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.
  - O 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.
  - O 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.
  - O 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,

Susan H. Cook, PhD, CBSP Biological Safety Officer Environmental Health & Safety

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