, when will refresher training be conducted? Since your report will be presented to the IBC at the next meeting, we will need to be sure the follow up letter from the committee indicates what type of training documentation is required.

Thanks again for the report.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/17/2007 10:05:52 AM >>>
Angelia:

Please find attached another pdf of the investigative report on the Q fever titer. I inadvertently left off copies of the entry logs for

Thanks,

Brent

ID: 137
DATE: 2007-05-18 14:50:14
FROM: Angelia Raines <araines@vprmail.tamu.edu>
TO: Vernon Tesh <TESH@medicine.tamhsc.edu>, David S. Carlson <carlson@tamhsc.edu>, Richard Ewing <richard-ewing@tamu.edu>, Thomas Ficht <t-ficht@tamu.edu>, Fuller Bazer <Bazer@vprmail.tamu.edu>,Scott Kelly <S-Kelly@tamu.edu>
SUBJECT: Fwd: RE: Draft - RE: Investigative Report on Q Fever
MAILBOX: Exposures.mbox

This is a MIME message. If you are reading this text, you may want to consider changing to a mail reader or gateway that understands how to properly handle MIME multipart messages.

Based on Brent's email (attached), it does not appear that the employee = had access to the agent. We will still have training before June 1st to = ensure all Select Agent personnel understand the requirements for access.

The IBC has to review the entire incident report, so final disposition = wont be available after their next meeting (5/23/07).

Thank you,
Angie

ATTACHMENTS:

ID: 108
DATE: 2007-06-26 14:09:00
FROM: Richard Adams <RAdams@cvm.tamu.edu>
TO: Garry Adams <GADAMS@cvm.tamu.edu>, Gerald Bratton, <GBRATTON@cvm.tamu.edu>,
SUBJECT: HSC this time, I believe.
MAILBOX: Exposures.mbox

The Sunshine Project
News Release - 26 June 2007
http://www.sunshine-project.org

Bioweapons Infections Hit Texas A&M University Again (Q Fever Cluster)

- Accident Happened During Biodefense Experiments

- Q Fever Cluster Not Reported to the Centers for Disease Control

- Second Documented Violation of Federal Bioweapons Law by Texas A&M

- Further Sanctions under Texas Public Information Act possible

Three Texas A&M University biodefense researchers were infected with the biological weapons agent Q Fever in 2006. The infections were confirmed in April of that year, but Texas A&M officials did not report them to the Centers for Disease Control (CDC), as required by law. Instead, Texas A&M officials covered the infections up until now, illegally failing to disclose them despite freedom of information requests dating back to October 2006.

The Q Fever cluster is a separate incident than the 2006 infection at Texas A&M with the bioweapons agent Brucella, first reported this April by the Sunshine Project. Texas A&M is liable for $750,000 or more in federal fines ($1.5 million including the brucella incident) for failure to report, as well as possible charges under the Texas Public Information Act.

After a lengthy freedom of information battle, documents received by the Sunshine Project yesterday (June 25th) reveal that the infections were confirmed on 3 April 2006. On that day, Scott & White Hospital called A&M Professor James Samuel as well as Brent Maddox, the university's institutional biosafety officer, to tell them that three of Samuel's lab workers had tested positive for Q Fever (Coxiella burnetti). The mechanism of exposure is not stated in the records released; but the Samuel lab conducts aerosol challenges of pigs and other studies with the Q Fever bacteria.

"It is apparent that brucella was only the beginning of Texas A&M's problems." says Sunshine Project Director Edward Hammond, "A&M's infection of its staff and students with bioweapons agents and its serial violations of the Select Agent Rule demand law enforcement. If the US government fails to severely sanction Texas A&M, then the Select Agent Rule might as well be tossed in the trash can." Adds Hammond, "Unpunished, Texas A&M's impunity reduces Bioterrorism Act to mere half-hearted suggestion, rather than the law of the land. Congress surely did not intend biology professors to consider law to prevent bioterrorism optional."

What prompted the infected individuals to visit the hospital is not stated in the documents received by the Sunshine Project. Yet three individuals from the same lab visited the hospital at the same time and had the same tests for a very unusual pathogen performed. Circumstances

strongly suggest a lab accident that led the researchers to suspect (correctly) that had become infected. According to the A&M records, upon learning of the infections, the main action of the biosafety officer was to report the accident to the co-chairs of the Texas A&M Institutional Biosafety Committee, who include Thomas Ficht, the professor responsible for the researcher who contracted Brucella in February 2006. But no mention of a Q Fever accident appears in Texas A&M's biosafety committee meeting minutes.

In fact, Texas A&M has produced zero documentation, such as accident reports, lab paperwork, lessons learned, modified operating procedures, or anything else except a few sparse e-mails for either the Q Fever or the Brucella accident. This is despite open records requests for such paperwork. "If Texas A&M's replies under the Texas Public Information Act are to be believed," says Hammond, "then four people at the University have been infected with bioweapons agents without responsible A&M professors and other officials even bothering to file a simple incident report, much less alert the community or report to public health officials."

According to federal law, A&M was required to report the infections immediately upon their discovery and to file a federal report, called APHIS/CDC Form 3, within 7 days. It did not do so. Under the Texas Public Information Act, which includes civil and criminal penalties for false responses, Texas A&M has denied filing any report of the Q Fever infections. By not reporting the infections to the government, Texas A&M thus violated (again) the Select Agent Rule, the main federal law intended to protect Americans from biodefense research gone awry.

Samuel is a professor of Medical Microbiology and Immunology and teaches courses at Texas A&M's Center for Homeland Security, which is funded by the US Department of Homeland Security. Samuel also receives biodefense funding from the National Institutes of Allergy and Infectious Disease (NIAID) and the NIH-funded Southwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research, managed by the University of Texas Medical Branch at Galveston. The records released to the Sunshine Project do not contain information concerning the treatment of the infected individuals.

Several freedom of information requests to Texas A&M remain unanswered. The Sunshine Project will continue to pursue these and other requests until a satisfactory resolution, including federal and state government action, is achieved.

For more information:

Records released by Texas A&M on 25 June 2007:
http://www.sunshine-project.org/publications/pr/support/TAMUQFEVER.pdf

(Brucella:) Texas A&M Violates Federal Law in Biodefense Lab Infection
http://www.sunshine-project.org/publications/pr/pr120407.html

---

ID: 107
DATE: 2007-06-27 16:43:07
FROM: Yeager, Susan <s-yeager@tamu.edu>
TO: Ewing, Richard <richard-ewing@tamu.edu>, Calvin, James <j-calvin@tamu.edu>,
Bazer, Fuller <fbazer@cvm.tamu.edu>, Raines, Angelia <araines@vprmail.tamu.edu>,
Clark, Charley <cbc@tamu.edu>, Meyer, Chris <c-m-meyer@tamu.edu>,
Salsman, John M <jmsalsman@tamu.edu>, Mattox, Brent S <bsmattox@tamu.edu>,
Tom Ficht <tficht@cvm.tamu.edu>, <jsamuel@medicine.tamhsc.edu>,
<dmcmurray@medicine.tamhsc.edu>, Garry Adams <gadams@cvm.tamu.edu>,Kelly, Sc
Callcott, Diane <D-Callcott@tamu.edu>, Lawson, Caroline <Caroline-Lawson@tamu.
Sherylon J. Carroll <s-carroll@tamu.edu>, Alicia Dorsey <dorsey@tamhsc.edu>,
Parker, Terri <T-Parker@tamu.edu>, McConnell, Bill <w-mcconnell@tamu.edu>,
Spang Terry <tspang@tamu.edu>, McClendon, Rodney P <rpm@tamu.edu>,
Bisor, Robert T <r-bisor@tamu.edu>
SUBJECT: Public Information Request 07-176 Amy Rosen/Dallas Morning News
MAILBOX: Exposures.mbox

Scott Kelly asked that I send the attached Public Information Request to each of you for response. Please see Mr. Kelly's note below:

"Although documents responsive to this request were provided in response to an earlier request from Edward Hammond, it is necessary that responsive documents be produced again in response to this new request. Furthermore, this request needs to be considered under the standard for reporting suspected occupational exposures adopted by the university in April 2007. Elevated titers are now regarded by the university as a reportable suspected occupational exposure."

Thank you for your assistance. Suzy

Suzy Yeager

Director, Open Records

Texas A&M University

1181 TAMU

College Station, TX 77843-1181

979/862-4571 (Phone)

979/862-7778 (Fax)

s-yeager@tamu.edu <mailto:s-yeager@tamu.edu>

ATTACHMENTS:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella, Brucella,* or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for Room and all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

10. Please provide any personal protective equipment or entry requirements that may be needed prior to entry into your laboratories.
11. Please provide any documents regarding unexpected animal illness.
12. Please provide an assessment of the risks of continuing to utilize the aerosol chamber.
13. Please provide a detail description of the measures implemented to protect the employees from exposures while decontaminating the aerosol chamber including any enhanced personal protective equipment (PPE) utilized and the medical surveillance activities implemented. The long term follow-up of employees should be included in this response.

The DSAT will be conducting an inspection of your entity on April 16, 2007 to assess the measures implemented by Texas A& M University to protect the staff and public from exposure to pathogenic microorganism, the measures implemented to prevent further incidents and to evaluate your entity's compliance with the select agent regulations. Please make available all staff members involved in the incident described in your report dated April 11, 2007 to be interviewed by the inspection team.

On April 16, 2007, the following representatives from the CDC will be visiting Texas A& M University:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Officer
Melissa Resnick, EIS Officer

Please have the response and any supporting documentation available for the inspectors upon their arrival to your entity on April 16, 2007.

Please contact Lori Bane, Compliance Officer with the DSAT at 404-718-2006 or at the address listed below if you have questions.

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins.

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the RO or facility director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

2. The RO or facility director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   A. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
   B. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."

3. The RO or facility director faxes or mails the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University
2. Entity registration number (if applicable): APHIS# CDC# 200606050489
3. Entity address (NOT a post office address): 1112 TAMU
4. City: College Station
5. State: TX
6. Zip Code: 77843-1112
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing
8. Telephone: (979) 847-9362
9. FAX: (979) 862-3176
10. E-mail: araines@vprmail.tamu.edu
11. RO or facility director address (NOT a post office address): 1112 TAMU
12. City: College Station
13. State: TX
14. Zip Code: 77843-1112
15. Type of incident: ☐ Theft ☐ Loss ☑ Release
16. Immediate notification provided to: ☐ APHIS ☑ CDC
17. Date of immediate notification: 04/10/2007
18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 02/09/2006
28. Date of last inventory: 03/12/2007
29. Name of principal investigator for laboratory with select agents and toxins First: Thomas MI: A Last: Ficht
30. Location of incident (building and room #):
31. Location of incident (within room (e.g., freezer, incubator)): Aerosol Chamber
32. Biosafety level of laboratory where incident occurred: BSL3
33. Name and telephone number of agencies or local authorities notified: Health Dept. (512) 458-7318
34. Symbols or markings on vials (if any):
35. Agent was recovered (theft/loss): ☐ No ☐ Yes
36. Provide a summary of actions taken: ☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database ☐ Called police department (case #) ☑ Other (explain): See below
37. Provide a detailed summary of events (attach additional sheets if necessary):

Several months ago, one of our laboratory employees had an elevated titer (1:160) for Brucella. The lab report stated "...evidence of prior exposure", but "it does not confirm that the exposure was recent." While the exact cause is not known, the exposure could have occurred on 02/09/2006, and would have been the result of improper decontamination procedures. Specifically, the employee may have reached into an aerosol chamber after a run. The chamber was located within the BL3 lab. The laboratory's Bio-safety plan has since been updated and all lab personnel have been retrained. All other lab personnel have also been tested and found to be negative. The incident occurred during the time we were transitioning CDC compliance responsibilities within our organizational structure. This information should have been immediately reported to the CDC, but it was not. We now have a process in place to ensure notification of a loss, theft or release and we are auditing all records to ensure all incidents have been properly reported.

FAZD CENTER
NATIONAL CENTER FOR FOREIGN ANIMAL AND ZOONOTIC DISEASE DEFENSE

A Department of Homeland Security
National Center of Excellence
at Texas A&M University
in partnership with
the University of California Davis,
the University of Southern California,
and the University of Texas Medical Branch

June 1, 2007

Dr. Garry Adams
College of Veterinary Medicine
MS 4461
College Station, TX 77843-4461

Dear Dr. Adams,

Please find attached the Office of Naval Research (ONR) award modification, stating "The Texas A&M University shall cease conducting any research funded under this grant involving 'Select Agents and Toxins' as defined/listed at 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121." The award modification is effective as of May 15, 2007. As Science Leader for the Biological Systems of the National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center), this is being transmitted to you so that you can take the necessary actions needed in the College of Veterinary Medicine for the projects being conducted under this grant.

If you have any questions, please contact me.

Sincerely,

Neville P. Clarke, Director
National Center for Foreign Animal and Zoonotic Disease Defense

Attachment

cc: Dr. Richard Ewing

AWARD/ MODIFICATION

3a. ISSUED BY:
Office of Naval Research
875 North Randolph Street
Arlington, VA 22203-1995

1. INSTRUMENT TYPE: Grant
3b. CFDA: 12.300
2. AUTHORITY: 10 USC 2358, 31 USC 6304
3c. DUNS NUMBER:

4. AWARD NO.:	5. MODIFICATION NO.:	6. MODIFICATION TYPE:	7. PR NO.:
N00014-04-1-0660	P00004	Admin Mod	07PR07632-00

8. ACTIVITY/AGENCY PROPOSAL NO.:	9. RECIPIENT PROPOSAL NO.:	10. PROPOSAL DATE:	11. ACTIVITY TYPE:	12. PROGRAM TYPE:
N/A	N/A	Undated	Research	

13. ISSUED TO
13a. ADDRESS:
TEXAS AGRICULTURAL EXPERIMENT STATION THE
TEXAS A AND M UNIVERSITY SYSTEM
ADMINISTRATION BLDG RM 6
COLLEGE STATION, TX 77843-2147

13b. CAGE: 00JP8
13c. EDI/EFT NUMBER: 5035AA

13d. BUSINESS OFFICE CONTACT:
DIANE M GILLILAND

13e. TELEPHONE NUMBER: (979) 8454761
13f. EMAIL ADDRESS: d gilliland@tamu.edu

14. REMITTANCE ADDRESS (IF DIFFERENT FROM BLOCK 13):
Same as block #13

15. RESEARCH TITLE AND/OR DESCRIPTION OF PROJECT AND/OR PROPOSAL TITLE:
National Center for Foreign Animals and Zoonotic Disease Defense

16. FUNDING	ACTIVITY/AGENCY SHARE	RECIPIENT SHARE	TOTAL
PREVIOUSLY OBLIGATED:	$18,000,000.00	$.00	$18,000,000.00
OBLIGATED BY THIS ACTION:	$.00	$.00	$.00
TOTAL OBLIGATED ON AWARD:	$18,000,000.00	$.00	$18,000,000.00
FUTURE FUNDING:	$.00	$.00	$.00
GRANT TOTAL:	$18,000,000.00	$.00	$18,000,000.00

17. CURRENT FUNDING PERIOD
N/A THROUGH N/A

18. PERIOD OF PERFORMANCE
01-JUN-04 THROUGH 30-SEP-07

19. ACCOUNTING AND APPROPRIATION DATA:
See attached Financial Accounting Data Sheet (s)

20a. PRINCIPAL INVESTIGATOR/RECIPIENT TECHNICAL REPRESENTATIVE:
NEVILLE P CLARKE

20b. TELEPHONE NUMBER: (979) 8452855
20c. EMAIL ADDRESS: n-clarke@tamu.edu

21. TECHNICAL REPRESENTATIVE
21a. NAME: LAURA PETONITO
21b. CODE: ONR 0811
21c. ADDRESS:
University Programs
Washington, DC 20528

21d. TELEPHONE NUMBER: (202) 2545840
21e. EMAIL ADDRESS: laura.petonito@dhs.gov

22. AWARDING OFFICE CONTACT
22a. NAME: Brian K. Kehoe
22b. CODE: ONR BD252
22c. ADDRESS:
Office of Naval Research
875 North Randolph Street
Arlington, VA 22203-1995

22d. TELEPHONE NUMBER: (703) 588-0610
22e. EMAIL ADDRESS: kehoeb@onr.navy.mil

23a. ADMINISTRATIVE OFFICE:
23b. CODE: N66018
ONR REG SAN DIEGO-N66018
FAX 619 221 5615
140 SYLVESTER ROAD
BLDG 140 ROOM 213
SAN DIEGO, CA 92106-3521
FAX: ()

24. SUBMIT PAYMENT REQUEST TO:
Same as block #23a

25a. PAYING OFFICE:
25b. CODE: N68892
DFAS CHARLESTON-N68892
CHARLESTON, SC 29423-8054

26a. PATENT OFFICE:
26b. CODE: N00014
Office of Naval Research
ATTN: ONR 00CC
One Liberty Center
875 North Randolph Street, Suite 1425
Arlington, VA 22203-1995

ONR AWARD FORM (10/03) - version 1.1

AWARD NO. N00014-04-1-0660	**AWARD/MODIFICATION**	MODIFICATION NO. P00004	

27. SPECIAL INSTRUCTIONS:
See "Special Requirements" Attachment

28. DELEGATIONS: The administration duties listed below have been delegated to the administrative office (block 23a). Upon request the awarding office contact (block 22) will make their full text available. Please direct questions to the contacts @: http://www.onr.navy.mil/02/024/offices.asp

Full Delegation

29. TERMS AND CONDITIONS: The following terms and conditions are incorporated herein by reference with the same force and effect as if they were given in full text. Upon request the awarding office contact named in block 22 will make their full text available, or they can be found at the specified URL.

DOCUMENT	URL	CLAUSES
UAAC Acceptance C	http://www.onr.navy.mil/02/terms.htm	
UAWA Award A	http://www.onr.navy.mil/02/terms.htm	
UBB1 FDP IV APR 2005	http://www.onr.navy.mil/02/docs/2005apr_fdp_general_terms_conditions.pdf	
UVV1 ONR FDP Specific OCT 2002	http://www.nsf.gov/pubs/fdp/onr02.pdf	

30. OPTIONS OPTION NO. AMOUNT PERIOD
(1)
(2)
(3)
(4)

31. REPORTS: The following reports must be submitted to the indicated addressees, in the indicated quantities, within 90 days following the expiration or termination of the project. Final Technical Reports must have a SF298, Report Documentation Page, accompanying them. Unless otherwise stated in the award/modification, complete Block 12a of the SF298 as follows: "Approved for Public Release; distribution is Unlimited".

ADDRESSEE	REPORT TYPE	COPIES
See block #21 (Frequency)	Final Technical Report with SF298 Performance/Technical Report (Annually) with SF298	1 1
See block #23a	Report of Inventions and Subcontracts - DD 882 Final Technical Report - Transmittal Letter only Performance/Technical Report (Annually) Final Financial Status Report - SF269A - If advances used	1 1 1 1
Defense Technical Information Center 8725 John J Kingman Road Ste 0944 Fort Belvoir, VA 22060-6218	Final Technical Report with SF298 Performance/Technical Report (Annually) with SF298	1 1
See block #26a	Report of Inventions and Subcontracts - DD 882	1
Naval Research Laboratory ATTN: CODE 5596 4555 Overlook Avenue SW Washington, DC 20375-5320	Final Technical Report Performance/Technical Report (Annually) with SF298	1 1

32. FOR THE RECIPIENT		33. FOR THE UNITED STATES OF AMERICA	
32a. SIGNATURE OF PERSON AUTHORIZED TO SIGN N/A, SIGNATURE NOT REQUIRED ON THIS AWARD		33a. SIGNATURE OF AWARDING OFFICER Brian D. Glance	
32b. NAME AND TITLE OF SIGNER	32c. DATE SIGNED	33b. NAME AND TITLE OF AWARD OFFICER Brian D. Glance	33c. DATE SIGNED 16-MAY-07

FINANCIAL ACCOUNTING DATA SHEET - NAVY

1. CONTRACT NUMBER (CRITICAL)	2. SPIIN (CRITICAL)	3. MOD (CRITICAL)	4. PR NUMBER
N00014-04-1-0660		P00004	07PR07632-00

CLIN/SLIN	6. LINE OF ACCOUNTING A. ACRN (CRITICAL)	B. APPROPRIATION (CRITICAL)	C. SUBHEAD (CRITICAL)	D. OBJ CLS	E. PARM	F. RFM	G. SA	H. AAA (CRITICAL)	I. IT	J. PAA	K. COST CODE PROJ UNIT	MCC	PDU & SUF	7. AMOUNT (CRITICAL)	NAVY INTERNAL USE ONLY REF DOC/ACRN

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	PAGE TOTAL	$ .00
	GRAND TOTAL	$ .00

PREPARED/AUTORIZED BY:

DATE:

COMPTROLLER APPROVAL
FOR FISCAL DATA AND SIGNATURE
BY _____ for COMPTROLLER, ONR CONTRACT REVIEWED
DATE:

ONR AWARD FORM (10/99) - version 1.1

FINANCIAL ACCOUNTING DATA SHEET – NON-NAVY DoD ACTIVITIES

1. CONTRACT NUMBER (CRITICAL)	2. SPIIN (CRITICAL)	3. MOD (CRITICAL)	4. PR NUMBER	
N00014-04-1-0650		P00004	07PR07632-00	

5. CLIN/SUB	6. ACRN (CRITICAL)	7. ACCOUNTING CITATION	8. AMOUNT (CRITICAL)		NAVY INTERNAL USE ONLY REF DOC/ACRN
		This page is intentionally blank			
		PAGE TOTAL	$.00		
		GRAND TOTAL	$.00		

PREPARED/AUTHORIZED BY:

DATE:

COMPTROLLER APPROVAL:
FOR FISCAL DATA AND SIGNATURE
BY _____ for COMPTROLLER, ONR CONTRACT REVIEWED
DATE:

ONR AWARD FORM (10/99) - version 1.1

AWARD NO.	SPECIAL REQUIREMENTS	MODIFICATION NO.	
N00014-04-1-0660		P00001	

Effective as of the date of this modification:

The Texas A&M University shall cease conducting any research funded under this grant involving "Select Agents and Toxins" as defined/listed at 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121 . Activities authorized are limited to the administration of awards to its subrecipients.

After the effective date of the modification, any costs incurred by the Texas A&M University for research involving "Select Agents and Toxins" as defined/listed at 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121 conducted by Texas A&M University shall be considered unallowable.

This restriction may only be altered by written modification to the grant.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella, Brucella,* or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for Room and all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

10. Please provide any personal protective equipment or entry requirements that may be needed prior to entry into your laboratories.
11. Please provide any documents regarding unexpected animal illness.
12. Please provide an assessment of the risks of continuing to utilize the aerosol chamber.
13. Please provide a detail description of the measures implemented to protect the employees from exposures while decontaminating the aerosol chamber including any enhanced personal protective equipment (PPE) utilized and the medical surveillance activities implemented. The long term follow-up of employees should be included in this response.

The DSAT will be conducting an inspection of your entity on April 16, 2007 to assess the measures implemented by Texas A& M University to protect the staff and public from exposure to pathogenic microorganism, the measures implemented to prevent further incidents and to evaluate your entity's compliance with the select agent regulations. Please make available all staff members involved in the incident described in your report dated April 11, 2007 to be interviewed by the inspection team.

On April 16, 2007, the following representatives from the CDC will be visiting Texas A& M University:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Officer
Melissa Resnick, EIS Officer

Please have the response and any supporting documentation available for the inspectors upon their arrival to your entity on April 16, 2007.

Please contact Lori Bane, Compliance Officer with the DSAT at 404-718-2006 or at the address listed below if you have questions.

Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and
Emergency Response

OPERATING PROCEDURES FOR THE BIOSAFETY LABORATORY SUITE, BUILDING

THOMAS A. FICHT, PROFESSOR AND L. GARRY ADAMS, PROFESSOR

VETERINARY PATHOBIOLOGY

Table of Contents

Acknowledgements

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

Personnel wearing appropriate personal protective clothing and equipment conduct all procedures involving the manipulation of infectious materials. Additionally, all procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices. The laboratory has special engineering and design features.

The following standard and special safety practices, equipment and facilities apply to the Biosafety Level 3 Laboratory Suite in the . Disinfectants used include ethanol, 1% (w/v) Virkon-S and 10% (v/v) commercial bleach. Virkon-S is safe for use on human skin and is as effective as bleach at reducing *Brucella* viability. Ethanol is used for flame sterilization and may be used to clean surfaces, but is much less effective than either Virkon-S or bleach at inactivating *Brucella*.

1. ACCESS TO BSL3

1.1 Access is limited to areas working with SBAT is regulated by CDC/DOJ.

1.1 Only approved personnel may work with SBAT in registered areas.

1.2 Personnel are issued a key and pass card when you have been assigned a CDC/DOJ approval number and successfully completed all training requirements under the direction of the PI or designee.

1.2 Non-approved personnel must be escorted by approved personnel and are not permitted to work with or gain access to SBAT.

2.1 Non-approved personnel must be escorted at all times in the BSL3 and sign a certificate of training to acknowledge the laws governing access to SBAT.

2.2 It is the responsibility of the escort to maintain contact with the trainee and to correctly and completely fill in the Facility Access Log.

2. GENERAL DESCRIPTION OF THE BSL3 SUITE

2.1 The rooms of the BSL3 suite are color-coded to indicate levels of risk of exposure. Each area requires that certain minimum levels of precaution be followed.

1.1 Signage on rooms have been updated to include contact names, telephone numbers, and entry requirements.

2.2 GREEN: The changing rooms and airlock are the only green areas in the BSL3 suite. In these rooms, personnel change out of street clothes before entering the suite and into street clothes before exiting the suite. Street clothes are not worn inside the BSL3 suite; scrub suits are not worn outside the BSL3 suite.

2.3 YELLOW: In these areas, risk of exposure is minimized by keeping all potentially contaminated items inside of double-containers. All personnel will be wearing a minimum of:

3.1 scrub suit,

3.2 clogs or shoe covers,

3.3 latex exam gloves (1 pair), and

3.4 face mask.

2.4 Pink (Beige): The main labs are under negative pressure relative to the hallway to contain any accidental release of the agent. Culture flasks, tubes and plates may be transported between incubators and BSC in this area. Colonies may be counted on the plates.

4.1 No additional clothing is required at this point

2.5 RED: All biosafety cabinets are potential sites of exposure. These are the

only places where contaminated materials may be opened. In addition, the animal room is a site of high risk of exposure when animals are being housed. When actually working with contaminated items, clothing requirements include:

5.1 clothing required in the YELLOW zone,

5.2 wrap-around lab coat,

5.3 1 pair of Tyvek sleeves, and

5.4 latex exam gloves (2 pairs).

2.6 When working with animals, additional precautions are required, including the use of Tyvek coveralls and full-face respirator as described in section 5.7 below. Specific procedures for large animal work are outlined in Appendix I. Entry Procedures

2.7 The entry doors from the outer hallway into the Men's and Women's changing rooms are kept locked at all times.

7.1 Before entering BSL3, make sure that someone else knows where you are.

7.2 Indicate your entry into the BSL3 suite on the marker board in the outer hallway. Upon entry, log your name, time of day and date, and the room in which you will be working in the logbooks present in the outer locker rooms.

7.3 Keys and cards are issued to individuals and are not shared.

7.4 When escorting individuals be sure to have the visitor fill in all the information requested. It is your responsibility to verify their ID.

2.8 An additional logbook will be maintained in the "airlock" area to record entries of personnel and deliveries, as well as maintenance.

2.9 In the Changing Rooms (Green):

9.1 OUTER CHANGING ROOM:

1.1 Change out of street clothes. Store street clothes in a locker.

9.2 INNER CHANGING ROOM

2.1 Put on a scrub suit (shirt and pants).

2.2 Put on clogs or shoe covers.

2.3 Put on a face mask.

2.4 Put on 1 pair of latex exam gloves.

2.10 In the procedure laboratories:

10.1 Place signs on laboratory doors indicating the nature of the work performed.

1.1 Additional signage on rooms has been updated to include contact names, telephone numbers, and entry requirements.

10.2 Wrap-around lab coat are recommended over scrubs for procedures generating aerosols.

10.3 Put on 1 pair of Tyvek sleeves, covering both the exam gloves and the sleeves of the lab coat.

2.11 When working in the BIOSAFETY CABINET,

11.1 Put on a **second** pair of latex exam gloves.

11.2 When you move away from the BIOSAFETY CABINET:

2.1 Remove the outer gloves.

2.2 Disinfect the inner gloves with 70% ethanol.

3. PROCEDURES WHILE WORKING IN THE BSL3 SUITE

3.1 Follow all procedures outlined below under:

3.2 "Standard Microbiological Practices,"

3.3 "Special Practices: Biosafety Level 3," and

3.4 "Safety Equipment (Primary Barriers): Biosafety Level 3."

3.5 These sections are taken directly from "Biosafety in the Microbiological and Biomedical Laboratories."

3.6 The following specimens should be considered contaminated:

1.1 all items or liquids known to contain infectious agents;

1.2 any liquids or tissues of animal origin; and

1.3 any liquids containing cells or tissues of animal origin.

1.4 If there is any question about a substance, it should be considered contaminated.

3.7 All contaminated materials should be kept in double-containers when not inside a biosafety cabinet. The use of double-containers will protect against the possibility of a tube being cracked or incompletely sealed and against the possibility of breakage if dropped.

7.1 The tube, plate, dish, or zip-lock bag containing the contaminated material is the first (inner) container.

7.2 The second (outer) container may be:

2.1 a stainless steel container with lid (taped closed);

2.2 a plastic container with lid (taped or "locked" closed); or

2.3 a centrifuge carrier with plastic safety cover locked in place.

7.3 Exceptions to this include animals kept in Hepa filtered cages and plates containing bacterial colonies which are counted on the benchtop. The latter is transferred to the benchtop in sealed containers, but these are opened to visualize the colonies.

3.8 Handling sharp objects

8.1 Sharp objects include:

1.1 syringe needles,

1.2 glass Pasteur pipets (or any thin glass tubing),

1.3 broken glass,

1.4 knife (scalpel) blades, and

1.5 anything else that could puncture human skin.

8.2 Whenever possible, avoid the use of sharp objects and glass objects. Substitute plasticware for glassware.

8.3 Never re-cap bend, or break a hypodermic needle.

8.4 Never handle broken glass, use tweezers or tongs. Use a dustpan and broom to clean up broken glass.

3.9 When using the biological safety cabinets:

9.1 Minimize the number of items inside the biological safety cabinet. The only items should be those that are immediately required for the experiment. Too many items in the cabinet disrupt laminar airflow and reduce the level of protection provided by the cabinet.

9.2 Never obstruct the vents in the cabinet. These include:

2.1 the vent in the front of the cabinet (covered by the grill),

2.2 the vents on the left and right sides of the cabinet, and

2.3 the vent in the back of the cabinet.

9.3 Use plastic-backed absorbent paper for working with contaminated material.

3.10 Centrifugation of viable select agent (or any other BSL3 agent) may only be performed in sealed centrifuge cups. Signs to this effect must be placed on all centrifuges. Room ' are used for centrifugation and appropriate signage has been posted.

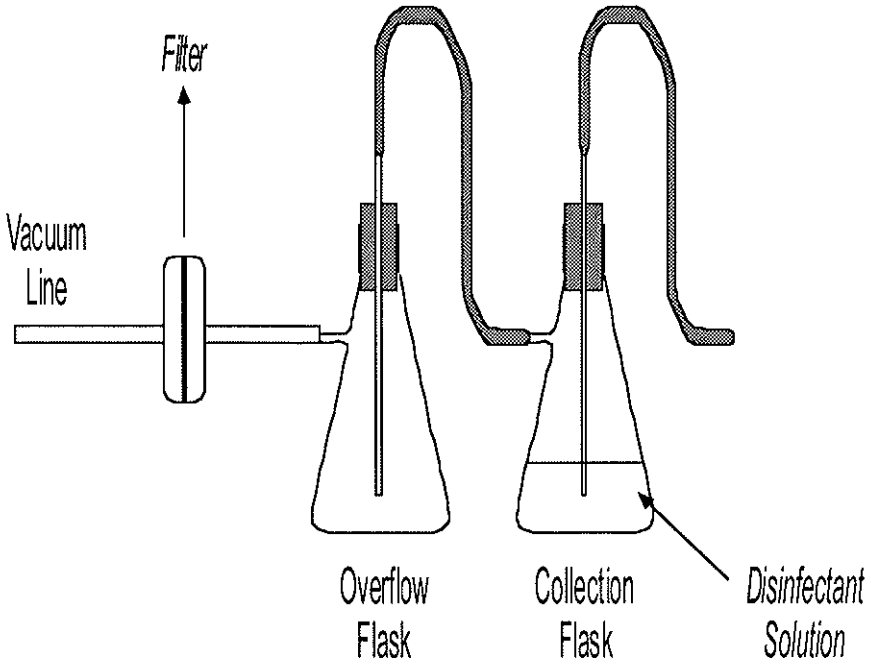

Fig. 1 Safety trap setup for use with in house vacuum line.

3.11 Spill procedures have been posted in rooms

3.12 To use the vacuum lines for aspirating biological fluids, use two large flasks in series with a microbiological filter (0.2 – 0.45 μm).

3.13 The telephones in the BSL3 suite are for emergency use only, to provide additional safety for you. Remember that you are holding potentially contaminated latex gloves very close to your face, that these gloves are touching the receiver, which is very close to your face and mouth, and that someone else will be using the receiver after you.

13.1 Remove the outer pair of latex exam gloves before picking up the receiver.

13.2 Decontaminate the receiver immediately after every use.

13.3 Do not give the BSL3 phone number to friends. They can leave a message, and you can return their calls when you leave the BSL3 suite. If there is an emergency, laboratory or office staff can transfer the call or come into the BSL3 suite to give you the message.

4. AEROSOL CHALLENGES

4.1 Intrafacility transfer forms are completed and faxed to EHSD before transfer.

4.2 *Brucella* suspensions used for inoculations are prepared and loaded into

conical tubes in rooms of building in the biological safety cabinets.

4.3 Inoculum containing viable organisms is transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease.

3.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

3.2 Such samples are transported through the men's or women's locker rooms at the CMP facility under constant supervision from approved persons.

4.4 At the CMP facility, personnel will change from street clothes into appropriate wardrobe

4.1 In the outer locker room, street clothes are removed and scrubs put on.

4.2 In the inner changing room, two pairs of gloves, facemask, tyvek suits and masks (N95 rated 3M 8210 or Tecnol PFR95) are put on before entry into the main hallway.

4.5 At the CMP facility, animals will be transported to room in microisolyzer cages and removed in the biological safety cabinets and loaded into cages for challenges.

4.6 Madison Chamber preparation and use

6.1 Plug cord from control box into the wall socket. Check the light on the control box. Connect the source of compressed air (e.g., building; tank) through the small flow meter to the nebulizer. Make sure that the compressed air regulator reads at least 30 psig. When the main switch is on, the vacuum pump, fans, and timer should be operating.

6.2 Carefully unscrew the glass jar from the nebulizer and place about 10 ml of challenge suspension in the jar. Attach the jar to the nebulizer unit and adjust the vertical stainless steel tube so that the lower (intake) end is about half an inch below the level of fluid in the jar.

6.3 Load the animal basket into the chamber, being careful to center it so that it doesn't touch the fan blades. Close the door and turn on the main switch, activating the vacuum pump, fans, and timer. Reset the timer to zero.

6.4 Check the main (room) air flow meter (the larger meter on the right). The center of the float (ball) should run about "21".

6.5 Turn on the compressed air and simultaneously start the timer. The air flow rate through the compressed air flow meter should read about 5 psig. Check visually to be certain that the challenge inoculum is being nebulized.

6.6 After exactly 300 seconds (5 min), the compressed air supply to the nebulizer should be shut off and the nebulization process will stop. Flow through the small meter will drop to zero, and visual inspection of the nebulizer will show no

activity. The timer should continue to run.

6.7 After an additional 600 seconds (10 min) or 900 seconds (15 min) total on the timer, turn off the main switch, stopping the vacuum pump, fans, and timer.

6.8 Open the chamber door and remove the animal basket. Remove the glass nebulizer jar, discard the challenge suspension, wash the jar thoroughly, and reload a fresh 10 ml volume of nebulizer suspension. Return to Step 3 above.

6.9 At the end of the infection procedure, spray the inside of the chamber with disinfectant and wipe down very thoroughly. Leave clean nebulizer jar upside down on paper towels on the sideboard to drain and dry.

4.7 Nebulizer jars are filled with inoculum under the safety cabinet.

7.1 After use, culture will be decanted back into 50 ml conical tubes under the cabinet and saved and transported back to building rooms

7.2 The nebulizer jar is filled with bleach to disinfect. The nebulizer "probe" is dipped in 10% bleach, followed by two dips in sterile water.

4.8 Mice are removed from the chamber and placed back into the microisolyzer cages under the biological safety cabinet. Sealed cages are transported back to the room housing the mice.

4.9 After animals are removed, tubes are disinfected under the safety cabinet (Clorox bleach wipes, 10% bleach on paper towels, 1% (w/v) virkon on paper towels) before being brought to the sink for washing.

4.10 The inside of the chamber is cleaned from front to back with 10% bleach or 1% (w/v) virkon to surface decontaminate the chamber.

4.11 The innoculum is returned to building in approved containers

11.1 After thorough decontamination of container containing innoculum, containers are placed inside approved durable (leak-proof) transport container that is then closed, sealed, and disinfected as well.

4.12 Personnel remove tyvek suits and place in approved containers to be autoclaved by CMP personnel.

12.1 Full-face respirators are surface decontaminated with 70% ethanol.

12.2 Scrubs are removed in inner changing rooms and placed in containers to be autoclaved by CMP personnel. Facemasks and gloves are thrown away.

12.3 Hands are thoroughly washed before entering the outer changing room.

12.4 Street clothes and personal belongings are worn and collected before exiting BL-3 suite.

5. Routine Cleaning and Decontamination Procedures

5.1 Sharp objects

1.1 Whenever possible, avoid the use of sharp objects and glass objects. Substitute plasticware for glassware.

1.2 All sharp objects (section 3.8.1 above) are to be disposed of in the Isolyzer® bottles provided in each laboratory.

2.1 When the contents of the bottle reach the fill line (prior to expiration), add the catalysts according to directions on the bottle to encapsulate all sharp objects.

2.2 The outside of the isolyzer is decontaminated and it is disposed with trash (do not autoclave).

5.2 At the very minimum, all laboratory surfaces should be disinfected before and after work. The following disinfectants may be used:

2.1 70% ethanol or isopropyl alcohol

2.2 Wexcide® (diluted 1:256, or 15 ml per gallon of water)

2.3 Phenocide® (diluted 4 ml per liter of water)

2.4 10% household bleach (diluted 100 ml per liter of water)

2.5 Virkon-S (1% solution in water)

5.3 All material to be autoclaved are stored in leak proof pans

3.1 Glassware is kept in separate, stainless steel pans, from other disposables (tip boxes, etc) to minimize accidental injuries.

5.4 All other (non-sharp) waste and trash generated in the laboratories are placed in biosafety bags and autoclaved.

4.1 Decontamination

1.1 When a biohazard waste bag is approximately $^2/_3$-full, it should be autoclaved.

1.2 Close the bag loosely with the rubber bands supplied.

1.3 Place autoclave tape over all occurrences of the word "Biohazard" on the bag.

1.4 Place the bag in a leak-proof pan before carrying the bag into the hallway (to prevent possible leakage of liquid onto the floor).

1.5 Autoclave using the "Gravity" program for trash (solid). Bacterial plates are autoclaved using the liquid cycle for spent media.

1.6 Test strips are also provided and at least one strip should be inserted into the opening of a bag. The bags should not be sealed tightly to prevent bursting open during autoclaving.

1.7 When autoclave cycle is complete, place the bag in the utility bin provided in the "clean room" that is lined with a black plastic bag.

1.8 When the bin is full these bags are transferred to the general trash (dumpster).

1.9 All autoclave runs are recorded and the autoclaves are certified weekly using thermotolerant spores (commercial supplier).

1.10 Autoclaves are operated as described on the EHSD web page (http://finance.tamu.edu/ehsd/resources/biosafety.asp) using conditions recommended by NIH and described in the IBC application form.

5.5 Disposal of liquid waste:

5.1 Large volumes of liquid waste are kept in autoclaveable containers less than ¾ full, and autoclaved in pans to catch any spills.

1.1 Decontamination with appropriate dilution of bleach or Virkon-S may also be used (section 5.2 above).

5.2 Smaller cultures in disposable plasticware are placed inside biohazard bags and placed in autoclaveable pans (for double-containment) before autoclaving.

5.3 Liquid waste is autoclaved on the "Liquid" as described on the Environmental Health and Safety web page and the IBC application form.

5.4 When the cycle is complete, open the autoclave door about 2 inches and wait at least 10 minutes before removing the liquids. (Follow directions given by the messages on the autoclave).

5.5 After 10 minutes, take the bottles out of the autoclave. If the autoclaved waste contains no coagulated solids, it may be poured down the sink. Bottles with coagulated solids must be sealed and placed directly in the dumpster outside the building.

5.6 Liquids may also be decontaminated by adding an equal volume of 10N NaOH, undiluted sodium hypochlorite (household bleach) to a final concentration of 10%, or addition of 1% (w/v) solid Virkon-S.

5.6 All biological specimens removed from the BSL3 that cannot be autoclaved must be disinfected prior to transfer

6.1 Cages are currently autoclaved off-site due to the small size of the autoclave.

6.2 Animal carcasses are autoclaved prior to disposal (incineration or biodigestion) by CMP as described in the IBC application form.

6.3 Any tissues containing viable organisms are transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease. [1]

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[1] Examples of the kinds of material that may need to be removed from biohazard areas usually the buildings in the research park for analysis and or transfer without autoclaving to another BSL3 laboratory:

-placental samples from live birth or aborted fetus

-selected tissues from necropsied animals (lung, liver, spleen, lymph nodes, milk, etc)

-abomasal fluid sample in either a sterile swab container or fluid placed into an empty vacutainer

-blood samples: either heparanized or non-heparanized blood in vacutainers

-sheets from door with log entries, and euthanasia logs (they do not go into the animal room; they are on the "dirty" side next to the showers

-isolyzer containers

-boots

-animal carcasses

-respirators

Sample disinfection:

-log sheets are sprayed with bleach and removed

3.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

3.2 Tissues are placed in sterile specimen bags and the outside of each bag is sprayed with disinfectant solution. Specimen bags are then placed within a secondary container that is also sprayed with the disinfectant solution.

3.3 All other specimens are inactivated using a number of different methods (heating at 65°C for at least 1 hour, the addition of gentamycin or following nucleic acid extraction). The killing of these samples is verified by evaluating growth on solid media for extended times (≥2 weeks at 37°C).

3.4 Such samples are transported through the men's or women's locker rooms.

3.5 Secondary containers are placed inside a durable outer container that is not brought to the BSL3 lab.

6.4 Blood samples in glass or plastic tubes are placed in test tube racks and sprayed with bleach. They are then placed within a secondary container that is also sprayed with the disinfectant solution.

4.1 After thorough decontamination, containers are placed inside a durable (leak-proof) container such as stainless steel that is then closed, sealed, and disinfected as well.

4.2 The outer surface of all containers must be disinfected. A 1:10 dilution of commercial bleach is effective in inactivating even highly concentrated suspensions of Brucella (up to 10^{11} CFU/ml) immediately. This concentration greatly exceeds any dosage used in these buildings or that may contaminate the exterior of bags or other containers.

4.3 The addition of sera is known to reduce the effectiveness of sodium hypochlorite. To enhance effective decontamination the bags or containers containing tissues are decontaminated multiple times. However, suspensions of bacteria do not normally contain added sera.

5.7 Brucella suspensions used for inoculations are prepared and loaded into syringes in rooms of building in the biological safety cabinets. The mice are brought to the individual labs in the microisolyzer cages and removed in the biological safety cabinets for injection. Alternatively, the mice are inoculated in the mouse room using the mobile cage changing station. In this latter case, researchers wear tyvek suits and full-face respirators and transport the loaded syringes in a sealed container.

5.8 Floors are mopped weekly with either:

-boots are disinfected with bleach and scrubbed to remove clods before disinfection.

-isolyzers are activated (solidified) and outsides sprayed with bleach.

-respirators are sprayed with bleach before removal

Autoclaved items:

-all trash (including gloves, tyvek suits, masks), surgical utensils, empty feed bags, are bagged and sprayed with bleach before removal and transport to the autoclave. Animal carcasses are triple bagged (bleach sprayed between layers) and brought to the vet school incinerator. They are treated as infectious substances and incinerated together.

8.1 Wexcide® or phenocide (as described above), or

8.2 Commercial bleach (1:10 dilution in water)

8.3 Virkon-S (1% w/v in water)

5.9 Caulk is used to fill any penetrations in walls and ceilings and corkboards replaced by dry erase board (laminated aluminum) from the facility.

6. Radioactive Waste Disposal

6.1 Liquid waste is maintained in leakproof carboys within a specifically designated and labeled area. This waste may be added to the regular radioactive waste stream after verifying that there is no threat of viable infectious agent.

1.1 Treatment of radioactive waste is usually performed by adjusting the liquid to a final concentration of 10% commercial bleach or 1% Virkon-S.

1.1 This liquid left up to one week and portions 100-1000 µl are tested for viability on tryptic soy agar plates in incubators. If the plates remain negative after one week of incubation at 37°C then the liquid is disposed of as radioactive waste.

1.2 If positive then the waste material is heated for 1 hour at 65°C and viability is checked again as described above.

1.3 The outside of the carboy is decontaminated with bleach and the liquid is added to the normal radioactive waste stream.

6.2 Solid waste (including test plates described above (section 6.1 above) is placed in biohazard bags and these are placed inside a second bag for chemical sterilization using ethylene oxide as described by the manufacturer.

2.1 After the proscribed treatment period the bag is unsealed and ethylene oxide is allowed to escape under a chemical fume hood.

1.1 The outside of the bag is decontaminated with bleach and the waste is added to the solid radioactive waste stream.

6.3 All radioactive work areas (or anything that may have come in contact) are surveyed using a Geiger counter and contaminated material is immediately removed. This material must not be left to expose co-workers. Even if shielded such material represents a potential source of harm. A swipe test should be performed weekly to better assess contaminatioin.

7. Decontamination Procedures for Spills

7.1 Immediately hold your breath. DON'T TAKE A DEEP BREATH!!

7.2 Signal others in the BSL3 labs of any spill outside Class IIa biological safety cabinet. All other personnel must exit and shower profusely with disinfectant soap and shampoo. Clothes must be removed within the BSL3 area and will be autoclaved by those cleaning up. Place a sign on the lab door to indicate unsafe condition.

7.3 Exit the lab and shower to remove any aerosol contamination.

7.4 Wait one hour to allow the room to evacuate any aerosol and put on a full-face respirator with HEPA cartridges and double gloves.

7.5 Use a polyzorb adsorbent pillow (one-liter) or paper towels to cover the spill. Prevent creation of contaminated aerosols.

7.6 Saturate all materials with disinfectant solution (see previous section for description).

7.7 Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in double autoclave bags.

7.8 Disinfect all exposed surfaces using any of the surface disinfecting agents (Wexcide, phenocide, bleach, Virkon-S) in aerosolizer. Virkon-S is the only disinfectant recommended for use on human skin.

7.9 Wipe surface of full face respirator with disinfectant, being careful to avoid skin contact with disinfectant.

7.10 Remove all clothing and shoes and place in double autoclave bag. Have a bag outside the room to transfer all contaminated material from room.

7.11 Remove full-face respirator and place in double plastic bag for ethylene oxide sterilization.

7.12 Continue sterilization of BSL3 area using aerosolizer with 1X Wexcide.

7.13 Make sure that all contaminated material is autoclaved or ethylene oxide sterilized.

7.14 Put on a clean wrap-around to go to locker room and shower profusely with disinfectant soap and shampoo.

8. PROCEDURE IN THE EVENT OF ACCIDENT

8.1 In the case of a spill proceed as described above and then report the accident to Dr. Thomas Ficht (979-845-4118 or , or your immediate supervisor and departmental administrator (979-845-5941).

8.2 In the event that you have an accident that causes a break in the skin (broken glass, etc) be sure to disinfect the area carefully using VirKonS (Dupont).

2.1 Always be certain to disinfect yourself carefully before leaving the BSL3 lab.

8.3 Make an appointment to see your physician or the Occupational Health Program Physicians at Scott & White clinic (979-691-3072).

3.1 Students (especially those on fellowship) should be sure to mention that this

accident is covered by Occupational Health and not Workman's Compensation.

9. Standard Microbiological Practices

9.1 Access to laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

9.2 Persons wash their hands after handling infectious materials and animals, after removing gloves, and on leaving the laboratory.

9.3 Eating, drinking, smoking, dipping tobacco or snuff, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear safety glasses, goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

9.4 Mouth pipetting is prohibited; mechanical pipetting devices are used.

9.5 All procedures are performed carefully to minimize the creation of aerosols.

9.6 Work surfaces are decontaminated at completion of any work and after any spill of viable material.

9.7 All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak proof container and closed for transport from the laboratory. Materials to be decontaminated at off-site from the laboratory are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

9.8 An insect and rodent control program is in effect.

10. Special Practices: Biosafety Level 3

10.1 Laboratory doors are kept closed when experiments are in progress.

10.2 The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

10.3 The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all

entry and exit procedures, enter the laboratory or animal rooms.

10.4 When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

10.5 Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

10.6 Baseline serum samples are collected and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

10.7 A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

10.8 Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

10.9 The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10.10 A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

10.1 Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal;

rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

10.2 Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

10.3 Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

10.11 A

ll manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

10.12 L

aboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials. Contaminated equipment should also be decontaminated before it is sent for repair or maintenance or package for transport in accordance with applicable local, state, or federal regulations, before removal from the facility. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.

10.13 C

ultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10.14 A

ll potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories or animal rooms are decontaminated before disposal or reuse.

10.15 S

pills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material.

10.16 S

pills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

10.17 A
nimals and plants not related to the work being conducted are not permitted in the laboratory.

11. Safety Equipment (Primary Barriers): Biosafety Level 3

11.1 Properly maintained biological safety cabinets are used (Class II or III) for all manipulation of infectious materials.

11.2 Outside of a biological safety cabinet, appropriate combinations of personal protective equipment are used (e.g., special protective clothing, masks, gloves, face protection, or respirators), in combination with physical containment devices (e.g., centrifuge safety cups, sealed centrifuge rotors, or containment caging for animals).

11.3 This equipment must be used for manipulations of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.

11.4 Face protection (goggles and mask, or faceshield) is worn for manipulations of infectious materials outside of a biological safety cabinet.

11.5 Respiratory protection is worn when aerosols cannot be safely contained (i.e., outside of a biological safety cabinet), and in rooms containing infected animals.

11.6 Protective laboratory clothing such as solid-front or wraparound gowns, scrub suits, or coveralls must be worn in, and not worn outside, the laboratory. Reusable laboratory clothing is to be decontaminated before being laundered.

11.7 Gloves must be worn when handling infected animals and when hands may contact infectious materials and contaminated surfaces or equipment. Disposable gloves should be discarded when contaminated, and never washed for reuse.

12. Exit Procedures

12.1 Any time you move away from the biosafety cabinet:

1.1 Remove the outer pair of gloves.

1.2 Disinfect the inner pair of gloves with 70% ethanol or 1% Virkon-S.

12.2 Before leaving the Procedure Laboratories (Pink or Beige):

2.1 Decontaminate all surfaces with appropriate disinfectant.

2.2 Turn on the ultraviolet light in the biosafety cabinet.
Leave the fan motor running in the biosafety cabinet (It requires a minimum of 20

minutes fan operation to establish laminar flow conditions.).

2.3 Take off the outer pair of gloves and discard in waste in bio-safety cabinet.

2.4 Take off the Tyvek sleeves and discard in waste in bio-safety cabinet.

2.5 Take off the wrap-around lab coat.

2.6 Disinfect the inner pair of gloves.

12.3 In the Changing Rooms (Green):

3.1 INNER CHANGING ROOM:

1.1 Take off the facemask.

1.2 Remove the inner pair of latex gloves.

1.3 Remove scrub suit and clogs.

1.4 Wash hands in the sink or use the shower.

3.2 OUTER CHANGING ROOM:

2.1 Put on street clothes.

2.2 Hands may be washed again in the men's or women's rest room on the first floor opposite the BSL3 changing rooms.

13. STORAGE AND INVENTORY OF SELECT AGENT (*BRUCELLA*)

13.1 Room has been designated a storage space and all freezers (-20°C and -80°C) in room are kept locked and the key may only be obtained by personnel having access to rooms

13.2 A daily record of select agent access from the freezers is maintained. The originals are kept in room Freezer inventories are maintained in the office of the PI.

2.1 The use of select agent must be indicated on the log including box number and slot number within the box.

2.2 All additions to the inventory must be registered in the agent access log.

2.3 Be certain to include the strain designation, freezer, box and slot number.

2.4 Destruction or complete use of inventory must be recorded on the freezer inventory log. This is especially critical, since the absence of tubes may be construed as lost or stolen.

2.5 Personal inventory sheets should be immediately updated to record the destruction and emailed to the PI, who will adjust the master electronic inventory accordingly.

13.3 Using the daily record of select agent access (previous section) inventory reconciliation will be performed monthly and finalized during IBC/EHSD inspection in January shutdown, maintenance.

13.4 A log is maintained to monitor animal removal from room to reconcile with animal inventory.

13.5 When plates are struck out and additional plates prepared the number of plates should be indicated in your notebook.

5.1 Subsequent plate disposal should be reconciled with the plates struck out. This will be evaluated weekly by the PI or appointed personnel.

14. INTRAFACILITY TRANSFERS

14.1 SBAT is transferred from the BSL3 suite in building using IATA approved packaging described in section 5.6 above and is maintained in the possession of approved personnel (CDC/DOJ clearance) on university property. In the event that public roads are taken a university police escort will be requested for a university vehicle.

1.1 The SBAT will only be handled within the interior BSL3 rooms of buildings or (CMP) and may be preloaded into syringes prior to transport.

1.2 All material that is not injected into animals is returned to this packaging that is decontaminated and returned to the BSL3 suite in building

1.3 The inoculant is re-titrated and the volume measured to verify return of the SBAT and the sample remaining is destroyed by autoclaving.

1.4 Tissues and other materials recovered from these animals is processed and once the bacterial burden is determined tissue samples and cultures are destroyed by autoclaving.

15. APPENDIX 1

The material on the following pages is taken from:

Biosafety in Microbiological and Biomedical Laboratories

Dept. Health & Human Services Public Health Service,
National Institutes of Health,
and the
Centers for Disease Control and Prevention

4th edition; May, 1999.

15.1 *Agent*: *Mycobacterium tuberculosis*, *M. bovis*

Mycobacterium tuberculosis and M. bovis infections are a proven hazard to laboratory personnel as well as others who may be exposed to infectious aerosols in the laboratory. The incidence of tuberculosis in laboratory personnel working with M. tuberculosis has been reported to be three times higher than those not working with the agent. Naturally or experimentally infected nonhuman primates are a proven source of human infection (e.g., the annual tuberculin conversion rate in personnel working with infected nonhuman primates is about 70/10,000 compared with less than 3/10,000 in the general population). Experimentally infected guinea pigs or mice do not pose the same problem since droplet nuclei are not produced by coughing in these species; however, litter from infected animals may become contaminated and serve as a source of infectious aerosols.

Laboratory Hazards: Tubercle bacilli may be present in sputum, gastric lavage fluids, cerebrospinal fluid, urine, and in lesions from a variety of tissues. Exposure to laboratory-generated aerosols is the most important hazard encountered. Tubercle bacilli may survive in heat-fixed smears, and may be aerosolized in the preparation of frozen sections and during manipulation of liquid cultures. Because of the low infective dose of M. tuberculosis for humans (i.e., ID_{50} <10 bacilli) and in some laboratories a high rate of isolation of acid-fast organisms from clinical specimens (>10%), sputa and other clinical specimens from suspected or known cases of tuberculosis must be considered potentially infectious and handled with appropriate precautions.

Recommended Precautions: Biosafety Level 2 practices, containment equipment and facilities are required for activities at American Thoracic Society (ATS) laboratory level I, preparation of acid-fast smears, and culturing of sputa or other clinical specimens, provided that aerosol generating manipulations of such specimens are conducted in a Class I or II biological safety cabinet. Liquefaction and concentration of sputa for acid-fast staining may also be conducted safely on the open bench by first treating the specimen (in a Class I or II safety cabinet) with an equal volume of 5% sodium hypochlorite solution (undiluted household bleach) and waiting 15 minutes before centrifugation.

Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities of ATS levels II and III) in the propagation and manipulation of cultures of M. tuberculosis or M. bovis, and for animal studies utilizing nonhuman primates experimentally or naturally infected with M. tuberculosis or M. bovis. Animal studies utilizing guinea pigs or mice can be conducted at Animal Biosafety Level 2. Skin testing with purified protein derivative (PPD) of previously skin-tested-negative laboratory personnel can be used as a surveillance procedure. A licensed attenuated live vaccine (BCG) is available but is not routinely used in the United States for laboratory personnel.

15.2 Agent: Mycobacterium spp. other than *M. tuberculosis* , *M. bovis* or *M. leprae*

Pike reported 40 cases of nonpulmonary "tuberculosis" thought to be related to accidents or incidents in the laboratory or autopsy room. Presumably these infections were due to mycobacteria other than *M. tuberculosis* or *M. bovis*. A number of mycobacteria that are ubiquitous in nature are associated with diseases, other than tuberculosis or leprosy, in humans, domestic animals, and wildlife. Characteristically, these organisms are infectious but not contagious. Clinically, the diseases associated with infections by these atypical-mycobacteria can be divided into three general categories:

- Pulmonary diseases resembling tuberculosis which may be associated with infection by *M. kansasii, M. avium* complex, and rarely, by *M. xenopi, M. malmoense, M. asiaticum, M. simiae* and *M. szulgai.*
- Lymphadenitis which may be associated with infection by *M. scrofulaceum, M. avium* complex, and rarely, by *M. fortuitum* and *M. kansasii.*
- Skin ulcers and soft tissue wound infections which may be associated with infection by *M. ulcerans, M. marinum, M. fortuitum,* and *M. chelonei.*

Laboratory Hazards: The agents may be present in sputa exudates from lesions, tissues, and in environmental samples (e.g., soil and water). Direct contact of skin or mucous membranes with infectious materials, ingestion, and accidental parenteral inoculation are the primary laboratory hazards associated with clinical materials and cultures. Infectious aerosols, created during the manipulation of broth cultures or tissue homogenates of these organisms associated with pulmonary disease, also pose a potential infection hazard to laboratory personnel.

Recommended Precautions: Biosafety Level 2 practices containment equipment and facilities are recommended for activities with clinical materials and cultures of *Mycobacterium* spp. other than *M. tuberculosis* or *M. bovis.* Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for animal studies with mycobacteria other than *M. tuberculosis, M. bovis,* or *M. leprae.*

15.3 Agent: Brucella (B. abortus, B. canis, B. melitensis, B. suis)

B. abortus, B. canis, B. melitensis, and *B. suis* have all caused illness in laboratory personnel. Brucellosis is the most commonly reported laboratory-associated bacterial infection. Hypersensitivity to *Brucella* antigens is also a hazard to laboratory personnel. Occasional cases have been attributed to exposure to experimentally and naturally infected animals or their tissues.

Laboratory Hazards. The agent may be present in blood, cerebrospinal fluid, semen, and occasionally urine. Most laboratory-associated cases have occurred in research facilities and have involved exposure to *Brucella* organisms being grown in large quantities. Cases have also occurred in a clinical laboratory setting: direct skin contact with cultures or with infectious clinical specimens from animals (e.g., blood, uterine discharges) are commonly implicated in these cases. Aerosols generated during laboratory procedures have caused large outbreaks. Mouth pipetting, accidental parenteral inoculations, and sprays into eyes, nose and mouth have also resulted in infection.

Recommended Precautions: Biosafety Level 2 practices are recommended for activities with clinical specimens of human or animal origin containing or potentially containing pathogenic *Brucella* spp. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment and facilities are recommended, respectively, for all manipulations of cultures of the pathogenic *Brucella* spp. listed in this summary, and for experimental animal studies. Vaccines are not available for use in humans.

15.4 Principals of Biosafety

The term "containment" is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of

containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

Primary containment, the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by both good microbiological technique and the use of appropriate safety equipment. The use of vaccines may provide an increased level of personal protection. Secondary containment, the protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices. Therefore, the three elements of containment include laboratory practice and technique, safety equipment, and facility design. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements.

4.1 Laboratory Practice and Technique.

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging for appropriate training of personnel.

Each laboratory should develop or adopt a biosafety or operations manual which identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks. Personnel should be advised of special hazards and should be required to read and to follow the required practices and procedures. A scientist trained and knowledgeable in appropriate laboratory techniques safety procedures, and hazards associated with handling infectious agents must direct laboratory activities.

When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures may be needed. The laboratory director is responsible for selecting additional safety practices, which must be in keeping with the hazard associated with the agent or procedure.

Laboratory personnel, safety practices, and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices.

4.2 Safety Equipment (Primary Barriers).

Safety equipment includes biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The biological safety cabinet (BSC) is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. Three types of biological safety cabinets (Class I, II, III) used in microbiological laboratories are described and illustrated in Appendix A. Open-fronted Class I and Class II biological safety cabinets are primary barriers which offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The Class II biological safety cabinet also provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet. The gas-tight Class III biological safety cabinet provides the highest attainable level of protection to personnel and the environment.

An example of another primary barrier is the safety centrifuge cup, an enclosed container designed to prevent aerosols from being released during centrifugation. To minimize this hazard, containment controls such as BSCs or centrifuge cups must be used for handling infectious agents that can be transmitted through the aerosol route of exposure.

Safety equipment also may include items for personal protection such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Personal protective equipment is often used in combination with biological safety cabinets and other devices which contain the agents, animals, or materials being worked with. In some situations in which it is impractical to work in biological safety cabinets, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

4.3 Facility Design (Secondary Barriers).

The design of the facility is important in providing a barrier to protect persons working inside and outside of the laboratory within the facility, and to protect persons or animals in the community from infectious agents which may be accidentally released from the laboratory. Laboratory management is responsible for providing facilities commensurate with the laboratory's function and the recommended biosafety level for the agents being manipulated.

The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in Biosafety Level 1 and 2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and handwashing facilities.

As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional air flow, air treatment systems to decontaminate or remove agents from exhaust air controlled access zones, airlocks as laboratory entrances, or separate buildings or modules for isolation of the laboratory. Design engineers for laboratories may refer to specific ventilation recommendations as found in the Applications Handbook for Heating, Ventilation, and Air-Conditioning (HVAC) published by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE).

4.4 Biosafety Levels.

Four biosafety levels (BSLs) are described which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity.

The recommended biosafety level(s) for the organisms in Section VII (see "Agent Summary Statements" at end of manual) represent those conditions under which the agent can ordinarily be safely handled. The laboratory director is specifically and primarily responsible for assessing risks and for appropriately applying the recommended biosafety levels. Generally, work with known agents should be conducted at the biosafety level recommended in Section VII. When specific information is available to suggest that virulence, pathogenicity, antibiotic resistance

patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Biosafety Level 1 practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. *Bacillus subtilis*, *Naegleria gruberi*, and infectious canine hepatitis virus are representative of those microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.

Biosafety Level 2 practices, equipment, and facilities are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus the salmonellae, and *Toxoplasma* spp. are representative of microorganisms assigned to this containment level. Biosafety Level 2 is appropriate when work is done with any human-derived blood, body fluids, or tissues where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the *Bloodborne Pathogen Standards* for specific, required precautions).

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Extreme precaution with contaminated needles or sharp instruments must be emphasized. Even though organisms routinely manipulated at BSL2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or devices such as a BSC or safety centrifuge cups. Other primary barriers should be used as appropriate, such as splash shields, face protection, gowns, and gloves.

Secondary barriers such as handwashing and waste decontamination facilities must be available to reduce potential environmental contamination.

Biosafety Level 3 practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. *Mycobacterium tuberculosis*, St. Louis encephalitis virus, and

Coxiella burnetii are representative of microorganisms assigned to this level. Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, and exposure to infectious aerosols.

At Biosafety Level 3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to

potentially infectious aerosols. For example, all laboratory manipulations should be performed in a BSC or other enclosed equipment, such as a gas-tight aerosol generation chamber. Secondary barriers for this level include controlled access to the laboratory and a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory.

Biosafety Level 4 practices, safety equipment, and facilities are applicable for work with dangerous and exotic agents, that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route, and for which there is no available vaccine or therapy. Additionally, agents with a close or identical antigenic relationship to Biosafety Level 4 agents should also be handled at this level. When sufficient data are obtained, work with these agents may continue at this level or at a lower level. Viruses such as Marburg or Congo-Crimean hemorrhagic fever are manipulated at BL4.

The primary hazards to personnel working with Biosafety Level 4 agents are respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and autoinoculation. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel, the community, and the environment.

The laboratory worker's complete isolation of aerosolized infectious materials is accomplished primarily by working in a Class III BSC or a full-body, air-supplied positive-pressure personnel suit. The Biosafety Level 4 facility itself is generally a separate building or completely isolated zone with complex, specialized ventilation and waste management systems to prevent release of viable agents to the environment.

The laboratory director is specifically and primarily responsible for the safe operation of the laboratory. His/her knowledge and judgment are critical in assessing risks and appropriately applying these recommendations. The recommended biosafety level represents those conditions under which the agent can ordinarily be safely handled. Special characteristics of the agents used, the training and experience of personnel, and the nature or function of the laboratory may further influence the director in applying these recommendations.

4.5 Animal Facilities.

Four biosafety levels are also described for activities involving infectious disease work with experimental mammals. These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1, 2, 3, and 4, and provide increasing levels of protection to personnel and the environment.

4.6 Clinical Laboratories.

Clinical laboratories, especially those in health care facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for "routine," acid-fast, and fungal cultures). It is the responsibility of the laboratory director to establish standard procedures in the laboratory which realistically address the issue of the infective hazard of clinical specimens.

Except in extraordinary circumstances (e.g., suspected hemorrhagic fever), the initial processing of clinical specimens and identification of isolates can be done safely at Biosafety Level 2, the recommended level for work with bloodborne pathogens such as hepatitis B virus

and HIV. The containment elements described in Biosafety Level 2 are consistent with the Occupational Exposure to Bloodborne Pathogens Standard 37 from the Occupational Safety and Health Administration (OSHA), that requires the use of specific precautions with all clinical specimens of blood or other potentially infectious material (Universal Precautions). Additionally, other recommendations specific for clinical laboratories may be obtained from the National Committee for Clinical Laboratory Standards.

Biosafety Level 2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as biological safety cabinets (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets. Biological safety cabinets should also be used for the initial processing of clinical specimens when the nature of the test requested or other information is suggestive that an agent readily transmissible by infectious aerosols is likely to be present (e.g., *M. tuberculosis*), or when the use of a biological safety cabinet (Class II) is indicated to protect the integrity of the specimen.

The segregation of clinical laboratory functions and limiting or restricting access to such areas is the responsibility of the laboratory director. It is also the director's responsibility to establish standard, written procedures that address the potential hazards and the required precautions to be implemented.

Importation and Interstate Shipment of Certain Biomedical Materials.

The importation of etiologic agents and vectors of human diseases is subject to the requirements of the Public Health Service Foreign Quarantine regulations. Companion regulations of the Public Health Service and the Department of Transportation specify packaging, labeling, and shipping requirements for etiologic agents and diagnostic specimens shipped in interstate commerce (see Appendix D).

The USDA regulates the importation and interstate shipment of animal pathogens and prohibits the importation, possession, or use of certain exotic animal disease agents which pose a serious disease threat to domestic livestock and poultry (see Appendix E).

4.7 Laboratory Facilities (Secondary Barriers): Biosafety Level 3

7.1 The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. A clothes change room (shower optional) may be included in the passageway.

7.2 Each laboratory contains a sink for handwashing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.

7.3 The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontamination.

7.4 Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

7.5 Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.

7.6 Windows in the laboratory are closed and sealed.

7.7 A method for decontaminating all laboratory wastes is available, preferably

within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method).

7.8 A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air from "clean" areas into the laboratory toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building, and is discharged to the outside with filtration and other treatment optional. The outside exhaust must be dispersed away from occupied areas and air intakes. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper.

7.9 The High Efficiency Particulate Air (HEPA)-filtered exhaust air from Class II or Class III biological safety cabinets is discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class II or III biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system. Exhaust air from Class II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months.

7.10 Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.

7.11 Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent, which are routinely maintained and replaced as needed.

7.12 An eyewash facility is readily available.

16. APPENDIX 2

16.1 Animal Biosafety:Standard Practices

1.1 Access to the animal facility is limited or restricted at the discretion of the laboratory or animal facility director and is secured using locked keypad access.

1.2 Personnel use double glove procedures as in the other laboratories and their inner gloves are washed after removing outer gloves, and before leaving the animal facility.

1.3 Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in animal rooms. Persons who wear contact lenses in animal rooms should also wear goggles or a face shield.

1.4 All procedures are carefully performed to minimize the creation of aerosols.

1.5 Work surfaces are decontaminated after use or after any spill of viable materials.

1.6 Doors to animal rooms open inward, are self-closing and are kept closed when experimental animals are present.

1.7 All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers .

1.8 An insect and rodent control program is in effect.

16.2 Animal Biosafety:Special Practices

2.1 The laboratory director or other responsible person restricts access to the animal room to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when infected animals are present. Persons who are at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal room. Persons at increased risk may include children, pregnant women, and persons who are immunodeficient or immunosuppressed. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the facility.

2.2 The laboratory director or other responsible person establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., for immunization) may enter the animal room.

2.3 When the infectious agent(s) in use in the animal room requires special entry provisions (e.g., the need for immunizations and respirators) a hazard warning sign, incorporating the universal biohazard symbol, is posted on the access door to the animal room. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates the special requirement(s) for entering the animal room.

2.4 Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

2.5 Baseline serum samples from all personnel working in the facility and other at-risk personnel should be collected and stored. Additional serum samples may be collected periodically and stored. The serum surveillance program must take into account the availability of methods for the assessment of antibody to the agent(s) of concern. The program should provide for the testing of serum samples at each collection interval and the communication of results to the participants.

2.6 A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

2.7 Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes.

2.8 A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments are restricted in the laboratory for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

8.1 Only needle-locking syringes or disposable syringe needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container, preferably containing a suitable disinfectant, for transport to a processing area for decontamination, preferably by autoclaving.

8.2 Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

8.3 Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

2.9 Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

2.10 Cages are autoclaved or thoroughly decontaminated before bedding is removed or before they are cleaned and washed. Equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

2.11 Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

2.12 All wastes from the animal room are autoclaved before disposal. All animal carcasses are incinerated or biodigested. Dead animals are transported from the animal room after autoclaving to the incinerator/biodigestor in leakproof covered containers.

2.13 Animals not involved in the work being performed are not permitted in the lab.

16.3 Animal Biosafety: Equipment (Primary Barriers)

3.1 Personal protective equipment is used for all activities involving manipulations of infectious materials or infected animals.

1.1 Work in the animal room requires at a minimum additional wrap-around or solid-front gowns with shoe covers or Tyvek suits. Front-button laboratory coats are unsuitable. Full-face respirators are also available, but are considered unnecessary when working with the animals within a biological safety cabinet. All protective wear is appropriately contained within the animal room trash until decontamination or disposal.

1.2 Personnel wear extra gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.

1.3 Appropriate face/eye and respiratory protection is worn by all personnel entering animal rooms.

1.4 Boots, shoe covers, or other protective footwear, and disinfectant footbaths are available and used when indicated.

3.2 Physical containment devices and equipment appropriate for the animal species are used for all procedures and manipulations of infectious materials or infected animals.

3.3 The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in partial containment caging systems, such as open cages placed in ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

16.4 Animal Biosafety:Facilities (Secondary Barriers)

4.1 The animal facility is designed and constructed to facilitate cleaning and housekeeping, and is separated from areas which are open to unrestricted personnel traffic within the building. Passage through two sets of doors is the basic requirement for entry into the animal room from access corridors or other contiguous areas. Physical separation of the animal room from access corridors or other activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the animal room.

4.2 The interior surfaces of walls, floors, and ceilings are water resistant so that they may be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate fumigation or space decontamination.

4.3 A foot, elbow, or automatically operated hand washing sink is provided in each animal room near the exit door.

4.4 If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and a HEPA filter.

4.5 If floor drains are provided, they are protected with liquid traps that are always filled with water or disinfectant.

4.6 Windows in the animal room are non-operating and sealed.

4.7 Animal room doors are self-closing and are kept closed when infected animals are present.

4.8 An autoclave for decontaminating wastes is available, preferably within the animal facility. Materials are transferred to the autoclave in a covered leakproof container whose outer surface has been decontaminated.

4.9 A non-recirculating ventilation system is provided. The supply and exhaust components of the system are balanced to provide for directional flow of air into the animal room. The exhaust air is discharged directly to the outside and clear of occupied areas and air intakes. Exhaust air from the room can be discharged without filtration or other treatment. Personnel must periodically validate that proper directional airflow is maintained.

4.10 The HEPA filtered exhaust air from Class I or Class II biological safety cabinets or other primary containment devices is discharged directly to the outside or through the building exhaust system. Exhaust air from these primary containment devices may be recirculated within the animal room if the device is tested and certified at least every 12 months. If the HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged to the outside through the building exhaust system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the performance of either the cabinet or building exhaust system.

17. TEST OF COMPREHENSION

Question	Answer (True or False)
➢ Street clothes may be worn in the BSL3 area under certain circumstances.	
➢ Contaminated materials may be opened on the benchtop.	
➢ When not inside a biosafety cabinet all contaminated materials must be kept in double-containers.	
➢ All manipulations of contaminated material should be performed at least 6 inches inside the biological safety cabinets.	
➢ Disinfect all work surfaces, door handles and any other materials which you may have come in contact with during your work.	
➢ In the event of a spill, outer clothes must be left in the lab where the spill has occurred and the lab should be vacated for at least 1 hr.	
➢ Spills should be covered with absorbent material and the site disinfected with bleach or other agent.	

I have read and understood this procedures manual, and I agree to follow all procedures outlined herein.

I understand that violation of any of these procedures will result in disciplinary action against me:

First violation	Warning
Second violation	Probation and 2-month prohibition from working in the BSL3 suite
Third violation	Dismissal from the TAMU payroll

Employee **Date**

I have checked this employee's test answers and we have discussed the BSL3 procedures.

Employer **Date**

CONFIDENTIAL
2006 CDC INSPECTION - FIRST RESPONSE - UPDATE

CDC Facility Inspection Report for Texas A&M University:

Deficiencies noted February 22, 2006 at Texas A&M University, 1112 TAMU, College Station. TX 77843-1112 (sections from "Biosafety in Microbiological & Biomedical Laboratories" (BMBL, 4th Ed.), the NIH Guidelines for Research Involving Recombinant DNA Molecules" (April 2002), and citations from 29 CFR 1910.1450, 29 CRF 1910.1200 or 42 CFR 73 specifying each requirement are given in brackets).

1. Requirement: A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins). [42CFR § 73.7(h)]

CDC Observation:	**TAMU Response (dated 5/4/06 & 5/15/06):**
At the time of the site visit, PI Tesh's Select agents were stored in laboratory room Entity registration shows this storage location as In addition, laboratory room registered for storage only; however, inspectors were informed that centrifugation of select agent material is performed in this room. Please update registration to reflect current storage and manipulation locations for select agents.	The CDC Select Agent registration has been updated to reflect room as a storage location and room as both a storage and laboratory location. Registration amendment for PI Tesh has been included in Appendix A.
Additional Clarification Request from CDC (dated 6/7/06)	**TAMU Comment**
No additional clarification was noted.	No further response requested.

2. Requirement: An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must: Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documents, and any deficiencies identified during an inspection must be corrected. [42 CFR § 73.11(a)(5)]

CDC Observation:	**TAMU Response (dated 5/4/06 & 5/15/06):**
Records provided to inspectors did not consistently document corrective action for any deficiencies identified during internal inspections. Please provide documentation that this requirement has been addressed.	We have modified our inspection SOP to clearly document corrective action for any deficiencies identified during internal inspections. The Office of Research Compliance will inform the PI of any items that need to be corrected as well as a correction date. [See Appendix B]
Additional Clarification Request from CDC (dated 6/7/06)	**TAMU Comment**
No additional clarification was noted.	No further response requested.

3. Requirement: An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security. Allow access only to individuals with access approval from the HHS Secretary or Administrator. [42 CFR § 73.11(d)(1)]

OPERATING PROCEDURES FOR THE BIOSAFETY LABORATORY SUITE, BUILDING

THOMAS A. FICHT, PROFESSOR AND L. GARRY ADAMS, PROFESSOR

VETERINARY PATHOBIOLOGY

February 22, 2007

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Acknowledgements

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

Personnel wearing appropriate personal protective clothing and equipment conduct all procedures involving the manipulation of infectious materials. Additionally, all procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices. The laboratory has special engineering and design features.

The following standard and special safety practices, equipment and facilities apply to the Biosafety Level 3 Laboratory Suite in the Building. Disinfectants used include ethanol, 1% (w/v) Virkon-S and 10% (v/v) commercial bleach. Virkon-S is safe for use on human skin and is as effective as bleach at reducing *Brucella* viability. Ethanol is used for flame sterilization and may be used to clean surfaces, but is much less effective than either Virkon-S or bleach at inactivating *Brucella*.

1. ACCESS TO BSL3

1.1 Access is limited to areas working with SBAT is regulated by CDC/DOJ.

1.1 Only approved personnel may work with SBAT in registered areas.

1.2 Personnel are issued a key and pass card when you have been assigned a CDC/DOJ approval number and successfully completed all training requirements under the direction of the PI or designee.

1.2 Non-approved personnel must be escorted by approved personnel and are not permitted to work with or gain access to SBAT.

2.1 Non-approved personnel must be escorted at all times in the BSL3 and sign a certificate of training to acknowledge the laws governing access to SBAT.

2.2 It is the responsibility of the escort to maintain contact with the trainee and to correctly and completely fill in the Facility Access Log.

2. GENERAL DESCRIPTION OF THE BSL3 SUITE

2.1 The rooms of the BSL3 suite are color-coded to indicate levels of risk of exposure. Each area requires that certain minimum levels of precaution be followed.

1.1 Signage on rooms have been updated to include contact names, telephone numbers, and entry requirements.

2.2 GREEN: The changing rooms and airlock are the only green areas in the BSL3 suite. In these rooms, personnel change out of street clothes before entering the suite and into street clothes before exiting the suite. Street clothes are not worn inside the BSL3 suite; scrub suits are not worn outside the BSL3 suite.

2.3 YELLOW: In these areas, risk of exposure is minimized by keeping all potentially contaminated items inside of double-containers. All personnel will be wearing a minimum of:

3.1 scrub suit,

3.2 clogs or shoe covers,

3.3 latex exam gloves (1 pair), and

3.4 face mask.

2.4 Pink (Beige): The main labs are under negative pressure relative to the hallway to contain any accidental release of the agent. Culture flasks, tubes and plates may be transported between incubators and BSC in this area. Colonies may be counted on the plates.

4.1 No additional clothing is required at this point

2.5 RED: All biosafety cabinets are potential sites of exposure. These are the

only places where contaminated materials may be opened. In addition, the animal room is a site of high risk of exposure when animals are being housed. When actually working with contaminated items, clothing requirements include:

5.1 clothing required in the YELLOW zone,

5.2 wrap-around lab coat,

5.3 1 pair of Tyvek sleeves, and

5.4 latex exam gloves (2 pairs).

2.6 When working with animals, additional precautions are required, including the use of Tyvek coveralls and full-face respirator as described in section 5.7 below. Specific procedures for large animal work are outlined in Appendix I. Entry Procedures

2.7 The entry doors from the outer hallway into the Men's and Women's changing rooms are kept locked at all times.

7.1 Before entering BSL3, make sure that someone else knows where you are.

7.2 Indicate your entry into the BSL3 suite on the marker board in the outer hallway. Upon entry, log your name, time of day and date, and the room in which you will be working in the logbooks present in the outer locker rooms.

7.3 Keys and cards are issued to individuals and are not shared.

7.4 When escorting individuals be sure to have the visitor fill in all the information requested. It is your responsibility to verify their ID.

2.8 An additional logbook will be maintained in the "airlock" area to record entries of personnel and deliveries, as well as maintenance.

2.9 In the Changing Rooms (Green):

9.1 OUTER CHANGING ROOM:

1.1 Change out of street clothes. Store street clothes in a locker.

9.2 INNER CHANGING ROOM

2.1 Put on a scrub suit (shirt and pants).

2.2 Put on clogs or shoe covers.

2.3 Put on a face mask.

2.4 Put on 1 pair of latex exam gloves.

2.10 In the procedure laboratories:

10.1 Place signs on laboratory doors indicating the nature of the work performed.

1.1 Additional signage on rooms has been updated to include contact names, telephone numbers, and entry requirements.

10.2 Wrap-around lab coat are recommended over scrubs for procedures generating aerosols.

10.3 Put on 1 pair of Tyvek sleeves, covering both the exam gloves and the sleeves of the lab coat.

2.11 When working in the BIOSAFETY CABINET,

11.1 Put on a **second** pair of latex exam gloves.

11.2 When you move away from the BIOSAFETY CABINET:

2.1 Remove the outer gloves.

2.2 Disinfect the inner gloves with 70% ethanol.

3. PROCEDURES WHILE WORKING IN THE BSL3 SUITE

3.1 Follow all procedures outlined below under:

3.2 "Standard Microbiological Practices,"

3.3 "Special Practices: Biosafety Level 3," and

3.4 "Safety Equipment (Primary Barriers): Biosafety Level 3."

3.5 These sections are taken directly from "Biosafety in the Microbiological and Biomedical Laboratories."

3.6 The following specimens should be considered contaminated:

1.1 all items or liquids known to contain infectious agents;

1.2 any liquids or tissues of animal origin; and

1.3 any liquids containing cells or tissues of animal origin.

1.4 If there is any question about a substance, it should be considered contaminated.

3.7 All contaminated materials should be kept in double-containers when not inside a biosafety cabinet. The use of double-containers will protect against the possibility of a tube being cracked or incompletely sealed and against the possibility of breakage if dropped.

7.1 The tube, plate, dish, or zip-lock bag containing the contaminated material is the first (inner) container.

7.2 The second (outer) container may be:

2.1 a stainless steel container with lid (taped closed);

2.2 a plastic container with lid (taped or "locked" closed); or

2.3 a centrifuge carrier with plastic safety cover locked in place.

7.3 Exceptions to this include animals kept in Hepa filtered cages and plates

containing bacterial colonies which are counted on the benchtop. The latter is transferred to the benchtop in sealed containers, but these are opened to visualize the colonies.

3.8 Handling sharp objects

8.1 Sharp objects include:

1.1 syringe needles,

1.2 glass Pasteur pipets (or any thin glass tubing),

1.3 broken glass,

1.4 knife (scalpel) blades, and

1.5 anything else that could puncture human skin.

8.2 Whenever possible, avoid the use of sharp objects and glass objects. Substitute plasticware for glassware.

8.3 Never re-cap bend, or break a hypodermic needle.

8.4 Never handle broken glass, use tweezers or tongs. Use a dustpan and broom to clean up broken glass.

3.9 When using the biological safety cabinets:

9.1 Minimize the number of items inside the biological safety cabinet. The only items should be those that are immediately required for the experiment. Too many items in the cabinet disrupt laminar airflow and reduce the level of protection provided by the cabinet.

9.2 Never obstruct the vents in the cabinet. These include:

2.1 the vent in the front of the cabinet (covered by the grill),

2.2 the vents on the left and right sides of the cabinet, and

2.3 the vent in the back of the cabinet.

9.3 Use plastic-backed absorbent paper for working with contaminated material.

3.10 Centrifugation of viable select agent (or any other BSL3 agent) may only be performed in sealed centrifuge cups. Signs to this effect must be placed on all centrifuges. Room are used for centrifugation and appropriate signage has been posted.

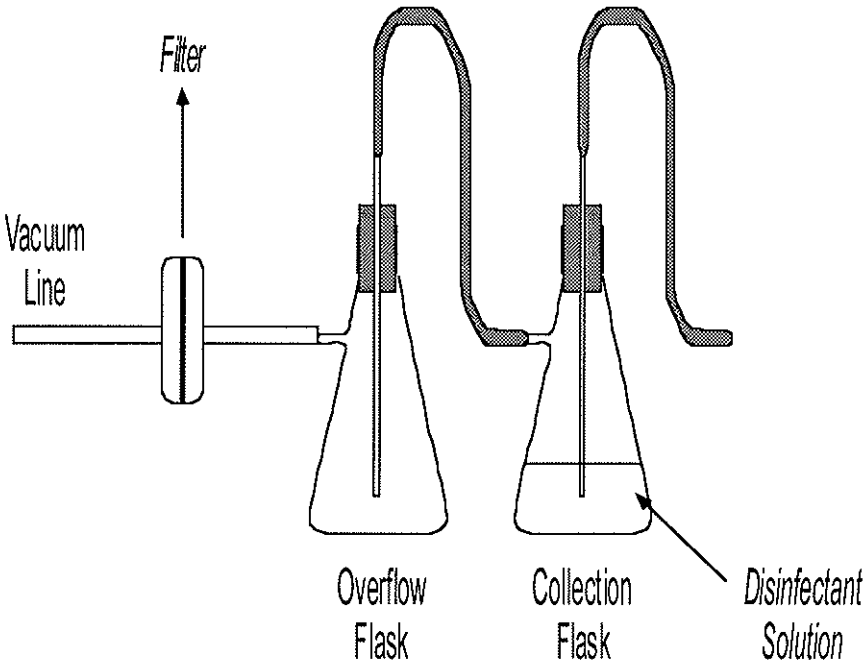

Fig. 1 Safety trap setup for use with in house vacuum line.

3.11 Spill procedures have been posted in rooms .

3.12 To use the vacuum lines for aspirating biological fluids, use two large flasks in series with a microbiological filter (0.2 – 0.45 μm).

3.13 The telephones in the BSL3 suite are for emergency use only, to provide additional safety for you. Remember that you are holding potentially contaminated latex gloves very close to your face, that these gloves are touching the receiver, which is very close to your face and mouth, and that someone else will be using the receiver after you.

13.1 Remove the outer pair of latex exam gloves before picking up the receiver.

13.2 Decontaminate the receiver immediately after every use.

13.3 Do not give the BSL3 phone number to friends. They can leave a message, and you can return their calls when you leave the BSL3 suite. If there is an emergency, laboratory or office staff can transfer the call or come into the BSL3 suite to give you the message.

4. AEROSOL CHALLENGES

4.1 *Brucella* suspensions used for inoculations are prepared and loaded into conical tubes in rooms building in the biological safety cabinets.

4.2 Inoculum containing viable organisms is transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease.

2.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

2.2 Such samples are transported through the men's or women's locker rooms at the CMP facility under constant supervision from approved persons.

4.3 At the CMP facility, personnel will change from street clothes into appropriate wardrobe

3.1 In the outer locker room, street clothes are removed and scrubs put on.

3.2 In the inner changing room, two pairs of gloves, facemask, tyvek suits and powered air-purifying respirators (PAPRs) are put on before entry into the main hallway.

4.4 At the CMP facility, animals will be transported to room in microisolyzer cages and removed in the biological safety cabinets and loaded into cages for challenges.

4.5 Madison Chamber preparation and use

5.1 Plug cord from control box into the wall socket. Check the light on the control box. Connect the source of compressed air (e.g., building; tank) through the small flow meter to the nebulizer. Make sure that the compressed air regulator reads at least 30 psig. When the main switch is on, the vacuum pump, fans, and timer should be operating.

5.2 Carefully unscrew the glass jar from the nebulizer and place about 10 ml of challenge suspension in the jar. Attach the jar to the nebulizer unit and adjust the vertical stainless steel tube so that the lower (intake) end is about half an inch below the level of fluid in the jar.

5.3 Load the animal basket into the chamber, being careful to center it so that it doesn't touch the fan blades. Close the door and turn on the main switch, activating the vacuum pump, fans, and timer. Reset the timer to zero.

5.4 Check the main (room) air flow meter (the larger meter on the right). The center of the float (ball) should run about "21".

5.5 Turn on the compressed air and simultaneously start the timer. The air flow rate through the compressed air flow meter should read about 5 psig. Check visually to be certain that the challenge inoculum is being nebulized.

5.6 After exactly 300 seconds (5 min), the compressed air supply to the nebulizer should be shut off and the nebulization process will stop. Flow through the small meter will drop to zero, and visual inspection of the nebulizer will show no activity. The timer should continue to run.

5.7 After an additional 600 seconds (10 min) or 900 seconds (15 min) total on the

timer, turn off the main switch, stopping the vacuum pump, fans, and timer.

5.8 Open the chamber door and remove the animal basket. Remove the glass nebulizer jar, discard the challenge suspension, wash the jar thoroughly, and reload a fresh 10 ml volume of nebulizer suspension. Return to Step 3 above.

8.1 Once the cycle has been completed (green light turns on) open the chamber, remove each individual housing cage (one at a time) transfer the mice into their micro-filter housing cages. One person should handle the mice while the other person open the cages.

8.2 Personnel handling the mice need to take extreme care and spray their gloves with Wexcide. After the transfer is complete, remove the outer pair of gloves and replace them immediately.

4.6 Post run decontamination.

6.1 Place each individual housing cage back in the rack, then place the rack back into the chamber. Seal chamber door using the attached latching system.

6.2 Remove with caution the inoculum from the nebulizer reservoir, empty the reservoir under the hood, and thoroughly clean the inside with 70% ethanol.

6.3 Clean the nebulizer with 70% ethanol

6.4 Place 15ml of 70% ethanol into the nebulizer reservoir, and re-attach the jar to the chamber and run the chamber for 15 min.

6.5 Once the cycle has been completed (green light turns on), open the chamber, and spray all external surfaces of the cage, rack and internal housing cages with Wexcide, covering all surfaces.

6.6 The cages/ rack should then be extensively rinsed out with water to remove Wexcide residue, wipe dry.

6.7 Spray internal surfaces of the chamber with Wexcide and soak for 10 minutes. Wipe dry, and spray with 70% ethanol to remove disinfectant residue. **WARNING: Be sure to spray ethanol after the Wexcide treatment as the residue will damage the chamber.**

4.7 Nebulizer jars are filled with inoculum under the safety cabinet.

7.1 After use, culture will be decanted back into 50 ml conical tubes under the cabinet and saved and transported back to building ooms

7.2 The nebulizer jar is filled with bleach to disinfect. The nebulizer "probe" is dipped in 10% bleach, followed by two dips in sterile water.

4.8 Mice are removed from the chamber and placed back into the microisolyzer cages under the biological safety cabinet. Sealed cages are transported back to the room housing the mice.

4.9 After animals are removed, tubes are disinfected under the safety cabinet (Clorox bleach wipes, 10% bleach on paper towels, 1% (w/v) virkon on paper towels) before being brought to the sink for washing.

4.10 The innoculum is returned to building in approved containers

10.1 After thorough decontamination of container containing innoculum, containers are placed inside approved durable (leak-proof) transport container that is then closed, sealed, and disinfected as well.

4.11 Personnel decontaminate the surface of their tyvek suits in room . prior to exiting.

11.1 The tyvek suits are removed in the hall outside room and placed in approved containers to be autoclaved by CMP personnel.

11.2 Full-face respirators are removed last and surface decontaminated with 70% ethanol.

11.3 Scrubs are removed in inner changing rooms and placed in containers to be autoclaved by CMP personnel. Facemasks and gloves are thrown away.

11.4 All personnel shower before entering the outer changing room.

11.5 Street clothes and personal belongings are collected before exiting BL-3 suite.

5. Routine Cleaning and Decontamination Procedures

5.1 Sharp objects

1.1 Whenever possible, avoid the use of sharp objects and glass objects. Substitute plasticware for glassware.

1.2 All sharp objects (section 3.8.1 above) are to be disposed of in the Isolyzer® bottles provided in each laboratory.

2.1 When the contents of the bottle reach the fill line (prior to expiration), add the catalysts according to directions on the bottle to encapsulate all sharp objects.

2.2 The outside of the isolyzer is decontaminated and it is disposed with trash (do not autoclave).

5.2 At the very minimum, all laboratory surfaces should be disinfected before and after work. The following disinfectants may be used:

2.1 70% ethanol or isopropyl alcohol

2.2 Wexcide® (diluted 1:256, or 15 ml per gallon of water)

2.3 Phenocide® (diluted 4 ml per liter of water)

2.4 10% household bleach (diluted 100 ml per liter of water)

2.5 Virkon-S (1% solution in water)

5.3 All material to be autoclaved are stored in leak proof pans

3.1 Glassware is kept in separate, stainless steel pans, from other disposables (tip boxes, etc) to minimize accidental injuries.

5.4 All other (non-sharp) waste and trash generated in the laboratories are placed in biosafety bags and autoclaved.

4.1 Decontamination

1.1 When a biohazard waste bag is approximately 2/3-full, it should be autoclaved.

1.2 Close the bag loosely with the rubber bands supplied.

1.3 Place autoclave tape over all occurrences of the word "Biohazard" on the bag.

1.4 Place the bag in a leak-proof pan before carrying the bag into the hallway (to prevent possible leakage of liquid onto the floor).

1.5 Autoclave using the "Gravity" program for trash (solid). Bacterial plates are autoclaved using the liquid cycle for spent media.

1.6 Test strips are also provided and at least one strip should be inserted into the opening of a bag. The bags should not be sealed tightly to prevent bursting open during autoclaving.

1.7 When autoclave cycle is complete, place the bag in the utility bin provided in the "clean room" that is lined with a black plastic bag.

1.8 When the bin is full these bags are transferred to the general trash (dumpster).

1.9 All autoclave runs are recorded and the autoclaves are certified weekly using thermotolerant spores (commercial supplier).

1.10 Autoclaves are operated as described on the EHSD web page (http://finance.tamu.edu/ehsd/resources/biosafety.asp) using conditions recommended by NIH and described in the IBC application form.

5.5 Disposal of liquid waste:

5.1 Large volumes of liquid waste are kept in autoclaveable containers less than 3/4-full, and autoclaved in pans to catch any spills.

1.1 Decontamination with appropriate dilution of bleach or Virkon-S may also be used (section 5.2 above).

5.2 Smaller cultures in disposable plasticware are placed inside biohazard bags and placed in autoclaveable pans (for double-containment) before autoclaving.

5.3 Liquid waste is autoclaved on the "Liquid" as described on the Environmental Health and Safety web page and the IBC application form.

5.4 When the cycle is complete, open the autoclave door about 2 inches and wait at least 10 minutes before removing the liquids. (Follow directions given by the messages on the autoclave).

5.5 After 10 minutes, take the bottles out of the autoclave. If the autoclaved waste contains no coagulated solids, it may be poured down the sink. Bottles with coagulated solids must be sealed and placed directly in the dumpster outside the building.

5.6 Liquids may also be decontaminated by adding an equal volume of 10N NaOH, undiluted sodium hypochlorite (household bleach) to a final concentration of 10%, or addition of 1% (w/v) solid Virkon-S.

5.6 All biological specimens removed from the BSL3 that cannot be autoclaved must be disinfected prior to transfer

6.1 Cages are currently autoclaved off-site due to the small size of the autoclave.

6.2 Animal carcasses are autoclaved prior to disposal (incineration or biodigestion) by CMP (, as described in the IBC application form.

6.3 Any tissues containing viable organisms are transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease. [1]

3.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

3.2 Tissues are placed in sterile specimen bags and the outside of each bag is sprayed with disinfectant solution. Specimen bags are then placed within a secondary container that is also sprayed with the disinfectant solution.

3.3 All other specimens are inactivated using a number of different methods (heating at 65°C for at least 1 hour, the addition of gentamycin or following nucleic acid extraction). The killing of these samples is verified by evaluating growth on solid media for extended times (≥2 weeks at 37°C).

3.4 Such samples are transported through the men's or women's locker rooms.

3.5 Secondary containers are placed inside a durable outer container that is not brought to the BSL3 lab.

6.4 Blood samples in glass or plastic tubes are placed in test tube racks and sprayed with bleach. They are then placed within a secondary container that is also sprayed with the disinfectant solution.

4.1 After thorough decontamination, containers are placed inside a durable (leak-proof) container such as stainless steel that is then closed, sealed, and

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[1] Examples of the kinds of material that may need to be removed from biohazard areas usually the buildings in the research park for analysis and or transfer without autoclaving to another BSL3 laboratory:

-placental samples from live birth or aborted fetus

-selected tissues from necropsied animals (lung, liver, spleen, lymph nodes, milk, etc)

-abomasal fluid sample in either a sterile swab container or fluid placed into an empty vacutainer

-blood samples: either heparanized or non-heparanized blood in vacutainers

-sheets from door with log entries, and euthanasia logs (they do not go into the animal room; they are on the "dirty" side next to the showers

-isolyzer containers

-boots

-animal carcasses

-respirators

Sample disinfection:

-log sheets are sprayed with bleach and removed

-boots are disinfected with bleach and scrubbed to remove clods before disinfection.

-isolyzers are activated (solidified) and outsides sprayed with bleach.

-respirators are sprayed with bleach before removal

Autoclaved items:

-all trash (including gloves, tyvek suits, masks), surgical utensils, empty feed bags, are bagged and sprayed with bleach before removal and transport to the autoclave. Animal carcasses are triple bagged (bleach sprayed between layers) and brought to the vet school incinerator. They are treated as infectious substances and incinerated together.

disinfected as well.

4.2 The outer surface of all containers must be disinfected. A 1:10 dilution of commercial bleach is effective in inactivating even highly concentrated suspensions of Brucella (up to 10^{11} CFU/ml) immediately. This concentration greatly exceeds any dosage used in these buildings or that may contaminate the exterior of bags or other containers.

4.3 The addition of sera is known to reduce the effectiveness of sodium hypochlorite. To enhance effective decontamination the bags or containers containing tissues are decontaminated multiple times. However, suspensions of bacteria do not normally contain added sera.

5.7 Brucella suspensions used for inoculations are prepared and loaded into syringes in rooms of building in the biological safety cabinets. The mice are brought to the individual labs in the microisolyzer cages and removed in the biological safety cabinets for injection. Alternatively, the mice are inoculated in the mouse room using the mobile cage changing station. In this latter case, researchers wear tyvek suits and full-face respirators and transport the loaded syringes in a sealed container.

5.8 Floors are mopped weekly with either:

8.1 Wexcide® or phenocide (as described above), or

8.2 Commercial bleach (1:10 dilution in water)

8.3 Virkon-S (1% w/v in water)

5.9 Caulk is used to fill any penetrations in walls and ceilings and corkboards replaced by dry erase board (laminated aluminum) from the facility.

6. Radioactive Waste Disposal

6.1 Liquid waste is maintained in leakproof carboys within a specifically designated and labeled area. This waste may be added to the regular radioactive waste stream after verifying that there is no threat of viable infectious agent.

1.1 Treatment of radioactive waste is usually performed by adjusting the liquid to a final concentration of 10% commercial bleach or 1% Virkon-S.

1.1 This liquid left up to one week and portions 100-1000 µl are tested for viability on tryptic soy agar plates in incubators. If the plates remain negative after one week of incubation at 37°C then the liquid is disposed of as radioactive waste.

1.2 If positive then the waste material is heated for 1 hour at 65°C and viability is checked again as described above.

1.3 The outside of the carboy is decontaminated with bleach and the liquid is added to the normal radioactive waste stream.

6.2 Solid waste (including test plates described above (section 6.1 above) is placed in biohazard bags and these are placed inside a second bag for chemical sterilization using ethylene oxide as described by the manufacturer.

2.1 After the proscribed treatment period the bag is unsealed and ethylene oxide is allowed to escape under a chemical fume hood.

1.1 The outside of the bag is decontaminated with bleach and the waste is added to the solid radioactive waste stream.

6.3 All radioactive work areas (or anything that may have come in contact) are surveyed using a Geiger counter and contaminated material is immediately removed. This material must not be left to expose co-workers. Even if shielded such material represents a potential source of harm. A swipe test should be performed weekly to better assess contaminatioin.

7. DECONTAMINATION PROCEDURES FOR SPILLS

7.1 Immediately hold your breath. DON'T TAKE A DEEP BREATH!!

7.2 Signal others in the BSL3 labs of any spill outside Class IIa biological safety cabinet. All other personnel must exit and shower profusely with disinfectant soap and shampoo. Clothes must be removed within the BSL3 area and will be autoclaved by those cleaning up. Place a sign on the lab door to indicate unsafe condition.

7.3 Exit the lab and shower to remove any aerosol contamination.

7.4 Wait one hour to allow the room to evacuate any aerosol and put on a full-face respirator with HEPA cartridges and double gloves.

7.5 Use a polyzorb adsorbent pillow (one-liter) or paper towels to cover the spill. Prevent creation of contaminated aerosols.

7.6 Saturate all materials with disinfectant solution (see previous section for description).

7.7 Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in double autoclave bags.

7.8 Disinfect all exposed surfaces using any of the surface disinfecting agents (Wexcide, phenocide, bleach, Virkon-S) in aerosolizer. Virkon-S is the only disinfectant recommended for use on human skin.

7.9 Wipe surface of full face respirator with disinfectant, being careful to avoid skin contact with disinfectant.

7.10 Remove all clothing and shoes and place in double autoclave bag. Have a bag outside the room to transfer all contaminated material from room.

7.11 Remove full-face respirator and place in double plastic bag for ethylene oxide sterilization.

7.12 Continue sterilization of BSL3 area using aerosolizer with 1X Wexcide.

7.13 Make sure that all contaminated material is autoclaved or ethylene oxide sterilized.

7.14 Put on a clean wrap-around to go to locker room and shower profusely with disinfectant soap and shampoo.

8. PROCEDURE IN THE EVENT OF ACCIDENT

8.1 In the case of a spill proceed as described above and then report the accident to Dr. Thomas Ficht (979-845-4118 or) or your immediate supervisor and departmental administrator (979-845-5941).

8.2 In the event that you have an accident that causes a break in the skin (broken glass, etc) be sure to disinfect the area carefully using VirKonS (Dupont).

2.1 Always be certain to disinfect yourself carefully before leaving the BSL3 lab.

8.3 Make an appointment to see your physician or the Occupational Health Program Physicians at Scott & White clinic (979-691-3072).

3.1 Students (especially those on fellowship) should be sure to mention that this accident is covered by Occupational Health and not Workman's Compensation.

9. STANDARD MICROBIOLOGICAL PRACTICES

9.1 Access to laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

9.2 Persons wash their hands after handling infectious materials and animals, after removing gloves, and on leaving the laboratory.

9.3 Eating, drinking, smoking, dipping tobacco or snuff, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear safety glasses, goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

9.4 Mouth pipetting is prohibited; mechanical pipetting devices are used.

9.5 All procedures are performed carefully to minimize the creation of aerosols.

9.6 Work surfaces are decontaminated at completion of any work and after any spill of viable material.

9.7 All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak proof container and closed for transport from the laboratory. Materials to be decontaminated at off-site from the laboratory are packaged in accordance with applicable local, state, and federal regulations,

before removal from the facility.

9.8 An insect and rodent control program is in effect.

10. Special Practices: Biosafety Level 3

10.1 Laboratory doors are kept closed when experiments are in progress.

10.2 The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

10.3 The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.

10.4 When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

10.5 Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

10.6 Baseline serum samples are collected and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

10.7 A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

10.8 Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural changes.

10.9 The laboratory director is responsible for ensuring that, before working with

organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10.10 A

high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

10.1 Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

10.2 Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

10.3 Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

10.11 A

ll manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

10.12 L

aboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials. Contaminated equipment should also be decontaminated before it is sent for repair or maintenance or package for transport in accordance with applicable local, state, or federal regulations, before removal from the facility. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.

10.13 C

ultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10.14 A
ll potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories or animal rooms are decontaminated before disposal or reuse.

10.15 S
pills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material.

10.16 S
pills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

10.17 A
nimals and plants not related to the work being conducted are not permitted in the laboratory.

11. Safety Equipment (Primary Barriers): Biosafety Level 3

11.1 Properly maintained biological safety cabinets are used (Class II or III) for all manipulation of infectious materials.

11.2 Outside of a biological safety cabinet, appropriate combinations of personal protective equipment are used (e.g., special protective clothing, masks, gloves, face protection, or respirators), in combination with physical containment devices (e.g., centrifuge safety cups, sealed centrifuge rotors, or containment caging for animals).

11.3 This equipment must be used for manipulations of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.

11.4 Face protection (goggles and mask, or faceshield) is worn for manipulations of infectious materials outside of a biological safety cabinet.

11.5 Respiratory protection is worn when aerosols cannot be safely contained (i.e., outside of a biological safety cabinet), and in rooms containing infected animals.

11.6 Protective laboratory clothing such as solid-front or wraparound gowns, scrub

suits, or coveralls must be worn in, and not worn outside, the laboratory. Reusable laboratory clothing is to be decontaminated before being laundered.

11.7 Gloves must be worn when handling infected animals and when hands may contact infectious materials and contaminated surfaces or equipment. Disposable gloves should be discarded when contaminated, and never washed for reuse.

12. EXIT PROCEDURES

12.1 Any time you move away from the biosafety cabinet:

1.1 Remove the outer pair of gloves.

1.2 Disinfect the inner pair of gloves with 70% ethanol or 1% Virkon-S.

12.2 Before leaving the Procedure Laboratories (Pink or Beige):

2.1 Decontaminate all surfaces with appropriate disinfectant.

2.2 Turn on the ultraviolet light in the biosafety cabinet.
Leave the fan motor running in the biosafety cabinet (It requires a minimum of 20 minutes fan operation to establish laminar flow conditions.).

2.3 Take off the outer pair of gloves and discard in waste in bio-safety cabinet.

2.4 Take off the Tyvek sleeves and discard in waste in bio-safety cabinet.

2.5 Take off the wrap-around lab coat.

2.6 Disinfect the inner pair of gloves.

12.3 In the Changing Rooms (Green):

3.1 INNER CHANGING ROOM:

1.1 Take off the facemask.

1.2 Remove the inner pair of latex gloves.

1.3 Remove scrub suit and clogs.

1.4 Wash hands in the sink or use the shower.

3.2 OUTER CHANGING ROOM:

2.1 Put on street clothes.

2.2 Hands may be washed again in the men's or women's rest room on the first floor opposite the BSL3 changing rooms.

13. STORAGE AND INVENTORY OF SELECT AGENT (*BRUCELLA*)

13.1 Room nas been designated a storage space and all freezers (-20°C and -80°C) in room are kept locked and the key may only be obtained by personnel having access to rooms

13.2 A daily record of select agent access from the freezers is maintained. The originals are kept in room Freezer inventories are maintained in the office of the PI.

2.1 The use of select agent must be indicated on the log including box number and slot number within the box.

2.2 All additions to the inventory must be registered in the agent access log.

2.3 Be certain to include the strain designation, freezer, box and slot number.

2.4 Destruction or complete use of inventory must be recorded on the freezer inventory log. This is especially critical, since the absence of tubes may be construed as lost or stolen.

2.5 Personal inventory sheets should be immediately updated to record the destruction and emailed to the PI, who will adjust the master electronic inventory accordingly.

13.3 Using the daily record of select agent access (previous section) inventory reconciliation will be performed monthly and finalized during IBC/EHSD inspection in January shutdown, maintenance.

13.4 A log is maintained to monitor animal removal from room to reconcile with animal inventory.

13.5 When plates are struck out and additional plates prepared the number of plates should be indicated in your notebook.

5.1 Subsequent plate disposal should be reconciled with the plates struck out. This will be evaluated weekly by the PI or appointed personnel.

14. INTRAFACILITY TRANSFERS

14.1 SBAT is transferred from the BSL3 suite in building using IATA approved packaging described in section 5.6 above and is maintained in the possession of approved personnel (CDC/DOJ clearance) on university property. In the event that public roads are taken a university police escort will be requested for a university vehicle.

1.1 The SBAT will only be handled within the interior BSL3 rooms of buildings or (CMP) and may be preloaded into syringes prior to transport.

1.2 All material that is not injected into animals is returned to this packaging that is decontaminated and returned to the BSL3 suite in building

1.3 The inoculant is re-titrated and the volume measured to verify return of the SBAT and the sample remaining is destroyed by autoclaving.

1.4 Tissues and other materials recovered from these animals is processed and once the bacterial burden is determined tissue samples and cultures are destroyed by autoclaving.

15. APPENDIX 1

The material on the following pages is taken from:

Biosafety in Microbiological and Biomedical Laboratories

Dept. Health & Human Services Public Health Service,
National Institutes of Health,
and the
Centers for Disease Control and Prevention

4th edition; May, 1999.

15.1 Agent: Mycobacterium tuberculosis, M. bovis

Mycobacterium tuberculosis and M. bovis infections are a proven hazard to laboratory personnel as well as others who may be exposed to infectious aerosols in the laboratory. The incidence of tuberculosis in laboratory personnel working with M. tuberculosis has been reported to be three times higher than those not working with the agent. Naturally or experimentally infected nonhuman primates are a proven source of human infection (e.g., the annual tuberculin conversion rate in personnel working with infected nonhuman primates is about 70/10,000 compared with less than 3/10,000 in the general population). Experimentally infected guinea pigs or mice do not pose the same problem since droplet nuclei are not produced by coughing in these species; however, litter from infected animals may become contaminated and serve as a source of infectious aerosols.

Laboratory Hazards: Tubercle bacilli may be present in sputum, gastric lavage fluids, cerebrospinal fluid, urine, and in lesions from a variety of tissues. Exposure to laboratory-generated aerosols is the most important hazard encountered. Tubercle bacilli may survive in heat-fixed smears, and may be aerosolized in the preparation of frozen sections and during manipulation of liquid cultures. Because of the low infective dose of M. tuberculosis for humans (i.e., ID_{50} <10 bacilli) and in some laboratories a high rate of isolation of acid-fast organisms from clinical specimens (>10%), sputa and other clinical specimens from suspected or known cases of tuberculosis must be considered potentially infectious and handled with appropriate precautions.

Recommended Precautions: Biosafety Level 2 practices, containment equipment and facilities are required for activities at American Thoracic Society (ATS) laboratory level I, preparation of acid-fast smears, and culturing of sputa or other clinical specimens, provided that aerosol generating manipulations of such specimens are conducted in a Class I or II biological safety cabinet. Liquefaction and concentration of sputa for acid-fast staining may also be conducted safely on the open bench by first treating the specimen (in a Class I or II safety cabinet) with an equal volume of 5% sodium hypochlorite solution (undiluted household bleach) and waiting 15 minutes before centrifugation.

Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities of ATS levels II and III) in the propagation and manipulation of cultures of M. tuberculosis or M. bovis, and for animal studies utilizing nonhuman primates experimentally or naturally infected with M. tuberculosis or M. bovis. Animal studies utilizing guinea pigs or mice can be conducted at Animal Biosafety Level 2. Skin testing with purified protein derivative (PPD) of previously skin-tested-negative laboratory personnel can be used as a surveillance procedure. A licensed attenuated live vaccine (BCG) is available but is not routinely used in the United States for laboratory personnel.

15.2 Agent: Mycobacterium spp. other than *M. tuberculosis* , *M. bovis* or *M. leprae*

Pike reported 40 cases of nonpulmonary "tuberculosis" thought to be related to accidents or incidents in the laboratory or autopsy room. Presumably these infections were due to mycobacteria other than *M. tuberculosis* or *M. bovis.* A number of mycobacteria that are ubiquitous in nature are associated with diseases, other than tuberculosis or leprosy, in humans, domestic animals, and wildlife. Characteristically, these organisms are infectious but not contagious. Clinically, the diseases associated with infections by these atypical-mycobacteria can be divided into three general categories:

- Pulmonary diseases resembling tuberculosis which may be associated with infection by *M. kansasii, M. avium* complex, and rarely, by *M. xenopi, M. malmoense, M. asiaticum, M. simiae* and *M. szulgai.*
- Lymphadenitis which may be associated with infection by *M. scrofulaceum, M. avium* complex, and rarely, by *M. fortuitum* and *M. kansasii.*
- Skin ulcers and soft tissue wound infections which may be associated with infection by *M. ulcerans, M. marinum, M. fortuitum,* and *M. chelonei.*

Laboratory Hazards: The agents may be present in sputa exudates from lesions, tissues, and in environmental samples (e.g., soil and water). Direct contact of skin or mucous membranes with infectious materials, ingestion, and accidental parenteral inoculation are the primary laboratory hazards associated with clinical materials and cultures. Infectious aerosols, created during the manipulation of broth cultures or tissue homogenates of these organisms associated with pulmonary disease, also pose a potential infection hazard to laboratory personnel.

Recommended Precautions: Biosafety Level 2 practices containment equipment and facilities are recommended for activities with clinical materials and cultures of *Mycobacterium* spp. other than *M. tuberculosis* or *M. bovis.* Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for animal studies with mycobacteria other than *M. tuberculosis, M. bovis,* or *M. leprae.*

15.3 Agent: Brucella (B. abortus, B. canis, B. melitensis, B. suis)

B. abortus, B. canis, B. melitensis, and *B. suis* have all caused illness in laboratory personnel. Brucellosis is the most commonly reported laboratory-associated bacterial infection. Hypersensitivity to *Brucella* antigens is also a hazard to laboratory personnel. Occasional cases have been attributed to exposure to experimentally and naturally infected animals or their tissues.

Laboratory Hazards. The agent may be present in blood, cerebrospinal fluid, semen, and occasionally urine. Most laboratory-associated cases have occurred in research facilities and have involved exposure to *Brucella* organisms being grown in large quantities. Cases have also occurred in a clinical laboratory setting: direct skin contact with cultures or with infectious clinical specimens from animals (e.g., blood, uterine discharges) are commonly implicated in these cases. Aerosols generated during laboratory procedures have caused large outbreaks. Mouth pipetting, accidental parenteral inoculations, and sprays into eyes, nose and mouth have also resulted in infection.

Recommended Precautions: Biosafety Level 2 practices are recommended for activities with clinical specimens of human or animal origin containing or potentially containing pathogenic *Brucella* spp. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment and facilities are recommended, respectively, for all manipulations of cultures of the pathogenic *Brucella* spp. listed in this summary, and for experimental animal studies. Vaccines are not available for use in humans.

15.4 Principals of Biosafety

The term "containment" is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of

containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

Primary containment, the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by both good microbiological technique and the use of appropriate safety equipment. The use of vaccines may provide an increased level of personal protection. Secondary containment, the protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices. Therefore, the three elements of containment include laboratory practice and technique, safety equipment, and facility design. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements.

4.1 Laboratory Practice and Technique.

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging for appropriate training of personnel.

Each laboratory should develop or adopt a biosafety or operations manual which identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks. Personnel should be advised of special hazards and should be required to read and to follow the required practices and procedures. A scientist trained and knowledgeable in appropriate laboratory techniques safety procedures, and hazards associated with handling infectious agents must direct laboratory activities.

When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures may be needed. The laboratory director is responsible for selecting additional safety practices, which must be in keeping with the hazard associated with the agent or procedure.

Laboratory personnel, safety practices, and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices.

4.2 Safety Equipment (Primary Barriers).

Safety equipment includes biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The biological safety cabinet (BSC) is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. Three types of biological safety cabinets (Class I, II, III) used in microbiological laboratories are described and illustrated in Appendix A. Open-fronted Class I and Class II biological safety cabinets are primary barriers which offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The Class II biological safety cabinet also provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet. The gas-tight Class III biological safety cabinet provides the highest attainable level of protection to personnel and the environment.

An example of another primary barrier is the safety centrifuge cup, an enclosed container designed to prevent aerosols from being released during centrifugation. To minimize this hazard, containment controls such as BSCs or centrifuge cups must be used for handling infectious agents that can be transmitted through the aerosol route of exposure.

Safety equipment also may include items for personal protection such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Personal protective equipment is often used in combination with biological safety cabinets and other devices which contain the agents, animals, or materials being worked with. In some situations in which it is impractical to work in biological safety cabinets, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

4.3 Facility Design (Secondary Barriers).

The design of the facility is important in providing a barrier to protect persons working inside and outside of the laboratory within the facility, and to protect persons or animals in the community from infectious agents which may be accidentally released from the laboratory. Laboratory management is responsible for providing facilities commensurate with the laboratory's function and the recommended biosafety level for the agents being manipulated.

The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in Biosafety Level 1 and 2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and handwashing facilities.

As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional air flow, air treatment systems to decontaminate or remove agents from exhaust air controlled access zones, airlocks as laboratory entrances, or separate buildings or modules for isolation of the laboratory. Design engineers for laboratories may refer to specific ventilation recommendations as found in the Applications Handbook for Heating, Ventilation, and Air-Conditioning (HVAC) published by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE).

4.4 Biosafety Levels.

Four biosafety levels (BSLs) are described which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity.

The recommended biosafety level(s) for the organisms in Section VII (see "Agent Summary Statements" at end of manual) represent those conditions under which the agent can ordinarily be safely handled. The laboratory director is specifically and primarily responsible for assessing risks and for appropriately applying the recommended biosafety levels. Generally, work with known agents should be conducted at the biosafety level recommended in Section VII. When specific information is available to suggest that virulence, pathogenicity, antibiotic resistance

patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Biosafety Level 1 practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. *Bacillus subtilis*, *Naegleria gruberi*, and infectious canine hepatitis virus are representative of those microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.

Biosafety Level 2 practices, equipment, and facilities are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus the salmonellae, and *Toxoplasma* spp. are representative of microorganisms assigned to this containment level. Biosafety Level 2 is appropriate when work is done with any human-derived blood, body fluids, or tissues where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the *Bloodborne Pathogen Standards* for specific, required precautions).

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Extreme precaution with contaminated needles or sharp instruments must be emphasized. Even though organisms routinely manipulated at BSL2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or devices such as a BSC or safety centrifuge cups. Other primary barriers should be used as appropriate, such as splash shields, face protection, gowns, and gloves.

Secondary barriers such as handwashing and waste decontamination facilities must be available to reduce potential environmental contamination.

Biosafety Level 3 practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. *Mycobacterium tuberculosis*, St. Louis encephalitis virus, and

Coxiella burnetii are representative of microorganisms assigned to this level. Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, and exposure to infectious aerosols.

At Biosafety Level 3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to

potentially infectious aerosols. For example, all laboratory manipulations should be performed in a BSC or other enclosed equipment, such as a gas-tight aerosol generation chamber. Secondary barriers for this level include controlled access to the laboratory and a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory.

Biosafety Level 4 practices, safety equipment, and facilities are applicable for work with dangerous and exotic agents, that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route, and for which there is no available vaccine or therapy. Additionally, agents with a close or identical antigenic relationship to Biosafety Level 4 agents should also be handled at this level. When sufficient data are obtained, work with these agents may continue at this level or at a lower level. Viruses such as Marburg or Congo-Crimean hemorrhagic fever are manipulated at BL4.

The primary hazards to personnel working with Biosafety Level 4 agents are respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and autoinoculation. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel, the community, and the environment.

The laboratory worker's complete isolation of aerosolized infectious materials is accomplished primarily by working in a Class III BSC or a full-body, air-supplied positive-pressure personnel suit. The Biosafety Level 4 facility itself is generally a separate building or completely isolated zone with complex, specialized ventilation and waste management systems to prevent release of viable agents to the environment.

The laboratory director is specifically and primarily responsible for the safe operation of the laboratory. His/her knowledge and judgment are critical in assessing risks and appropriately applying these recommendations. The recommended biosafety level represents those conditions under which the agent can ordinarily be safely handled. Special characteristics of the agents used, the training and experience of personnel, and the nature or function of the laboratory may further influence the director in applying these recommendations.

4.5 Animal Facilities.

Four biosafety levels are also described for activities involving infectious disease work with experimental mammals. These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1, 2, 3, and 4, and provide increasing levels of protection to personnel and the environment.

4.6 Clinical Laboratories.

Clinical laboratories, especially those in health care facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for "routine," acid-fast, and fungal cultures). It is the responsibility of the laboratory director to establish standard procedures in the laboratory which realistically address the issue of the infective hazard of clinical specimens.

Except in extraordinary circumstances (e.g., suspected hemorrhagic fever), the initial processing of clinical specimens and identification of isolates can be done safely at Biosafety Level 2, the recommended level for work with bloodborne pathogens such as hepatitis B virus

and HIV. The containment elements described in Biosafety Level 2 are consistent with the Occupational Exposure to Bloodborne Pathogens Standard 37 from the Occupational Safety and Health Administration (OSHA), that requires the use of specific precautions with all clinical specimens of blood or other potentially infectious material (Universal Precautions). Additionally, other recommendations specific for clinical laboratories may be obtained from the National Committee for Clinical Laboratory Standards.

Biosafety Level 2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as biological safety cabinets (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets. Biological safety cabinets should also be used for the initial processing of clinical specimens when the nature of the test requested or other information is suggestive that an agent readily transmissible by infectious aerosols is likely to be present (e.g., *M. tuberculosis*), or when the use of a biological safety cabinet (Class II) is indicated to protect the integrity of the specimen.

The segregation of clinical laboratory functions and limiting or restricting access to such areas is the responsibility of the laboratory director. It is also the director's responsibility to establish standard, written procedures that address the potential hazards and the required precautions to be implemented.

Importation and Interstate Shipment of Certain Biomedical Materials.

The importation of etiologic agents and vectors of human diseases is subject to the requirements of the Public Health Service Foreign Quarantine regulations. Companion regulations of the Public Health Service and the Department of Transportation specify packaging, labeling, and shipping requirements for etiologic agents and diagnostic specimens shipped in interstate commerce (see Appendix D).

The USDA regulates the importation and interstate shipment of animal pathogens and prohibits the importation, possession, or use of certain exotic animal disease agents which pose a serious disease threat to domestic livestock and poultry (see Appendix E).

4.7 Laboratory Facilities (Secondary Barriers): Biosafety Level 3

7.1 The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. A clothes change room (shower optional) may be included in the passageway.

7.2 Each laboratory contains a sink for handwashing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.

7.3 The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontamination.

7.4 Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

7.5 Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.

7.6 Windows in the laboratory are closed and sealed.

7.7 A method for decontaminating all laboratory wastes is available, preferably

within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method).

7.8 A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air from "clean" areas into the laboratory toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building, and is discharged to the outside with filtration and other treatment optional. The outside exhaust must be dispersed away from occupied areas and air intakes. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper.

7.9 The High Efficiency Particulate Air (HEPA)-filtered exhaust air from Class II or Class III biological safety cabinets is discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class II or III biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system. Exhaust air from Class II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months.

7.10 Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.

7.11 Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent, which are routinely maintained and replaced as needed.

7.12 An eyewash facility is readily available.

16. APPENDIX 2

16.1 Animal Biosafety:Standard Practices

1.1 Access to the animal facility is limited or restricted at the discretion of the laboratory or animal facility director and is secured using locked keypad access.

1.2 Personnel use double glove procedures as in the other laboratories and their inner gloves are washed after removing outer gloves, and before leaving the animal facility.

1.3 Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in animal rooms. Persons who wear contact lenses in animal rooms should also wear goggles or a face shield.

1.4 All procedures are carefully performed to minimize the creation of aerosols.

1.5 Work surfaces are decontaminated after use or after any spill of viable materials.

1.6 Doors to animal rooms open inward, are self-closing and are kept closed when experimental animals are present.

1.7 All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers .

1.8 An insect and rodent control program is in effect.

16.2 Animal Biosafety:Special Practices

2.1 The laboratory director or other responsible person restricts access to the animal room to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when infected animals are present. Persons who are at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal room. Persons at increased risk may include children, pregnant women, and persons who are immunodeficient or immunosuppressed. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the facility.

2.2 The laboratory director or other responsible person establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., for immunization) may enter the animal room.

2.3 When the infectious agent(s) in use in the animal room requires special entry provisions (e.g., the need for immunizations and respirators) a hazard warning sign, incorporating the universal biohazard symbol, is posted on the access door to the animal room. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates the special requirement(s) for entering the animal room.

2.4 Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

2.5 Baseline serum samples from all personnel working in the facility and other at-risk personnel should be collected and stored. Additional serum samples may be collected periodically and stored. The serum surveillance program must take into account the availability of methods for the assessment of antibody to the agent(s) of concern. The program should provide for the testing of serum samples at each collection interval and the communication of results to the participants.

2.6 A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures.

2.7 Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes.

2.8 A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments are restricted in the laboratory for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

8.1 Only needle-locking syringes or disposable syringe needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by

hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container, preferably containing a suitable disinfectant, for transport to a processing area for decontamination, preferably by autoclaving.

8.2 Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

8.3 Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

2.9 Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

2.10 Cages are autoclaved or thoroughly decontaminated before bedding is removed or before they are cleaned and washed. Equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

2.11 Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

2.12 All wastes from the animal room are autoclaved before disposal. All animal carcasses are incinerated or biodigested. Dead animals are transported from the animal room after autoclaving to the incinerator/biodigestor in leakproof covered containers.

2.13 Animals not involved in the work being performed are not permitted in the lab.

16.3 Animal Biosafety: Equipment (Primary Barriers)

3.1 Personal protective equipment is used for all activities involving manipulations of infectious materials or infected animals.

1.1 Work in the animal room requires at a minimum additional wrap-around or solid-front gowns with shoe covers or Tyvek suits. Front-button laboratory coats are unsuitable. Full-face respirators are also available, but are considered unnecessary when working with the animals within a biological safety cabinet. All protective wear is appropriately contained within the animal room trash until decontamination or disposal.

1.2 Personnel wear extra gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.

1.3 Appropriate face/eye and respiratory protection is worn by all personnel entering animal rooms.

1.4 Boots, shoe covers, or other protective footwear, and disinfectant footbaths are available and used when indicated.

3.2 Physical containment devices and equipment appropriate for the animal species are used for all procedures and manipulations of infectious materials or infected animals.

3.3 The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in partial containment caging systems, such as open cages placed in ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

16.4 Animal Biosafety:Facilities (Secondary Barriers)

4.1 The animal facility is designed and constructed to facilitate cleaning and housekeeping, and is separated from areas which are open to unrestricted personnel traffic within the building. Passage through two sets of doors is the basic requirement for entry into the animal room from access corridors or other contiguous areas. Physical separation of the animal room from access corridors or other activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the animal room.

4.2 The interior surfaces of walls, floors, and ceilings are water resistant so that they may be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate fumigation or space decontamination.

4.3 A foot, elbow, or automatically operated hand washing sink is provided in each animal room near the exit door.

4.4 If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and a HEPA filter.

4.5 If floor drains are provided, they are protected with liquid traps that are always filled with water or disinfectant.

4.6 Windows in the animal room are non-operating and sealed.

4.7 Animal room doors are self-closing and are kept closed when infected animals are present.

4.8 An autoclave for decontaminating wastes is available, preferably within the animal facility. Materials are transferred to the autoclave in a covered leakproof container whose outer surface has been decontaminated.

4.9 A non-recirculating ventilation system is provided. The supply and exhaust components of the system are balanced to provide for directional flow of air into the animal room. The exhaust air is discharged directly to the outside and clear of occupied areas and air intakes. Exhaust air from the room can be discharged without filtration or other treatment. Personnel must periodically validate that proper directional airflow is maintained.

4.10 The HEPA filtered exhaust air from Class I or Class II biological safety cabinets or other primary containment devices is discharged directly to the outside or through the building exhaust system. Exhaust air from these primary containment devices may be recirculated within the animal room if the device is tested and certified at least every 12 months. If the HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged to the outside through the building exhaust system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the performance of either the cabinet or building exhaust system.

17. TEST OF COMPREHENSION

Question	Answer (True or False)
➢ Street clothes may be worn in the BSL3 area under certain circumstances.	
➢ Contaminated materials may be opened on the benchtop.	
➢ When not inside a biosafety cabinet all contaminated materials must be kept in double-containers.	
➢ All manipulations of contaminated material should be performed at least 6 inches inside the biological safety cabinets.	
➢ Disinfect all work surfaces, door handles and any other materials which you may have come in contact with during your work.	
➢ In the event of a spill, outer clothes must be left in the lab where the spill has occurred and the lab should be vacated for at least 1 hr.	
➢ Spills should be covered with absorbent material and the site disinfected with bleach or other agent.	

I have read and understood this procedures manual, and I agree to follow all procedures outlined herein.

I understand that violation of any of these procedures will result in disciplinary action against me:

First violation	Warning
Second violation	Probation and 2-month prohibition from working in the BSL3 suite
Third violation	Dismissal from the TAMU payroll

Employee **Date**

I have checked this employee's test answers and we have discussed the BSL3 procedures.

Employer **Date**