



Facility Inspections Under the CDC Select Agent Rule

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Facilities required to register under the CDC Select Agent Rule (42 CFR 73) are subject to inspection by the Select Agent Program to verify that the facilities meet the requirements of the rule. Authorization allowing for inspection of entities is specified in 42 CFR §73.16: “The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part (§73.16) are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.”

The Select Agent Program inspects only entities that are registered or have applied for registration with the Select Agent Program. Most entities registered with the Select Agent Program have been inspected and have an idea of what is required. For those of you who have been inspected this will be a review and, for those that have not been inspected, this will be an opportunity to find out what you can expect.

After the security risk assessments and application for registration have been approved, you should receive a certificate of registration. This certificate of registration is specific to the select agents or toxins at your entity, the select agent activities, the locations within buildings, as specified, and the names of individuals and select agents they have access to. It applies to a single physical location. The laboratory may or may not be inspected prior to receiving your registration certificate. The registration is valid for 2 to 3 years.

The purpose of conducting an inspection is four-fold: (1) to verify that the information you provided on your application sent to the Select Agent Pro-

gram is complete and a true reflection of your facility and your practices; (2) to ensure that the facility meets minimum safety and security requirements as set forth in the regulation; (3) to review the records maintained at your facility to assure that those required are present; and, (4) to exchange information. The inspectors will provide you with updated information on the program and you will have an opportunity to ask the inspectors questions that you may have.

Minimum standards used when conducting inspections include the following:

1. For entities that work with infectious agents: the *Biosafety in Microbiological and Biomedical Laboratories* (“BMBL”), 4th edition and the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (April 2002)
2. For entities that work with select agent toxins: the Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910), the toxin guidelines in Appendix I of the *BMBL*, the *BMBL* or *NIH Guidelines*, and the Hazard Communication Regulation

The inspection process can be separated into three phases: the Preinspection, Inspection, and Postinspection. In the Preinspection, your file is reviewed by the assigned inspection team, which usually consists of at least two inspectors. There may be more than two inspectors, depending on the size of your facility and the situation. In general, CDC inspectors have years of experience working in research and clinical laboratories. You will be contacted to arrange a date and a time for the inspection, and you will receive written notification listing the inspectors

who will conduct the inspection and the date and time of the inspection.

There are several things that you can do before the inspection team arrives. First, notify members of your organization who are using select agents and toxins, or are supporting select agent and toxin work in the laboratories, to make them aware of the pending inspection. Second, provide CDC inspectors directions to the facility and any requirements regarding parking or access to your campus. This helps ensure that we get to your facility at the scheduled time. Third, it is important that you provide us with your entry requirements, such as special security requirements, identification credentials, or immunizations.

Prior to the inspection we also recommend that you review: (1) the requirements of the regulation to assure that your facility is following the regulations; (2) review the appropriate biosafety and security guidelines mentioned earlier, and; (3) review your application for registration. It is very important that you keep your application up to date. It is always a good idea to conduct an internal audit prior to the inspection. Organize and review your records, in-

cluding safety, security, and emergency response plans, and have these available for us to examine because we will look at them in great detail. Finally, call the Select Agent Program if you have questions.

The inspection begins with introductory remarks by the inspectors that include who we are and why we are conducting the inspection. We ask for a brief presentation by the principal investigators or laboratory managers to give us an idea of how you are using select agents and toxins. We inspect all of the laboratories that you have registered, and we examine your records and your safety, security plans and emergency response plans. We record our observations during the inspection on checklists that have been developed from the regulations and guidelines (mentioned previously). We examine who has access to the select agents and toxins at your facility, how they are stored, how you secure the agents, and how you ensure that people do not have access to the select agents and toxins that have not received security risk assessment approvals. We also inspect the personal protective equipment used at your laboratory and whether it is appropriate for the work being done and the agents used. An extensive examination

Figure 1

Why Inspections?

Ensure the facility meets minimum safety requirements:

- Laboratories working with infectious agents:
 - Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition
 - "NIH Guidelines for Research Involving Recombinant DNA molecules"



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of your records including training, inventory, and access to laboratories records is conducted by our inspectors.

We will also examine your EA-101 transfer records (if you have transferred select agents or toxins) and any Form 0.1318 records (if you have identified select agents and toxins from clinical specimens or environmental samples). We will ask to see your safety and security training programs. We will look for the kind of training you conduct, how often it is conducted, who you are training, who conducts that training, and how you verify and record that the training was understood. Your emergency response plan will be examined, including verification that it is specific to the select agents and toxins used at your entity. Inventory records will be inspected to confirm that they contain the information required by the regulations.

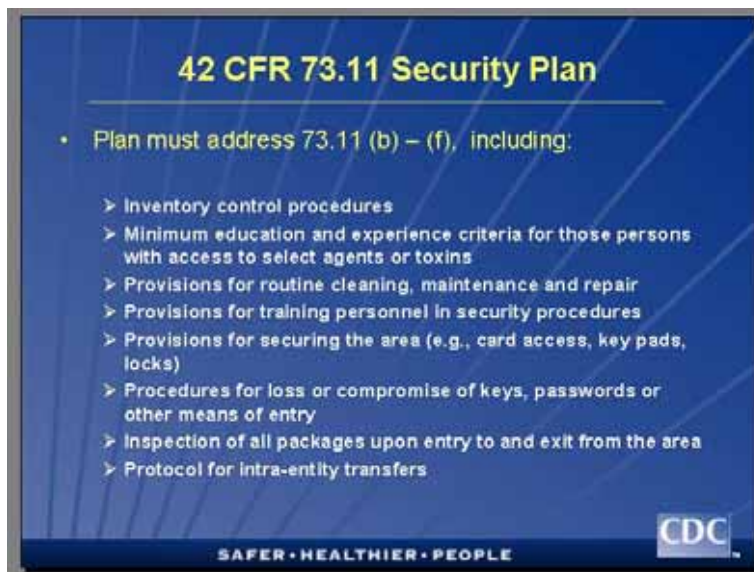
After the inspection event, the inspection team will return to the Select Agent Program office in Atlanta. They will review the observations that they made during the inspection with Program management and will review their observations with the regulation requirements and the guidelines that I mentioned. An inspection report listing any deficiencies will be prepared and this report will be sent to the Responsible Official at the entity. If the Animal and Plant Health Inspection Service (APHIS) of

the USDA participates in the inspection then their observations will be included in the report.

Once you receive the inspection report, we recommend that you review it with your staff. If there are deficiencies, we ask that you respond to those deficiencies within the time that is specified in the report. Generally, we request that you respond within 30 days, unless there are serious security or safety deficiencies in which case we will ask for a shorter turnaround time. We ask that you continually evaluate your biosafety and biosecurity procedures and practices. We recommend that you use the inspection report as a tool to improve your security and safety programs.

After conducting over 250 inspections in the last year and a half, we have developed some suggestions that we believe can make your laboratory a safer and more secure facility. First is the involvement or commitment of the Responsible Official. This is the person required by the regulations who is responsible for the Select Agent Program at your entity. The Responsible Official (RO) should have upper-level management support in order to effectively carry out his or her responsibilities as defined by the regulations. The RO should be familiar with the requirements of the select agent regulations and have the authority and responsibility to ensure that the requirements are met.

Figure 2



We also recommend that you create a biosafety and biosecurity committee, if you do not have one, and that you have representation from all the stakeholders. Remember the people who support the program—the individuals in finance, administration, and maintenance. It is important to have their input. We also suggest that you share the inspection report with all the stakeholders. Talk about the inspection report with them and discuss how you can resolve the deficiencies and make your laboratory safer and more secure. Use the inspection process to improve your biosafety and biosecurity programs, and use the inspection as an opportunity to educate

the stakeholders in your facility on biosafety and biosecurity.

Finally, access the Select Agent Program web site at <http://www.cdc.gov/od/sap> to find contact information and information resources and for links to APHIS and the FBI. If you have submitted an application to CDC an inspector has been assigned responsibility for your file. That inspector is your primary contact with the program and is expected to provide assistance to you. If you do not know who that person is, I encourage you to call or e-mail the CDC Select Agent Program to get the name of that person (404-498-2260 or e-mail: LRSAT@cdc.gov).



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