

From: "Richard Ewing" <richard-ewing@tam.u.edu>
To: <fbazer@cvm.tamu.edu>, <gadams@cvm.tamu.edu>, "Jerry Strawser" <JStrawser@mays.tamu.edu>, <jsamuel@medicine.tamhsc.edu>, <tesh@medicine.tamu.edu>, "David Carlson" <carlson@tamhsc.edu>, "Brent S Mattox" <bsmattox@tam.u.edu>, <c-m-meyer@tam.u.edu>, "Charley Clark" <cbc@tam.u.edu>, "Eddie J Davis" <edavis@tam.u.edu>, "James Calvin" <j-calvin@tam.u.edu>, "John Salsman" <jmsalsman@tam.u.edu>, "Mike McKinney" <MMcKinney@tam.u.edu>, "Neville Clarke" <n-clarke@tam.u.edu>, "Thomas Ficht" <t-ficht@tam.u.edu>, "Tiffany Agnew" <tmagnew@tam.u.edu>, "Angelia Raines" <ARaines@vprmail.tamu.edu>
Date: 7/1/2007 5:40:26 PM
Subject: CDC Cease and Desist Order

As you can see in the attached memorandum, the Department of Select Agents and Toxins (DSAT) has expanded the cease and desist order, originally issued April 20, 2007, to include all work with select agents and toxins at TAMU. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

Richard Ewing
Responsible Officer

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@tam.u.edu

CC: "Richard Ewing" <richard-ewing@tam.u.edu>

June 30, 2007

MEMORANDUM

FROM: Dr. Richard E. Ewing

TO: All employees involved in research with Select Biological Agents and Toxins

SUBJECT: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

As of today, June 30, 2007, the Department of Select Agents and Toxins (DSAT) has expanded the cease and desist order, originally issued April 20, 2007, to include all work with select agents and toxins at TAMU. Effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

As you are aware, the original cease and desist order issued by the Department of Select Agents of the Centers for Disease Control and Prevention (CDC) covered the following:

1. The use of Room Building Texas A&M University, for any and all manipulations and storage of *Brucella abortus*, *Brucella melitensis*, and *Brucella suis* until such time as a request for the amendment to the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.
2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.
3. Allowing access to select agents and toxins by any individual who has not been approved for such access by DSAT following a security risk assessment by the Attorney General of the United States.

While the order has now been expanded to cover work with all select agents on the campus of Texas A&M, effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

cc: Dr. Michael D. McKinney
Dr. Eddie J. Davis
Dr. Jerry R. Strawser

Dr. David Carlson
Dr. James A. Calvin
Dr. Fuller W. Bazer
Mr. Chris M. Meyers
Mr. Charley B. Clark
Mr. John M. Salsman
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Thomas A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew
IBC

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: "Richard Ewing" <richard-ewing@tamu.edu>, <S-Kelly@tamu.edu>, "Tiffany Agnew" <tmagnew@tamu.edu>
Date: 7/1/2007 11:27:43 PM
Subject: Re: Per Your Request- CONFIDENTIAL DRAFT

Attached is the letter with a correction in the agency's title (CDC's Division of Select Agents and Toxins (DSAT)). Thanks, Angie

>>> Tiffany Agnew 06/30/07 6:37 PM >>>
Dr. Ewing & Scott,

Attached please find the letter we discussed earlier today. As you will notice, I have included a list of individuals to copy; however, please feel free to modify.

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

CC: <fbazer@cvm.tamu.edu>, <jmsalsman@tamu.edu>, "Kathy Holt" <KHolt@vprmail.tamu.edu>

June 30, 2007

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While the order has now been expanded to cover work with all select agents on the campus of Texas A&M, effective immediately, all select agent and toxin work must stop and all select agents and toxins must be securely stored until further notice.

cc: Dr. Eddie J. Davis
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Mr. John M. Salsman
Ms. Angelia M. Raines
Mr. Brent S. Mattox
Dr. Vernon L. Tesh
Dr. Thomas A. Ficht
Dr. L. Garry Adams
Dr. James E. Samuel
Ms. Tiffany M. Agnew
IBC

From: "President" <s-carroll@tamu.edu>
To: s-carroll@tamu.edu
Date: 7/2/2007 4:33:05 PM
Subject: Centers for Disease Control and Prevention (CDC) Review

2 July 2007

MEMORANDUM

TO: Texas A&M Faculty & Staff
SUBJECT: Centers for Disease Control and Prevention (CDC) Review

As you may already be aware, the Centers for Disease Control and Prevention (CDC) notified us over the weekend that we must suspend our homeland security-related research with selected agents and toxins pending the outcome of another site visit by CDC representatives. That next visit is scheduled later this month in the July 9-23 timeframe.

The CDC notification stems from safety and reporting considerations. First, let me make the point that the cited incidents at Texas A&M University did not pose a continuing threat to anyone on or off our campus. The first incident, an exposure to Brucella, was the University's error in not reporting the exposure in a timely manner. The more recently reported exposure was simply due to the fact that we have initiated more stringent testing and reporting criteria than in prior periods and than is the norm at other similar research facilities. In fact, none of the individuals with the latest reported elevated blood tests (a reading known as a titer) became ill from that exposure. This is generally the standard at other select agent research facilities used in determining whether to report an exposure to the CDC. In our case, we are exceeding that standard. Safety is always of paramount importance when anyone on campus—be they faculty, staff or students—who handles or otherwise deals with materials that are hazardous or even potentially hazardous. Nothing is absolutely nothing is more important than safeguarding the health of our personnel.

We are unequivocally committed to taking all appropriate steps to ensure we are in full compliance with all CDC and any other relevant policies and regulations. In fact, we have already strengthened our safety, training and reporting procedures. In addition, we are retaining the services of an independent expert and the environmental health and safety group from the UT Health Science Center in Houston to provide their views on how we can most expeditiously redeploy a fully compliant select agent research program. This action, in coordination with further discussion with CDC, will form the basis for our action plan going forward.

In summary, we plan to cooperate fully with the CDC and look forward to resolving this matter in an appropriate manner as quickly as possible so that we can move forward in our work supporting the nation's homeland security initiatives. Texas A&M is among the world's leading

research institutions with a long history of producing solid results that help mankind in many different ways. This is apparent day in and day out in disciplines all across this campus and state. Our goal is to ensure that our select agent research continues to be recognized at that same high standard.

Eddie J. Davis
Interim President

From: "Lorraine Hough" <tsbr@realtime.net>
To: "Fuller Bazer" <fbazer@cvm.tamu.edu>
Date: 7/2/2007 4:39:57 PM
Subject: Radio Report

Greetings. I heard a report on the radio this am regarding A&M and the CDC. The TSBR stands ready to stand by/support you all. Could you please fill me in on the facts as you know them to date and let me know if there is anything that we can do on you behalf?

Take care.
Lorraine

From: "Richard Ewing" <richard-ewing@tamu.edu>
To: <scully@tamu.edu>
Date: 7/2/2007 6:28:27 PM
Subject: Centers for Disease Control and Prevention (CDC) Review

Dear Kimberly,

Dr. Scully's research program is not affected by the recent cease and desist order from CDC. Thank you for your inquiry.

Regards,
Richard Ewing

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

From: Marlan Scully [mailto:scully@physics.tamu.edu]
Sent: Monday, July 02, 2007 5:43 PM
To: Carroll, Sherylon
Cc: scully@tamu.edu
Subject: Re: Centers for Disease Control and Prevention (CDC) Review
Importance: High

Dear Dr. Carroll,

You indicated that "the Centers for Disease Control and Prevention (CDC) notified us over the weekend that we must suspend our homeland security-related research with selected agents and toxins pending . . ."

Do you have the list of specific "selected agents and toxins" which are temporarily being banned from use in research labs pending visit of CDC representatives? (i.e., does this effect the research being done in our lab using bacillus subtilis [harmless spore with very similar chemical markers as the very hazardous anthrax spore]). We are involved in homeland security research (i.e., detection of anthrax), but do currently have any biohazardous material in our labs and so are not sure if we are effected by the email below.

Thank you for the clarification.

Best regards,
Kimberly
Assistant to Dr. Scully
845-1534

> 2 July 2007
>

>
> MEMORANDUM
>
>
> TO: Texas A&M Faculty & Staff
>
> SUBJECT: Centers for Disease Control and Prevention (CDC)
> Review
>
>
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> Prevention (CDC) notified us over the weekend that we must suspend our
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> pending the outcome of another site visit by CDC representatives. That
> next visit is scheduled later this month-in the July 9-23 timeframe.
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> The CDC notification stems from safety and reporting considerations.
> First, let me make the point that the cited incidents at Texas A&M
> University did not pose a continuing threat to anyone on or off our
> campus. The first incident, an exposure to Brucella, was the
> University's error in not reporting the exposure in a timely manner.
> The more recently reported exposure was simply due to the fact that we
> have initiated more stringent testing and reporting criteria than in
> prior periods and than is the norm at other similar research
> facilities. In fact, none of the individuals with the latest reported
> elevated blood tests (a reading known as a titer) became ill from that
> exposure. This is generally the standard at other select agent
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> facilities used in determining whether to report an exposure to the
> CDC. In our case, we are exceeding that standard. Safety is always of
> paramount importance when anyone on campus-be they faculty, staff or
> students- who handles or otherwise deals with materials that are
> hazardous or even potentially hazardous. Nothing-absolutely nothing-is
> more important than safeguarding the health of our personnel.
>
> We are unequivocally committed to taking all appropriate steps to
> ensure we are in full compliance with all CDC and any other relevant
> policies and regulations. In fact, we have already strengthened our
> safety, training and reporting procedures. In addition, we are
> retaining the services of an independent expert and the environmental
> health and safety group from the UT Health Science Center in Houston
to
> provide their views on how we can most expeditiously redeploy a fully
> compliant select agent research program. This action, in coordination
> with further discussion with CDC, will form the basis for our action
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> In summary, we plan to cooperate fully with the CDC and look forward
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> homeland security initiatives. Texas A&M is among the world's leading
> research institutions with a long history of producing solid results
> that help mankind in many different ways. This is apparent day in and
> day out in disciplines all across this campus and state. Our goal is
to

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- > that same high standard.
- >
- >
- > Eddie J. Davis
- > Interim President
- >
- >

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

CC: <f-bazer@tamu.edu>, "Angelia Raines" <ARaines@vprmail.tamu.edu>

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: <rsw2@cdc.gov>
Date: 7/2/2007 6:55:17 PM
Subject: Animal Report

Hi Dr. Weyant,

Per your request, the following summarizes the animals impacted by the suspension. Please let me know if you need additional information and please let us know how you would like us to handle the animals.

Thank you,
Angie

Investigator: Ficht
Research Agent: Brucella
Animal Type and number: 184 Mice
Where the animals are in the protocol: All animals have been vaccinated and due to be challenged.

Investigator: Samuel
Research Agent: Coxiella
Animal Type and #: 62 Mice and 23 Guinea pigs
Where the animals are in the protocol: We have the following animal experiments with infected animals ongoing:

23 Guinea pigs have been challenged. They are waiting to be reinfected.
28 Balb/C mice have been challenged and are under observation until July 30, 2007.
28 Balb/C mice have been challenged and are under observation until October 6, 2007.
During observation, animals are scheduled to be monitored and serum samples drawn periodically.
6 infected mice are scheduled for the passive transfer study (Infected animals are scheduled to be terminated and used to adoptively transfer cells to naive animals).

CC: "Ash, Olivia" <JOA@vprmail.tamu.edu>, "Bazer, Fuller" <fbazer@cvm.tamu.edu>, "Ewing, Richard" <Ewing@vprmail.tamu.edu>, "Ficht, Thomas" <t-ficht@tamu.edu>, <jsamuel@medicine.tamhsc.edu>, "Kelly, Scott" <S-Kelly@tamu.edu>, "Mattox, Brent S" <bsmattox@tamu.edu>, <RHenkel@cdc.gov>

From: "Richard Ewing" <richard-ewing@tamu.edu>
To: "Jim Calvin" <calvin@stat.tamu.edu>, <f-bazer@tamu.edu>
Date: 7/3/2007 11:20:31 PM
Subject: Fwd: Re: Request for Contact Information

FYI

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

>>> Tiffany Agnew 7/2/07 6:10 PM >>>
Angelia,

While in the meeting this afternoon, I received a phone call from the Diane Carr in the President's Office with the request. When I returned the call, I spoke with Rodney McClendon. Rodney indicated that the President wanted to communicate directly with Dr. Gerberding and Dr. Weyant. He also indicated a sense of urgency in this matter, so while I awaited more information from our CDC contact Jim McGee, I gathered information from the CDC's Employee Directory to expedite the communication.

Hope this information helps!

Tiffany

>>> Angelia Raines 7/2/2007 5:53 PM >>>
Tiffany,

Please update us on who is requesting this information.

Dr. Weyant's email is Rsw2@cdc.gov . His office number is 404 718-2001. I hope this helps. Thanks!
Angie

>>> "McGee, James F. (CDC/COTPER/DSAT)" < anv5@cdc.gov > 7/2/2007 4:37 PM >>>
Tiffany,

I am sorry I was unable to provide you the requested contact information for Dr. Gerberding this afternoon. I have forwarded your request to my superiors and I will follow-up with you tomorrow as soon as I have the information.

REQUEST: Contact information for Dr. Robbin Weyant, DSAT Director and
Dr. Julie Gerberding, CDC Director

Jim

James McGee, MSPH
Microbiologist & Laboratory Inspector
CDC/COTPER/DSAT, Mail Stop A-46
V: 404.718.2036 F: 404.718.2096
M: 404.697.9097 E: jmcgee@cdc.gov <mailto:jmcgee@cdc.gov> (ANV5)

From: "Carol Cantrell" <C-Cantrell@TAMU.EDU>
To: "Leo Pattera" <lpaterra@rf-mail.tamu.edu>
Date: 7/4/2007 1:46:44 PM
Subject: Re: Subject: CDC's suspension of work on select agents

Leo,

The Office of Research Compliance reports to Fuller Bazer and not me, so I am not very involved in this. But I can tell you what I do know.

All of the projects are either TAES or HSC so they will be contacting you with instructions. The ORC (Office of Research Compliance) has notified the PIs and Dick and Jim notified TAES and HSC today after they received a list of the projects. Not knowing whether or not these projects are RF or done in-house, they assumed that TAES and HSC will provide you with instructions as to the impact of the suspension on the statement of work of each individual projects. There may be some projects that have other activities (other than work with select agents) so spending may not have to stop but of course, all of this will be the sponsor's call. Also, I believe that there are only 4 PIs currently on campus working with select agents.

I did request from the ORC that in the future the IBC information include the contract administrator and the contracting entity administering the project so that the IBC or the ORC can contact the contract administrator in addition to the PI. The contract administrator can then work with the PI and contact the sponsor as to any stop work instructions.

Let me know if you have other questions.
Carol

>>> "Leo Pattera" <lpaterra@rf-mail.tamu.edu> 7/3/2007 3:15 PM >>>

Hi Carol,

Yesterday we saw the notice regarding CDC suspension. I'm sure your office is very busy dealing with this but can you provide some direction regarding how you want the Research Foundation to work with the VPR's office on this issue?

For example, have all the PI's and their related projects affected by the CDC suspension been identified? If so, can you share that list with us, at least for the projects we administer?

Is the VPR's office notifying the specific PI's that have projects affected by the suspension?

For the projects affected by the suspension should we freeze the

accounts so no funds can be expended for expenses incurred as of July 2, 2007?

If accounts are not frozen and that later result in cost overruns or disallowed costs, how will those costs be covered?

Is there any communication you want the Foundation to forward to sponsors?

Is there a particular response the Research Foundation should include when responding to any sponsor inquiries about this issue?

Does the suspension affect only TAMU projects or is this a System-wide suspension?

Is there anything the VPR's office wants the Research Foundation to do differently for projects involving select agents that are currently being negotiated or for proposals that are being submitted during this suspension period?

Again I realize you must be very busy with this issue but your assistance to make sure our actions are in alignment with the VPR's office is greatly appreciated.

Leo

Carol J. Cantrell
Senior Associate Vice President for Research
Texas A&M University
979 862-1478
c-cantrell@tamu.edu

CC: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Linda Woodman" <LFW@rf-mail.tamu.edu>, "Mark Smock" <MSS@rf-mail.tamu.edu>, "Jim Joyce" <joyce@tamhsc.edu>, "Diane Gilliland" <d-gilliland@tamu.edu>

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: <mihrig@cvm.tamu.edu>
Date: 7/5/2007 7:32:48 AM
Subject: Re: CDC inspectors

I will let them know. We also need to talk about using rooms for SBAT and non-SBAT use and the process for verifying what work can be performed at LARR. I will call later today. Thanks!

>>> "Melanie Ihrig" <mihrig@cvm.tamu.edu> 07/04/07 3:04 PM >>>
Angie,

Any of the CDC inspectors that will be going into the LARR ABSL3 suite must have had a TB test within the past 3 months and must have recent titres for Brucella and Coxiella. Will you please give the site visitors our requirements?

Thanks.

Melanie

CC: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Julie Barker" <j-barker@tam.u.edu>, "Richard Ewing" <richard-ewing@tam.u.edu>

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Julie Barker" <j-barker@tamu.edu>, "Richard Ewing" <richard-ewing@tamu.edu>
Date: 7/5/2007 7:45:35 AM
Subject: CDC trip update

I wanted to let you know that I have left messages for the CDC representatives regarding scheduling the site visit but I have not heard back from them yet. I will update you once I speak with them. Thanks!
Angie

CC: "Tiffany Agnew" <tmagnew@tamu.edu>

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Julie Barker" <j-barker@tamu.edu>, "James Calvin" <j-calvin@tamu.edu>, "Richard Ewing" <richard-ewing@tamu.edu>
Date: 7/5/2007 10:41:17 PM
Subject: Re: Key Pads

I tried to call Melanie earlier today but was not able to reach her. I will call her again to discuss. We need a way of completely separating SBAT rooms from non-SBAT rooms. Since all employees have the code, people without CDC approval could potentially gain access to the agent. I will update you after I have spoken to Melanie. Thanks, Angie

>>> James Calvin 07/05/07 8:34 PM >>>
Angie:

I know that you asked about key pads in the BSL-3 suite. Melanie indicated that all rooms had them, but that the problem was that all knew the code. She thought that the agreed upon solution was better signage so that when a select agent was in use a sign would be posted so that people unauthorized for that agent would know to stay out of the procedure room.

Jim

From: "Spencer, Thomas E." <tspencer@tam.u.edu>
To: "Acuff, Gary R." <gacuff@tam.u.edu>
Date: 7/7/2007 9:10:06 AM
Subject: RE: Very Important and Time Sensitive

Nope, Fuller and I do not work with any of these agents. Tom

From: Acuff, Gary R.
Sent: Saturday, July 07, 2007 8:24 AM
To: Adelson, David L; Alejandro Castillo (a-castillo@tam.u.edu); Bazer, Fuller; Bryan Johnson (catherine-tate@ansc.tam.u.edu); Chris Elsik (c-elsik@tam.u.edu); Clare Gill (clare-gill@tam.u.edu); Clay Cavinder (ccavinder@tam.u.edu); Dan Hale (dhale@tam.u.edu); Davey Griffin (dgriff@tam.u.edu); Forrest, David; Friend, Theodore H.; Gary R. Acuff (gacuff@tam.u.edu); g-carstens@tam.u.edu; Gibbs, Pete; Glenn Holub (gholub@tam.u.edu); Harms, Paul; Harry Kunkel ; Herring, Andy; Ing, Nancy; Jason Cleere (jcleere@ag.tam.u.edu); Jeff Savell (j-savell@tam.u.edu); Jimmy Keeton (jkeeton@tam.u.edu); Josie Coverdale; Kerri Harris (kharris@tam.u.edu); Knabe, Darrell A; m.amstalden@tam.u.edu; Michael Tomaszewski; Osburn, Wesley N; Penny Riggs; Ramsey, Shawn; Rhonda Miller (rmiller@tam.u.edu); Ron Randel (r-randel@tam.u.edu); Ronnie Edwards (r-edwards@tam.u.edu); Sanders, James; Sawyer, Jason (jsaw@mail.ansc.ad.tam.u.edu); Scott, Brett; Sigler, Dennis H.; Skaggs, Chris; Spencer, Thomas E.; Stephen Smith (sbsmith@tam.u.edu); Sterle, Jodi A.; Tedeschi, Luis; Tom Welsh; Vogelsang, Martha; Wickersham, Tryon A.; Wu, Guoyao; Zerle Carpenter (z-carpenter@tam.u.edu)
Cc: Glenn, Grace
Subject: Very Important and Time Sensitive

RAPID RESPONSE NEEDED - By July 9, 2007

All ANSC Faculty...

I have been asked to provide TAES with a list of faculty members who are working with select agents and toxins, as defined by the attached list from the Centers for Disease Control and Prevention (CDC). This information is needed by July 9.

Please reply to this e-mail only if you are working with any of these select agents, providing me with a list of the select agents and the source of funding for that research.

I will interpret a non-response as an indication that you are not working with any of these organisms or toxins.

Thanks for your help with this...

Gary

CC: "Bazer, Fuller" <fbazer@cvm.tamu.edu>

Nope, Fuller and I do not work with any of these agents. Tom

From: Acuff, Gary R.

Sent: Saturday, July 07, 2007 8:24 AM

To: Adelson, David L; Alejandro Castillo (a-castillo@tam.u.edu); Bazer, Fuller; Bryan Johnson (catherine-tate@ansc.tamu.edu); Chris Elsik (c-elsik@tam.u.edu); Clare Gill (clare-gill@tam.u.edu); Clay Cavinder (ccavinder@tam.u.edu); Dan Hale (dhale@tam.u.edu); Davey Griffin (dgriff@tam.u.edu); Forrest, David; Friend, Theodore H.; Gary R. Acuff (gacuff@tam.u.edu); g-carstens@tam.u.edu; Gibbs, Pete; Glenn Holub (gholub@tam.u.edu); Harms, Paul; Harry Kunkel / Herring, Andy; Ing, Nancy; Jason Cleere (jjcleere@ag.tamu.edu); Jeff Savell (j-savell@tam.u.edu); Jimmy Keeton (jkeeton@tam.u.edu); Josie Coverdale; Kerri Harris (kharris@tam.u.edu); Knabe, Darrell A; m.amstalden@tam.u.edu; Michael Tomaszewski; Osburn, Wesley N; Penny Riggs; Ramsey, Shawn; Rhonda Miller (rmiller@tam.u.edu); Ron Randel (r-randel@tam.u.edu); Ronnie Edwards (r-edwards@tam.u.edu); Sanders, James; Sawyer, Jason (jsaw@mail.ansc.ad.tamu.edu); Scott, Brett; Sigler, Dennis H.; Skaggs, Chris; Spencer, Thomas E.; Stephen Smith (sbsmith@tam.u.edu); Sterle, Jodi A.; Tedeschi, Luis; Tom Welsh; Vogelsang, Martha; Wickersham, Tryon A.; Wu, Guoyao; Zerle Carpenter (z-carpenter@tam.u.edu)

Cc: Glenn, Grace

Subject: Very Important and Time Sensitive

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Thanks for your help with this...

Gary

From: "Richard Ewing" <richard-ewing@tamu.edu>
To: <fbazer@cvm.tamu.edu>, "Carol Cantrell" <C-Cantrell@TAMU.EDU>, "Julie Barker" <j-barker@tamu.edu>, "James Calvin" <j-calvin@tamu.edu>, <l-coe@tamu.edu>, "Angelia Raines" <ARaines@vprmail.tamu.edu>, "Private REE" <Ewingprv@vprmail.tamu.edu>
Date: 7/8/2007 10:51:53 AM
Subject: Fwd: Biosafety observations CONFIDENTIAL

All,

Here is the report that we finally got from Emery. It seems to me to be a bit more critical than before... but I'm biased. We need to be prepared to speak to this and how it impacts.,

Regards,
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

>>> "Emery, Robert J" <Robert.J.Emery@uth.tmc.edu> 07/08/07 8:31 AM >>>
Chancellor McKinney, Interim President Davis and others:

Attached is the requested written summary of observations stemming from our recent meeting to discuss the Texas A&M University biosafety program. I hope the comments included will be of assistance.

I can send a hard copy upon my return to Houston if needed - I'm in Portland OR right now.

If any additional information is needed, please do not hesitate to call or e-mail.

Bob Emery

Memorandum

TO: Eddie J. Davis, Interim President
Texas A&M University

FROM: Robert Emery, Assistant Vice President
for Safety, Health, Environment & Risk Management
The University of Texas Health Science Center at Houston

SUBJECT: Review of the Texas A&M University Biological Safety Program,
Summary of findings and recommendations for subsequent actions

Texas A&M University requested that representatives from the University of Texas Health Science Center (UTHSCH) conduct a best practices review of the Biological Safety Program at Texas A&M University. On Tuesday, May 8, 2007, meetings were held with representatives from UTHSCH regarding the Biological Safety Program at Texas A&M University. The meetings occurred from 1:30 p.m. to 4:30 p.m. and included the following participants from UTHSCH: Robert Emery, Dr.PH; Bruce Brown, MPH; and Scott Patlovich, MPH.

As a basis for comparison, the current UTHSCH resource commitment for the biosafety program and in particular the select agent lab was discussed. UTHSCH's current select agent activities require at least 1 full time equivalent. The entire UTHSCH biosafety program consists of a manager and 3 safety specialists.

Key Findings

- Encountered a source of possible confusion regarding the diffuse location and organizational reporting of the designated Responsible Official (VP Research), and the three Alternate Responsible Officials: the Associate VP for Research, the Biosafety Officer, and the Research Compliance Officer. The importance of communication amongst these positions was stressed and regular meetings to ensure key actions are not overlooked, such as assuming the other person or entity completed a certain task was recommended.
- The importance of cross representation on key committees – the IBC and IACUC particularly, for continuity of information flow regarding review of protocols was discussed. Of particular note was the expectation (and UTHSCH's recommendation) that lab compliance status is a regular consideration when protocols are reviewed. The ability to provide this information to the committees would be predicated upon the biosafety program's performance of independent lab assessments (see next comment).

- The importance of routine independent safety surveillance of labs was discussed. UTHSCH recommended placing a priority on the biosafety program conducting independent regular evaluations of labs. The follow up on noted action items and the reporting of persistent issues of non-compliance were also discussed.
- The biosafety program needs to consider taking more of a leadership role in the fulfilling of the annual requirements for training and drills as required by the CDC.
- An area of historical challenges appeared to be maintaining open, positive channels of communication between lab personnel and the biosafety program. The importance of communication was discussed and an evaluation was recommended.

Subsequent Actions

- UTHSCH provided the following bulleted list of programmatic elements that should be considered for research involving regulated select agents and toxins:

Registration / Permitting

- How were pre-existing select agent activities identified when the new select agent rules were enacted?
- What institutional mechanisms exist for identifying research that includes the use of select agents/toxins?
- Who are the designated institutional authorities regarding select agent/toxin use [i.e. Responsible Official and Alternate Responsible Official(s)]?
- Has your Institutional Biological Safety Committee (IBC) reviewed and approved all select agent/toxin work?
- If the select agent/toxin research involves animal models, has your IACUC reviewed and approved the protocol?
- Is all select agent/toxin work appropriately registered with the CDC and/or USDA?

Policies / Procedures

- Does each select agent lab have a laboratory specific select agent/toxin manual?
 - Biosafety plan, incident response plan, security plan, training sections all present?
 - Are all records present and up to date?
 - Annual review and revision of all plan sections conducted?
- Annual drill conducted and documented to test the current incident response and security plans?
- Is there a process in place for clinical or diagnostic specimen reporting for select agents?

Training

- Annual select agent/toxin regulations training provided for all authorized laboratory personnel?
- Does the training include information about how, when, and to whom to report incidents involving select agents/toxins?
- Process in place for capturing all new personnel and ensure training performed before initiation of work in registered labs?

Surveillance

- How often are documented independent inspections for compliance and safety concerns performed? Who performs these surveys? RO, EH&S?
- Employee occupational health services available on site or plans in place for seeking outside medical care and/or emergency medical services?
- Notice sent to local hospital to ensure they will be able to treat any select agent exposed individual?
- Vaccinations current if available?
- Are select agent/toxin inventory records kept up to date and reviewed by PI?
 - On what frequency is this review performed?
- Do you monitor exempt amount of toxins to ensure they remain below exempt threshold levels?

Information Feedback

- How is the internal reporting mechanism set up from lab to responsible official(s)?
 - Through what individuals does the information flow?
- Are relationships established and procedures in place for notification of local health authorities (city and county health departments) of adverse reportable event?
- Are the results from drill exercises, actual events, or other learning exercises reviewed and incorporated into the appropriate select agent/toxin plan as necessary?

Annual Reviews

- Are the following annual requirements performed and properly documented:
 - Select agent/toxin regulations training
 - Drill testing incident response and security plan
 - Annual RO/ARO facility inspection
 - Laboratory commissioning/verification activities

Security Reviews

- Vulnerability assessment performed by local authorities (police) with jurisdiction over registered laboratories?

- Laboratory security features verified to function properly on regular basis?
- As part of the laboratory security plan, is there an appropriate system in place for visitors to the lab, housekeeping, maintenance personnel, etc.?
- What procedures are in place when an individual leaves the lab? Reset passwords, etc.

Institutional Biosafety Committee

- What topics are covered by the IBC?
- How often does the IBC meet?
- Is the IBC registered with the NIH?
- What is the membership make up for the IBC? Do you have at least 2 community members?
- What department organizes the IBC, IBC meeting, agenda, and minutes?

Biological Safety Program

- What activities are within the scope of the Biosafety program?
- Where does the Biosafety program report organizationally?
- How many full time equivalents are dedicated to biological safety?
- What level of involvement does the Biosafety program have with the Office of Research, select agent work, and IBC?

UTHSCH also offered to have Brown and Patlovich return to College Station in the future to visit the labs and review associated policies and procedures, based on TAMU's scheduling and availability. Likewise an offer was made to the TAMU EH&S program for visiting UTHSCH to see how their biosafety program operates. Furthermore, UTHSCH will be available to conduct follow up independent reviews of TAMU's program in the future, for example a six month review and a one year review.

Cc: Mike D. McKinney, Chancellor
Jay Kimbrough, Deputy Chancellor
Jerry R. Strawser, Interim Executive Vice President and Provost
Richard E. Ewing, Vice President for Research
Scott A. Kelly, Deputy General Counsel

From: "Henkel, Richard (CDC/COTPER/DSAT)" <bzz3@cdc.gov>
To: "Angelia Raines" <araines@vprmail.tamu.edu>
Date: 7/6/2007 9:29:05 AM
Subject: update on pending site visit to TAMU

We are still in the process of working out the logistics of the site visit. We have to coordinate the schedules of a number of site team members from DSAT and other agencies. We have a conference call this afternoon to hopefully nail down some of the details. We should be able to provide you with more details early next week. Thanks

Richard Henkel, PhD
Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Rd NE Mailstop A 46
Atlanta, Georgia 30333
(Office) 404.718.2020
(Fax) 404.718.2096

CC: "Holmes, David (CDC/COTPER/DSAT)" <cuv4@cdc.gov>

From: "Moore, Steve" <steve.moore@tamu.edu>
To: "Roebuck, Von (CDC/OD/OEC)" <ver5@CDC.GOV>
Date: 7/9/2007 1:57:14 PM
Subject: RE: Meeting on investigation

Von, so sorry for the delay in responding, but I was out of town, as was Dr. Bazer and we did not make contact. As I understand it, the CDC team will most likely visit us the week of July 23rd. In the interim, Dr. Bazer is happy to begin a "scientist to scientist" dialogue in support of a highly productive visit. I have copied him on this email for ease of communication.

Let us know how you would like to proceed and thanks for reaching out to us.

Steven B. Moore
 Chief Marketing Officer & VP Communications
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 Texas A&M University
 steve.moore@tamu.edu

1180 TAMU | College Station, TX 77843

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www.tamu.edu

Welcome to Aggieland

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

From: Roebuck, Von (CDC/OD/OEC) [mailto:ver5@CDC.GOV]
Sent: Thursday, July 05, 2007 2:57 PM
To: Moore, Steve
Subject: RE: Meeting on investigation

Got it Steve and your clarification is appreciated. Let me send along your note regarding Dr. Bazer and the 9th to our program and see how we might be able to connect. I will be back in touch. Thanks. Von.

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

From: Moore, Steve [mailto:steve.moore@tamu.edu]
Sent: Thursday, July 05, 2007 3:51 PM
To: Roebuck, Von (CDC/OD/OEC)
Subject: RE: Meeting on investigation

Von, thanks for the note. I may have confused your message, but let me be clear on our end.

First, there definitely has to be a visit to campus by your team and I hear that could be as early as the 12th or 13th.

Second, on the 9th, if appropriate, our scientist in charge, Fuller Bazer, could be available in the afternoon to discuss any specifics or other preparation needed to move this situation forward as productively as possible. Dr. Bazer is a Distinguished Professor in our Animal Science Department.

I hope that clarifies our intent. Let me know how you would like to proceed.

Steven B. Moore
Chief Marketing Officer & VP Communications Division of Marketing &
Communications Texas A&M University steve.moore@tamu.edu

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From: Roebuck, Von (CDC/OD/OEC) [<mailto:ver5@CDC.GOV>]

Sent: Thursday, July 05, 2007 1:04 PM

To: Moore, Steve

Subject: Meeting on investigation

Steve, I did receive your voicemail on Tuesday. Let me talk to folks here about meeting between the scientists by phone on Monday, July 9.

I have relayed your questions and documents to the CDC investigation team that will be going there soon - perhaps that might be another option to consider in lieu of a meeting on the 9th?. Let me know if that will work best.

We do appreciate your heads up on Monday to us regarding the release of documents. Thanks. Von.

CC: "Bazer, Fuller" <fbazer@cvm.tamu.edu>

From: "Roebuck, Von (CDC/OD/OEC)" <ver5@CDC.GOV>
To: "Moore, Steve" <steve.moore@tamu.edu>
Date: 7/9/2007 2:15:13 PM
Subject: RE: Meeting on investigation

Not a problem Steve, welcome back.

Dr. Bazer, I am sending a note to Rob Weyant, director of the Select Agent Program at CDC, to see when he or a member of his staff can schedule a meeting before the visit. I will ask Rob or someone from his program to contact you direct if that is okay with you.

Steve, let me know how else I can help from my end. Von.

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

From: Moore, Steve [mailto:steve.moore@tamu.edu]
Sent: Monday, July 09, 2007 2:57 PM
To: Roebuck, Von (CDC/OD/OEC)
Cc: Bazer, Fuller
Subject: RE: Meeting on investigation

Von, so sorry for the delay in responding, but I was out of town, as was Dr. Bazer and we did not make contact. As I understand it, the CDC team will most likely visit us the week of July 23rd. In the interim, Dr. Bazer is happy to begin a "scientist to scientist" dialogue in support of a highly productive visit. I have copied him on this email for ease of communication.

Let us know how you would like to proceed and thanks for reaching out to us.

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Sent: Thursday, July 05, 2007 1:04 PM
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I have relayed your questions and documents to the CDC investigation team that will be going there soon - perhaps that might be another option to consider in lieu of a meeting on the 9th?. Let me know if that will work best.

We do appreciate your heads up on Monday to us regarding the release of documents. Thanks. Von.

CC: "Bazer, Fuller" <fbazer@cvm.tamu.edu>

From: Fuller Bazer
To: president@tam.u.edu; Richard Ewing
Date: 7/9/2007 4:31:26 PM
Subject: Update - July 8, 2007

1. 11 AM - Met with Interim President Davis and others to discuss responses to report of Robert Emery, Asst VP at UTHSC-Houston - Responses will be completed by end of business on Wednesday. All agreed that the report raised important points and provides a checklist of metrics to meet.

It was agreed that Biosafety Officer will report to RO and with dotted line to EHS - current and future staff with this specialty, i.e., biosafety.

Responses to document from Dr. Gerberding will also be completed by Wednesday, July 11th.

Angie Raines and I will take lead to get the responses to Emery and Gerberding completed.

2. 1 PM Meeting - Discussion of inspection that is now likely to be July 23-26, 2007 involving 10 to 17 persons representing CDC, USDA-Animal and Plant Health Inspection Services (APHIS) and Health and Human Services (HHS).

Angie Raines will notify CDC that Board of Regents meeting is July 25-27, 2007 for which attendance by leadership is required.

Leadership of Texas A&M and TAMUS to greet and make statement of support for research and strong compliance program.

NBAF finalist will be announced Wednesday - Texas A&M is preparing a statement to address either outcome.

3. As requested, I sent full CV and updated biosketch to Ms. Janet Smalley and Mr. Rodney McClendon for use by Chancellor and President.

4. Suggestion:

I think that the smaller the group of key administrators to greet and state position of Texas A&M and TAMUS on research with select agents and commitment to compliance is preferable to having a large group that may detract from focus of the opening session.

Please let me know if you have questions or need additional information.

Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone: 979-324-7364
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: <http://recovery.tamu.edu>
URL: <http://animalscience.tamu.edu/>

CC: Jim Calvin; Julie Barker

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: <jsamuel@medicine.tamhsc.edu>
Date: 7/9/2007 8:24:11 PM
Subject: Table top Drills

Hi Dr. Samuel,

On 6/14/07, you emailed a document that indicated table top drills were completed for your team, however the 'after action reports' were not completed. Please complete a report for each of the drills and return it to our office by Thursday of this week. These documents will be included in the materials we are preparing for CDC review. Thanks! Angie

CC: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Vernon Tesh" <TESH@medicine.tamhsc.edu>, <ibc@tamu.edu>, "Richard Ewing" <richard-ewing@tamu.edu>, "Tiffany Agnew" <tmagnew@tamu.edu>

From: Fuller Bazer
To: Steve Moore
Date: 7/10/2007 6:45:56 AM
Subject: RE: Meeting on investigation

Thanks for cc on this correspondence Steve. I will stand by for further information regarding establishment of a "scientist to scientist" dialogue on biosecurity and related issues. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone:
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: <http://recovery.tamu.edu>
URL: <http://animalscience.tamu.edu/>

>>> "Moore, Steve" <steve.moore@tamu.edu> 07/09/07 1:56 PM >>>

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From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Vernon Tesh" <TESH@medicine.tamhsc.edu>, <c-m-meyer@tamu.edu>, "John Salsman" <jmsalsman@tamu.edu>
Date: 7/10/2007 7:36:12 AM
Subject: Confidential - Do not distribute - Please review and give feedback

Hi Everyone,

Please review the attached position description (PD) for a proposed biological safety officer position. Please note, to avoid confusion with the existing BSO position, I titled the new position "Biological Safety Compliance Officer."

The responsibilities of the new position center around 4 areas, Risk Group 3 (RG3)/Select Agent review and consulting; RG3/Select Agent program monitoring and outreach, communication to the RO and other key representatives regarding RG3/Select Agent activities and the review and disposition of research that qualifies for one of the NIH review exemptions

Please review the description and let me know ASAP - today what changes you propose.

Thanks John for all of your help!

Angie

CC: "Julie Barker" <j-barker@tamu.edu>, <Jan-Faber@tamu.edu>, "Richard Ewing" <richard-ewing@tamu.edu>, "Tiffany Agnew" <tmagnew@tamu.edu>

THE TEXAS A&M UNIVERSITY POSITION DESCRIPTION

I. General Instructions:

The Position Description form is used to record the duties, responsibilities, qualifications sought and fiscal impact of classified and nonclassified staff positions. This information is the basis for determining the title, salary rate, and Fair Labor Standards Act exemption status for staff positions. To achieve these purposes, it is essential that detailed and exact information pertaining to current duties, responsibilities, and qualifications be accurately recorded on this form. Please attach a current organizational chart when submitting this form.

A. Member(s) of TAMU System: Texas A&M University	B. Department or Division: Vice President for Research --
C. Member ADLOC Account No.: 02-158001	D. Source of Funds E&G
E. Member Funding Account No. (s) & Account Title(s): 02-158001/VPR	F. Duration of Position: Permanent
G. Place of Work or Headquarters (Bldg. Name and Room No.): Centeq Building- 150 B	H. Employee's Name (leave blank if position is new or vacant): New Institutional Biosafety Compliance Officer

II. General Information:

A. This Questionnaire: (check box and complete title(s), title code(s), PIN and salary data as appropriate)

Establishes A New Position Changes A Budgeted Position Updates Job Description Determines FLSA Exemption Status

Security Sensitive Position? Yes No

Position restricted by the USA Patriot Act? (see <http://hr.tamu.edu/faq/#patriotact>) Yes No

Present Title _____ Title Code _____

PIN _____ Present Salary _____ Per _____

Proposed Title Institutional Biosafety Compliance Officer Title Code _____

Proposed Salary 65,000-80,000 Per Year _____ (hour/month/year)

B. Secondary costs that will be incurred as a result of this action such as equipment, travel, clerical support, etc. (describe and give amount):

Computer

C. Titles and number of employees supervised by this position. If no employees are supervised, indicate "None":

None

D. Does the employee customarily and regularly exercise discretion and independent judgment and have the authority to make important decisions?

Yes

No

Percent of Total Time _____

E. Machines or equipment used by the position. Indicate hours during an average week that each piece of equipment is actually used. For most positions the combined total usage will seldom approach 40 hours:

Computer	25 hrs.	Copier/Scanner	6 hrs.	Fax	1 hrs.
Telephone	5 hrs.		hrs.		hrs.

F. Qualifications required in filling a future vacancy in this position. Keep the position in mind rather than the current or potential occupant.

	Necessary Qualifications	Preferred Qualifications
Education:	Master's in a biomedical science (e.g., microbiology, biology, molecular biology, biochemistry) or related field or equivalent; relevant experience includes but is not limited to BioSafety officer, BioSafety professional, biological laboratory scientist, biological lab tech	

Experience:	<p>Must be familiar with biocontainment principles, the CDC BMBL requirements, NIH IBC Guidelines, and Select Agent Programs.</p> <p>Two years experience involving the application of federal or state BioSafety related regulatory standards.</p> <p>Knowledge of safe research practices for handling biological and chemical agents</p> <p>Registered Biological Safety Professional (RBP)</p>	<ul style="list-style-type: none"> Two year's experience with BioSafety beyond degree requirements Research lab experience, particularly experience working in a molecular biology, biomedical, or microbiological research laboratory
Licenses, certificates or registration:	None	Certified Biological Safety Professional (CBSP)
Special knowledge, abilities and skills:	Working knowledge of word processing, spreadsheet and database software programs. Interpersonal and communication skills.	
Other requirements or other factors:	Ability to multi-task and work cooperatively with others.	Two years supervisory or project management experience.

Statement of Responsibility:

A. General Summary: Please summarize in three or four sentences the general purpose, scope and responsibilities of this position:

This position oversees safety and compliance program for all Risk Group 3 (RG3) or higher biological agents, advises on the policy and programs necessary to assure the control of biological agents, provides BioSafety training and compliance assurances related to the use of biological agents. Serves as the Alternate Responsible Official as needed by the Responsible Official (RO)

B. Specific Duties: Please list in order of importance, and in detail, the duties assigned to this position and estimate the percent of time given to each duty over a period of time. Percentages must add to 100%, including "other duties as assigned". Essential duties are why the job was created. They are the basic chores or tasks that must be performed by any incumbent, with or without reasonable accommodation. Please attach additional sheets as necessary.

Place Asterisk if Essential Duty	Work Performed	Percent of Total Time
----------------------------------	----------------	-----------------------

*	<p>Based on federal requirements and institutional policy, oversees safety and compliance program for all Risk Group 3 (RG3) or higher biological agents.</p> <ul style="list-style-type: none"> • plans and directing regulatory programs • Investigates adverse events, including incidents related to the loss, release or theft of a Select biological agent, complaints of injury, illness. • With input from the Responsible Official (RO), and the Safety Committee, initiates actions against violators • Advises the research community on methods of applying and interpreting of bio-safety regulations and guidelines 	25%
*	<p>Provides guidance and outreach through ongoing training, consulting and monitoring of RG3 or Select Agent activities</p> <ul style="list-style-type: none"> • Conducts orientation for students, faculty and staff, regarding the use of Select Agents or RG3 agents. • Develops presentations and other training materials • Provides information to ensure web-site has the most current and accurate information • Schedules and facilitates training sessions • Develops and implements ongoing monitoring and inspections of RG3 labs, in coordination with EHSD. Provides inspection report to the lab director, Safety committee and Responsible Official • Communicates serious deficiencies with Responsible Official, Safety Committee and other Key institutional Officials. • Immediately communicates and reports incidents involving the loss, theft or release of a select agent to the RO and/or ARO and other institutional representatives 	15%
*	<p>Provides a monthly report to the Responsible Official regarding all RG3 biosafety activities. Provides support in the following are:</p> <ul style="list-style-type: none"> • Works with EHSD to ensure all annual maintenance checks are performed • Works with Lab Directors and EHSD to ensure all lab workers have correct personal protection equipment (PPE) • Works with the Director for the Office of Research Compliance or other ARO's to ensure Select Agent or NIH paperwork is properly submitted, and incident reports are submitted in a correct and timely manner. 	5%

*	<ul style="list-style-type: none"> • Consults with Lab directors or principal investigators on matters related to lab safety and compliance; conducts and documents safety assessments with input from the Lab director and conducts application pre-reviews to ensure proper safety standards are included. Based on Safety assessment, and with input from EHSD, establishes, maintains and manages exposure monitoring for biological hazards to assess short-term (acute) or long-term (chronic) health risks to employees from occupational exposure to these agents. Conducts risk analyses of research operations with hazardous agents and/or activities and identifies appropriate mitigation of the risks identified. Prepares technical reports based on expert interpretation of measurements, observations, technical publications and regulations to communicate concerns and corrective measures and to document conditions. Assesses and analyzes the potential safety and health risks of research projects that involve biological materials and determines effective engineering or administrative controls to mitigate those risks 	10%
	<ul style="list-style-type: none"> • Responds to requests for assistance or responds to emergencies that could affect the health or safety of employees. Conducts accident/incident investigations and works with management to identify corrective actions to prevent reoccurrence. Acts as an investigation team leader should an incident occur involving theft, loss or release of an agent or any incident involving the safety of staff 	5%
*	Screens all incoming Safety applications. Reviews and provides disposition for all applications meeting NIH guidelines for exemption. Serves as a member of the Safety committee	25%
*	Maintain paper and electronic office files, including records retention files related to job activities.	5%
	Assists in the preparation of correspondence and reports to the Safety Committee, RO or research community. Reproduce copies of reports and other correspondence for distribution. Provide staffing assistance for training, meetings, or other special functions and events, including on-site support.	5%
	Other duties as assigned	5%
	Total:	100%

Name, title and office telephone number of immediate supervisor

Fuller Bazer	Associate Vice President for Research
845-8585	

IV. Certifications:

Date Signature of Employee

Date Signature of Immediate Supervisor Title

Date Signature of Department Head or Comparable Unit
Title

Date Signature of Vice President, Dean or Director Title

From: "Angelia Raines" <araines@vprmail.tamu.edu>
To: "Fuller Bazer" <fbazer@cvm.tamu.edu>, "Julie Barker" <j-barker@tamu.edu>, "James Calvin" <j-calvin@tamu.edu>, "Richard Ewing" <richard-ewing@tamu.edu>
Date: 7/10/2007 8:33:20 AM
Subject: Confidential draft - Please review and give input

Hello everyone,

I spoke with Melanie Ihrig about the new requirement that Select labs are kept separate from Non-Select Agent labs. In speaking with Melanie, this could impact the 3 labs.

Room n was used for non-select agent and select agent work. The select agent work could potentially be moved to the and would continue to be used for non-Select Agent work. Melanie will discuss this option with Frank Stein and let us know what changes will be needed to ensure BL3 requirements. I have asked her to get back with us ASAP since we will need to review our plans with CDC. Please let me know if you have feedback or input regarding relocating SBAT work to .

Currently non-SBAT work is also going on in 1 or more of the buildings. I am requesting a security assessment for these buildings as well as to determine if the current set up is sufficient to ensure safety and security of the agent. By way of this email, I am asking Melanie to inform her staff that sometime early next week, Bert will be working with them to conduct the assessment.

Brent will be assessing lab safety during this weeks mock inspection of the lab.

Thanks and please let me know if you have changes to the process we will be following. Angie

CC: "Melanie Ihrig" <mihrig@cvm.tamu.edu>, <bertvk@tamu.edu>, "Brent S Mattox" <bsmattox@tamu.edu>, "Tiffany Agnew" <tmagnew@tamu.edu>

Hi Angie. I think that this looks good. I have mad a number of editorial changes, but substance of description seems excellent to me. Fuller

Fuller W. Bazer, Ph.D., Regents Fellow, Distinguished Professor and O.D. Butler Chair in Animal Science
Associate Vice President for Research
Texas A&M University
Telephone: 979-458-2876
Cell Phone: 979-324-7364
Facsimile: 979-845-1855
email: fbazer@cvm.tamu.edu
URL: <http://recovery.tamu.edu>
URL: <http://animalscience.tamu.edu/>

>>> "Angelia Raines" <araines@vprmail.tamu.edu> 07/10/07 7:35 AM >>>
Hi Everyone,

Please review the attached position description (PD) for a proposed biological safety officer position. Please note, to avoid confusion with the existing BSO position, I titled the new position "Biological Safety Compliance Officer."

The responsibilities of the new position center around 4 areas, Risk Group 3 (RG3)/Select Agent review and consulting; RG3/Select Agent program monitoring and outreach, communication to the RO and other key representatives regarding RG3/Select Agent activities and the review and disposition of research that qualifies for one of the NIH review exemptions

Please review the description and let me know ASAP - today what changes you propose.

Thanks John for all of your help!

Angie

From: Melanie Ihrig
To: Fuller Bazer,j-barker@tamu.edu,j-calvin@tamu.edu,richard-ewing@tamu.edu,araines@vprmail.tamu.edu
Date: 7/10/2007 1:09:06 PM
Subject: Re: Confidential draft - Please review and give input

Angie,

I'm not in this week, so I'm not sure if you have sent the response that went to the CDC, but without that we don't know what the starting point is for what is supposed to be happening. If you sent that directly to me, I will need to let my staff know that they should look at that. In addition, I spoke with Bert this morning and he also needed to know the SOP that was in place for room

Could you please let me know if the final draft of the CDC response will or has been sent to CMP.

Thanks.

Melanie

>>> "Angelia Raines" <araines@vprmail.tamu.edu> 07/10/07 8:32 AM >>>
Hello everyone,

I spoke with Melanie Ihrig about the new requirement that Select labs are kept separate from Non-Select Agent labs. In speaking with Melanie, this could impact the 3 labs.

Room was used for non-select agent and select agent work. The select agent work could potentially be moved to the Vet Med Park and ' would continue to be used for non-Select Agent work. Melanie will discuss this option with Frank Stein and let us know what changes will be needed to ensure BL3 requirements. I have asked her to get back with us ASAP since we will need to review our plans with CDC. Please let me know if you have feedback or input regarding relocating SBAT work to

Currently non-SBAT work is also going on in 1 or more of the buildings. I am requesting a security assessment for these buildings as well as to determine if the current set up is sufficient to ensure safety and security of the agent. By way of this email, I am asking Melanie to inform her staff that sometime early next week, Bert will be working with them to conduct the assessment.

Brent will be assessing lab safety during this weeks mock inspection of the lab.

Thanks and please let me know if you have changes to the process we will be following. Angie

CC: bertvk@tamu.edu,bsmattox@tamu.edu,tmagnew@tamu.edu