

Inspection Checklist for Training (7 CFR 331, 9 CFR 121, 42 CFR 73)

Entity Name:

Inspection Date:

Building/Rooms:

Inspectors:

When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."

Section	Regulation Text	Observation	Status	Comments
15(a)(1)	<p>An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual with access approval from the HHS Secretary or Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.</p>	<p>An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual with access approval from the HHS Secretary or Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.</p>	<p><input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A</p>	
15(a)(2)	<p>An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).</p>	<p>An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).</p>	<p><input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A</p>	

Section	Regulation Text	Observation	Status	Comments
15(b)	Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.	Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
15(c)	Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.	Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
15(d)	The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.	The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
15(e)	The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.	The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	