

Environmental Health & Safety

May 15, 2008

Maryam I. Daneshvar CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333

Dear Ms. Danashvar:

In response to the request for public comments on the forms used to collect information for the Select Agent program, I would offer the following on:

- The accuracy of the agency's estimate of the burden of the proposed collection of information.
  - Based on recent experience, a written appeal of access denial takes approximately 10 hours, rather than the 4 currently estimated, and preparation for and response to a facility inspection takes approximately 8 hours for each activity (16 hours total) rather than the 8 currently estimated.
- Ways to enhance the quality, utility, and clarity of the information to be collected.
  - Based on recent guidance, all accidents or incidents in the select agent facility, including bites from uninfected animals or sticks with anesthetic-containing needles that have never come in contact with select agent, must be reported on Form 3 as a release of select agent. While I agree that these sorts of incidents should be reported to CDC to track lab safety and training effectiveness, I do not agree that these incidents should be considered releases. I would suggest that either a new form be created for occupational exposures or that Form 3 be revised to read "Report of Theft, Loss, Release, or Occupational Exposure." There could still be some confusion as to whether uninfected animal bites count as occupational exposures, but I strongly feel this is a much better fit than calling these incidents a release and still captures the information that CDC needs to properly oversee safety in Select Agent facilities.
- Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.
  - The current electronic PDF versions of the forms are not at all easy to use and the auto-fill date fields are programmed such that you occasionally get trapped in a loop which won't allow you to change a date because it is tied to a different date which you also cannot change. If there were a secure on-line way to submit forms, the time needed to submit amendments and other forms would decrease dramatically.

Thank you for this opportunity to comment on the Select Agent program.

Sincerely,

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