

From: Bane, Lori (CDC/COTPER/DSAT)
Sent: Friday, May 30, 2008 2:26 PM
To: Logan, Marinda D. (CDC/COTPER/OD)
Cc: Weyant, Rob (CDC/COTPER/DSAT); Henkel, Richard (CDC/COTPER/DSAT);
Blaine, James (CDC/COTPER/DSAT); Holmes, David (CDC/COTPER/DSAT)
Subject: FW: CDC form comments 16May08.pdf - Adobe Acrobat Standard
(UNCLASSIFIED)

Attachments: CDC form comments 16May08

Please find below the response from the Program to the attached comment.

Thank you for your comments dated May 8, 2008 regarding the CDC 60 Day Federal Register Notice for [CDC 0920-0576], Possession, Use, and Transfer of Select Agents and Toxins (42 CFR 73). In an effort to address your comments, I have answer them separately below:

1. For the APHIS/CDC Form 1, the information is repetitive.

Response: CDC agreed with your comment and duplicative questions were deleted.

A. Could the RO and ARO signature block be incorporated into section 1A and 1B respectively and eliminate section 2 signatures?

Response: Due to spacing issues with Section 1, CDC was unable to incorporate this request.

B. Why can't the registration number be permanently assigned and renewed periodically? What bearing does the previous registration for the entity have on the package being submitted?

Response: Since this comment did not relate to a recommendation for Form 1, but to operations within the Program, this comment has been forwarded to the appropriate personnel.

C. Recommended to simplify Section 4A.

Response: CDC agreed with your comment. The Section 4A was removed and "Entity Summary" section was created. The "Entity Summary" section records the building and room number where the select agents will be used or stored for each Principal Investigator (Chief Scientist).

D. Recommended to simplify Section 4B.

Response: CDC agreed with your comment. The "Entity Personnel

Information" Section was revised to have individuals listed under Principal Investigators and not select agents and toxins.

E. For the Section 5, the information is repetitive.

Response: CDC agreed with your comment and duplicative questions were deleted.

F. Recommended to simplify Section 5B.

Response: CDC agreed with your comment. The "Select Agent/Toxin" table was revised to collect the select agent or toxin; the strain designation of the select agent or toxin, the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each PI (or Chief Scientist).

G. Recommended to have PI submit the risk assessment for the work that is being conducted.

Response: CDC agreed with your comment and added questions related to facility risk assessments that were performed to determine biosafety level.

H. Recommended a reorganization of the submission format that would allow certain information to be submitted once or for any changes.

Response: CDC agreed with your comment and the form was reorganized.

I. For Section 5K, the name of the individual doing inventory should be removed.

Response: CDC disagreed with your comment. The form asks for the name of the individual who is responsible for the select agent inventory because we believe it is essential to know who this person or persons are.

J. For Section 5L, recommended to not ask for the aggregate amount because the amount is not accurate the day after it is report.

Response: CDC disagreed with your comment because the form asked for the maximum quantities that will be used. However, the form has been revised to clarify this intent and states "Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 10⁵ cfu/ml)."

K. For Section 5K, recommended to remove section because information is covered under Section 4A.

Response: CDC disagreed with your comment because a description of work is needed to determine if a restricted experiment with select agents and toxins is being proposed.

2. For APHIS/CDC Form 2, recommended a signature block for the PI that receives the shipment on page 2 in lieu of the RO signature block.

Response: CDC agreed with your comment and requests for name of the individual who receives the shipment. However, the RO must certify that the provided information is correct.

3. For APHIS/CDC Form 3, recommended to remove the statement to "consult MSDS sheet."

Response: CDC agreed with your comment and removed the statement for consulting with MSDS.

4. For your comments regarding the "accuracy of the agencies estimate of burden," the Office of Management and Budget does not include federal government facilities as part of the statistics for calculating burden. Therefore, the calculations provided in the 60-day Federal Register Notice does not include federal government entities in the calculation of burden using the data obtained from the Programs database.

Thanks,

~~Lori J. Bane
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CDC Division of Select Agents and Toxins 1600 Clifton Road MS A-46 Atlanta,
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~~-----Original Message-----
From: Logan, Marinda D. (CDC/COTPER/OD)~~

~~Sent: Tuesday, May 27, 2008 2:24 PM
To: Bane, Lori (CDC/COTPER/DSAT)
Subject: FW: CDC form comments 16May08.pdf—Adobe Acrobat Standard
(UNCLASSIFIED)~~

~~FYI~~

~~Marinda Logan, MPH
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~~—Original Message—~~

~~From: Harris, Denise (CDC/OD/OCSO) (CTR) On Behalf Of OMB Comments
(CDC)
Sent: Tuesday, May 27, 2008 2:10 PM
To: Logan, Marinda D. (CDC/COTPER/OD)
Cc: OMB Comments (CDC)
Subject: FW: CDC form comments 16May08.pdf—Adobe Acrobat Standard
(UNCLASSIFIED)~~

~~Marinda,~~

~~Please see public comment for 0920-0576 below and send your program's
response to the Comment mailbox.~~

~~Thank you.~~

~~—Original Message—~~

~~From: Demmin, Gretchen L LTC USAMRIID
[mailto:Gretchen.Demmin@us.army.mil]
Sent: Friday, May 16, 2008 1:17 PM
To: OMB Comments (CDC)
Cc: Comontofski, Gary D Mr GOLDBELT RAVEN; Lofts, Richard S Dr USAMRIID
Subject: CDC form comments 16May08.pdf—Adobe Acrobat Standard
(UNCLASSIFIED)~~

~~Classification: UNCLASSIFIED
Caveats: NONE~~

~~Thank you for allowing our input into this important work.~~

~~Gretchen L. Demmin, Ph. D.~~

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~~Classification: UNCLASSIFIED~~

~~Caveats: NONE~~