

Biological Select Agents & Toxins: What All Researchers Should Know

NOTE: If you plan to receive or work with any biological agents or toxins that are currently listed as select agents (see link below), you must contact [Robin Trundy](#), Biosafety Officer and BSAT Responsible Official to ensure that you do not unknowingly violate federal regulations.

What are select agents?

Select agents include biological agents or toxins which have been declared by the U.S Department of Health & Human Services (HHS) or by the U.S. Department of Agriculture (USDA) to have the “potential to pose a severe threat to public health and safety”. The current list of agents (commonly referred to as BSAT) can be found at: <https://www.selectagents.gov/SelectAgentsandToxinsList.html>. Because of this designation, labs that possess, use or transfer a select agent must be registered with the applicable federal agency, and are highly regulated from a security perspective.

Individuals that must enter spaces where these agents are present, even if the agent is secured, must be cleared by the Department of Justice and included in the institution’s select agent registration. Personnel who are not cleared and approved (i.e., visitors), must be escorted at all times while in the select agent-registered space by an individual who is currently cleared and approved (i.e., BSAT authorized person).

BSAT Registration Oversight & Maintenance

The select agent regulations require the entity to designate a Responsible Official (RO) who is on-site and available to maintain all administrative aspects of the select agent registration and compliance program. RO administrative functions include (but are not limited to): review and revision of the 3 required Plans (security, incident response and biosafety), training for all personnel who will be entering the lab, managing security risk assessments, updating the entity’s select agent registration when activities, materials, spaces or personnel change, reporting any incidents that may have resulted in theft, loss or release of BSAT, coordination of annual drills/trainings, inspections, BSL-3 facility reverifications, and interfacing on a routine basis with the Select Agent Program Point of Contact. The entity also needs to designate an Alternate Responsible Official (ARO) who is expected to be able to perform all functions of the RO if the RO is not available to do so.

The entity’s select agent registration must be renewed every 3 years. This process involves revision and submission of the 3 Plans and supporting documentation to the applicable agency (CDC in the case of VUMC). Then, the agency will schedule a 3-day on-site visit to inspect all aspects of the lab operations including mechanical features and agent inventory. The inspection team will also interview individuals associated with the registration which may include the entity owner/controller. (If selected, Interview questions for the entity owner/controller will not exceed the basic information covered in this resource document.)

Upon satisfactory closure of the inspection, the entity will be issued a new registration for the next 3 years. Approximately midway through the approval period, the agency will initiate an unannounced site inspection. This inspection is not a full program inspection but is targeted on specific program elements which are randomly selected by the inspectors.

Additional considerations/resources:

1. Possession and/or use of BSAT that are designated as Tier 1 agents have additional security requirements and further personnel restrictions. Work with these agents is subject to the Dual Use Research of Concern (DURC) regulations. More information regarding VUMC management of DURC can be found at <https://www.vumc.org/oor/dual-use-research-concern-durc>.
2. All select agents are additionally subject to the provisions of Export Control regulations. More information regarding VUMC’s Export Compliance program can be found at: <https://ww2.mc.vanderbilt.edu/globalsupport/50084>
3. Contact [Robin Trundy](#) or visit www.selectagents.gov for more information regarding select agent requirements.