



Mark B Horton, MD, MSPH
Director

State of California—Health and Human Services Agency
Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

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

Dear Mrs. Daneshvar,

I have reviewed your "Proposed Data Collections" document. I was the ARO for the State of California Public Health Laboratory for 2 1/2 years. I have recently been bestowed that duty again. My ARO status is pending the review of my FD-961. I am not sure of the size of the average select agent program or budget. I do know that for us the completion times can take days to weeks particularly training.

January of 2007 we had to renew our application. The renewal included resolving a few outstanding inspection report issues. I found that an inspection report can take some time to resolve. Our most recent report consisted of 6 questions which took four days to complete. I had to review our records dating back to 2002. I became responsible for the program in 2005. My first initial assignment was to respond to the inspection report that consisted of over 200 questions. It took approximately three months to complete all the research required for the response.

Application responses vary depending on the amendment. RO/ARO changes, 5A submissions, 5A questions, and manual revisions take more time. The 5A should be compared with the form 4's and internal inventory sheet regularly. This is cumbersome for institutions with large archival collections.

Each year all of the safety manuals have to be updated. First we print the most current version of the law then proceed to look for changes. Updates to federal and state laws can take months for dissemination leaving laboratories completely unaware. After the law has been reviewed the manual/plan has to be reviewed and revised. The third step is to make sure all of the employees have read and signed the manual. Our program has large comprehensive manuals they can take months to get through chemical hygiene, respiratory protection, bloodborne pathogens, select agent safety, select agent security, select agent incident response, chemical fume hoods, biological safety cabinets, injury and illness prevention, immunization policies, laboratory animals, compressed gases, cryogenic hazards etc. This process is completed annually. Universities often have an office of environmental safety and health, an IACUC, and a biological review program. This decreases the workload because of distribution between groups. Laboratories that are responsible for all the manual and policy development struggle. This also takes the microbiologist away from laboratory work. I would like to see the select agent program reviewed for turn around time. I have submitted amendments that ended up lost. I had to resubmitted them. We have also experience turn over in file managers. I had five to six months worth of select agent

documentation lost in the transition between two file managers. My time was consumed by resubmissions.

Transfers do not take much time to complete (Form 2). The problem when the form two frequent fax transmission rendering it unreadable. We spend much of our time trying to decipher the information.

Form three take the most man hours. It takes about an hour to complete and review the form, but the internal/external investigations preceeding and following the incident can take weeks. Our most involved incident took approximately five weeks. We routinely investigate minor issues an report them in our incident binder. Our incident review committee reviews two to four incidents per meeting and makes recommendations for remediation. If there is training necessary or policy revisions to be made it can take up to a two months after a series of trainings meetings and follow up evaluations.

Form 4's generally take about 30 minutes to complete and about 30 minutes for the ARO to review. We average three per submission. We send a group of form four's every week. I would like to see CDC have online tutorials on form completion. This would save laboratories lots of training time.

Our annual select agent safety and security training takes a month. We have four training groups scheduled on four different dates. The first group is for janitorial, office, and administrative staff. The second group is facilities management/engineering staff and security guards with the ability to access some laboratory areas.. The third group includes non-department of justice approved microbiologists. The fourth group encompasses all of our select agent employees that work in select agent laboratories. The training takes five to six hours per scheduled date.

Our internal inspections are performed in teams of three. We have three different laboratories institutions not laboratory rooms each with it's own subset of select agent labs. We are applying for a fourth institution. We require the either the RO or ARO be present with two microbiologist inspectors. Our select agent laboratory inspections are conducted over two full days and one partial day. The ARO compiles the data after inspection. He writes a letter requesting supplemental information for his findings. The laboratory then receives a letter either approving their operation for another calendar year or disapproving their operation. It probably takes four days to complete the entire process.

CDC/USDA inspection are schedule in our entity over three full days. The follow-up begins after the exit meeting and takes weeks to months to resolve the outstanding issues.

Thank you,

Channing D. Sheets, MEd, RVT
Pending Alternate Responsible Official
Biosafety & Select Agent Officer
California Department of Public Health