VIRGINIA POLYTECHNIC INSTITUTE
AND STATE UNIVERSITY

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Select Agent and Toxin Program

Environmental, Health and Safety Services
Laboratory Safety Division
540-231-5864

ENVIRONMENTAL, HEALTH AND SAFETY SERVICES

Select Agent and Toxin Program

A Guide to Compliance for Researchers Possessing, Using, or Transferring Select Agents or Toxins

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Revision Status

Contact(s)	Implementation Date	Revision Number	Comments
Charlotte Waggoner	July 1998	0.0	Original document
Charlotte Waggoner	July 2003	1.0	Update format and addition of requirements; expansion of scope of program
Charlotte Waggoner	October 2003	1.1	Addition of appendix items Update of regulatory information
Charlotte Waggoner	February 2004	1.2	Grammar corrections
Charlotte Waggoner	January 2006	1.3	Update to include final rule regulatory information
Charlotte Waggoner	August 2006	1.4	Error and formatting corrections

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Virginia Tech Health and Safety

Virginia Tech Health and Safety Policy

The Vice President for Administration and Treasurer, Raymond D. Smoot, Jr., approved Virginia Tech's health and safety policy (No. 1005) January 10, 2001. Through its incorporation into the university's policies and procedures, all university members are expected to be familiar with their safety responsibilities and strive to follow safety practices at all times.

This policy affirms the university's commitment to safety and good environmental stewardship. Virginia Tech's Environmental, Health and Safety Services (EHSS) is expected to work closely with departments, safety committees, employees, and students to ensure compliance with this policy.

EHSS Mission

- To provide a safe and healthy living, learning, and working environment for every member of the university community by assuring safe work practices through effective education and consultation;
- To help individuals and departments achieve compliance with all health and safety local, state and federal regulations and University policies as economically as possible;
- To act as liaison with external regulatory agencies, and to monitor university compliance through audit, program development, education, and consultation; and
- To continuously improve services provided by incorporating team approaches to problem solving and actively seeking input from university employees and departments.

Program Overview

Regulatory Drivers

Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention (CDC)

"The Antiterrorism and Effective Death Penalty Act of 1996" required the Secretary of Health and Human Services to regulate the transfer of select biological agents and toxins that pose a severe threat to public health and safety. As a result, the Centers for Disease Control and Prevention (CDC) implemented its rule, 42 Code of Federal Regulations (CFR) 72.6: Additional Requirements for Facilities Transferring or Receiving Select Agents. The final rule became effective April 15, 1997.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, signed into law June 12, 2002 expanded the requirements of 42 CFR 72 to include possession and use under the new interim regulation 42 CFR Part 73: Possession, Use, and Transfer of Select Agents and Toxins. This interim regulation superseded 42 CFR 72.6 and became effective February 7, 2003. The final rule was published March 18, 2005 and became effective April 18, 2005.

United States Department of Agriculture (USDA)

Animal and Plant Health Inspection Service (APHIS)

The Public Health and Security and Bioterrorism Preparedness and Response Act of 2002 also included provisions for the regulation of certain biological agents and toxins that pose a severe threat to animal or plant health, or to animal or plant products by the Department of Agriculture through the Animal and Plant Health Inspection Service (APHIS). This regulation, 7 CFR Part 331 (for plants) and 9 CFR Part 121 (for animal and animal products), mirrors the CDC regulation in requirements.

Purpose

The intent of the CDC and APHIS regulations is to protect public health and safety, animal and plant health and safety, and animal and plant products by:

- providing a mechanism for determining where select agents and toxins are located;
- ensuring that their transfer, storage, and use can be tracked;
- screening of personnel with access to select agents or toxins; and
- requiring entities in possession of select agents and toxins to develop and implement effective biosafety, security, and incident response plans and procedures.

The Virginia Tech Select Agent and Toxin Program has been developed to:

- specify university policies, procedures, and requirements to ensure compliance with the CDC and APHIS regulations; and
- aid principal investigators, researchers, and supervisors in achieving compliance.

Scope

This program applies to:

- Specific biological agents and toxins listed by the HHS and the USDA

- Activities

  possession and use at Virginia Tech's main campus in Blacksburg, Virginia

  transfers made within the United States between Virginia Tech's main campus and other approved facilities

  importation from other countries (exportation is regulated by the Department of Commerce)

- Any individual (e.g., faculty, staff, students, visitors) requiring access to a select agent or toxin or an area where select agents and toxins are used
- Facilities where select agents and toxins are used and stored

Continued Program Improvement

Input from the university community is greatly valued. If you think you can help improve the efficiency and effectiveness of this program, please provide comments and suggestions to the University Biosafety Officer by:

- Phone (540-231-5864);
- Fax (540-231-3944); or
- E-mail (biosafety@vt.edu).

Your input is greatly appreciated!

Responsibilities

Laboratory Employees

Laboratory employees under the direct supervision of a Principal Investigator, Researcher, or Lab Supervisor have the responsibility to:

- read this document and be familiar with its requirements;
- know the specific hazards of the select agent and toxins utilized in their work and how to access additional information on these agents;
- immediately inform the Virginia Tech Police of any suspicious activity or persons, theft, or emergency related to select agent use areas;
- inform the lab supervisor, principal investigator, or University Biosafety Officer within 24 hours of any:
  - loss or compromise of their keys, passwords, or combinations to areas where select agents and/or toxins are used or stored;
  - suspicious use of select agents or toxins;
  - loss or release of a select agent or toxin; and
  - suspected alteration or compromise to inventory records.
- provide required information for inventory access and acquisition, room entry/exit, and transfers of select agents;
- ensure that unauthorized individuals are either escorted or denied entry into select agent areas; and
- comply with responsibilities for Laboratory Employees listed in Virginia Tech's *Biosafety for Laboratory Workers* which include:
  - wearing and properly maintaining any personal protective equipment necessary to perform each assigned task;
  - properly using engineering controls and safety equipment;
  - following good personal and laboratory hygiene practices;
  - participating in all required training;
  - reading, understanding, and signing off on laboratory-specific procedures and training;
  - informing the lab supervisor if any deficiencies are noted in the laboratory facility, equipment, and procedures;
  - ensuring all waste is properly packaged and promptly disposed of;
  - reporting, to the lab supervisor, any accident that results in injury or exposure to a hazardous substance; and
  - knowing all emergency procedures and what is expected of them during an emergency.

Principal Investigators/Researchers/Supervisors

Principal Investigators, Researchers, and Supervisors shall assume responsibility for the daily operations of a laboratory or group of laboratories. Principal Investigators/Researchers/Supervisors shall:

- read this document and be familiar with its requirements;
- determine whether or not labs under their direction must comply with this program;
- register their select agents and toxins with the University Biosafety Officer;
- complete a risk assessment for each select agent or toxin;
- annually review safety, security, and incident response procedures;
- ensure that:
  - transfers comply with regulatory requirements;
  - safety, security, and incident response plans are developed and implemented;
  - timely notice is provided to the University Biosafety Officer in the event of a loss, theft, or release of a select agent or toxin;
  - all required records are completed and maintained indefinitely;
  - only approved individuals are allowed access to select agents and toxins;
  - individuals are trained on the requirements of this program, as well as university and lab-specific security, safety, and incident response procedures;
  - annual mock drills or tabletop exercises and information-sharing sessions are conducted with local emergency responders; and
  - experiments involving the transfer of a drug resistance trait or the formation of a lethal toxin are not conducted unless approved by the University Biosafety Officer and CDC and/or APHIS.
- comply with responsibilities for Principal Investigators, Researchers, and Supervisors listed in Virginia Tech's *Biosafety for Laboratory Workers* which include:
  - ensuring all laboratory work is conducted in accordance with this program and all applicable federal, state, and local regulations/guidelines regarding laboratory safety;
  - selecting the appropriate control practices for handling hazardous substances;
  - preparing procedures for response to accidents/incidents involving hazardous substances;
  - preparing lab-specific policies and procedures;
  - ensuring that laboratory employees are properly trained on the hazards and how to handle hazardous substances in the laboratory;
  - ensuring that engineering controls and safety equipment are properly maintained;
  - working with the University Biosafety Officer to correct any laboratory deficiencies;
  - ensuring all abandoned hazardous material is promptly disposed of;
  - conducting regular self-audits; and
  - completing all necessary accident and incident reports.

Deans/Directors/Department Heads

Deans, Directors, and Department Heads shall assume overall responsibility for ensuring their respective college/department/center/facility complies with the requirements of this program. Deans/Directors/Department Heads shall:

- be aware of the requirements of this program;
- ensure that Principal Investigators, Researchers, and Supervisors are aware of the requirements of this program;
- mandate laboratory participation; and
- ensure all facilities and activities under their supervision comply with all applicable federal, state, and local regulations/guidelines regarding health and safety.

Responsible Official (RO)

This function shall be the responsibility of EHSS through its University Biosafety Officer. The University Biosafety Officer shall:

- act as liaison between Virginia Tech and regulatory agencies regarding the possession, use, and transfer of select agents and toxins;
- maintain Virginia Tech's registration with the CDC and/or APHIS;
- conduct regular inspections (at least annually) of laboratories using select agents and toxins;
- review and approve risk assessments completed for each select agent;
- annually review safety, security, and incident response procedures;
- in collaboration with the Principal Investigator, Researcher, or Supervisor, ensure that:
  - transfers comply with regulatory requirements;
  - safety, security, and incident response plans are developed and implemented;
  - timely notice is provided to the CDC and/or APHIS in the event of a loss, theft, or release of a select agent or toxin;
  - all records are completed and maintained indefinitely;
  - only approved individuals are allowed access to select agents and toxins;
  - individuals are trained on the requirements of this program, as well as university and lab-specific security, safety, and incident response procedures;
  - annual mock drills or tabletop exercises and information-sharing sessions are conducted with local emergency responders;
  - the identification of a biological select agent or toxin as a result of diagnosis, verification or proficiency testing is reported to the CDC and/or APHIS; and
  - experiments involving the transfer of a drug resistance trait or the formation of a lethal toxin are not conducted unless approved by the CDC and/or APHIS.
- comply with responsibilities for the University Biosafety Officer listed in Virginia Tech's *Biosafety for Laboratory Workers* which include:
  - assisting laboratory personnel in identifying hazardous operations, establishing safe work practices, and selecting protective equipment and other exposure controls;
  - maintaining the written *Biosafety for Laboratory Workers* and *Select Agent and Toxin Program* to include minimum requirements for lab activities and facilities;
  - developing and/or providing training programs in conjunction with principal investigators, researchers, and supervisors;

- coordinating exposure monitoring and respiratory protection, as needed, with EHSS' Occupational Health and Industrial Hygiene division;
- consulting with laboratory personnel on evaluation and correction of safety and security deficiencies;
- investigating and reporting to principal investigators, researchers, and lab supervisors any significant problems with equipment, facilities, and/or safe work practices/procedures; and
- remaining knowledgeable of regulatory and legal requirements associated with biological agents.

Alternate Responsible Official (ARO)

This function shall be the responsibility of EHSS through its Co-director of the Laboratory Safety Division. The responsibilities of the ARO are the same as the RO. The ARO may act on behalf of the RO in his/her absence.

Assistant Vice President for Research Compliance

The Assistant Vice Provost for Research Compliance in the Office of Research Compliance is charged with:

- oversight and regulatory compliance for:
  - animal use;
  - human subjects research;
  - radiation safety; and
  - laboratory safety.
- providing federally mandated training to university members in the areas of human subjects compliance and appropriate animal care and use; and
- chairing the Radiation Safety Committee and the Institutional Review Board.

University Safety Committees

Virginia Tech supports a number of safety oversight committees comprised of researchers, university officials, and EHSS representatives.

Biosafety Committee (BSC)

The BSC is charged with:

- reviewing and approving research proposals involving biological select agents and toxins;
- oversight of the safe use of biological agents by Virginia Tech personnel;
- reviewing and recommending changes to university policy regarding biological agent and toxin use;
- advising other regulatory compliance committees on compliance issues involving biological agents and toxins; and
- acting as a disciplinary body for non-compliant labs and peer groups.

Biotechnology Oversight Committee (BOC)

The BOC is charged with:

- reviewing recombinant DNA research proposals conducted at, or sponsored by, Virginia Tech for compliance with the National Institutes of Health (NIH) Guidelines;
- approving those research projects that conform with the NIH Guidelines; and
- periodically reviewing recombinant DNA research for continued compliance.

Institutional Animal Care and Use Committee (IACUC)

The IACUC is responsible for:

- reviewing proposed uses of animals in research, testing, or education;
- evaluating programs and animal activity areas; and
- inspecting facilities used to house animals.

Radiation Safety Committee (RSC)

The RSC is charged with:

- reviewing and approving research projects utilizing radiation or radioactive materials;
- establishing institutional policies on radiation safety; and
- monitoring existing programs.

Institutional Review Board (IRB)

The IRB is responsible for:

- reviewing and approving research projects utilizing human subjects (including nonviable fetuses, fetal material, and the placenta); and
- monitoring research using human subjects.

Regulated Select Agents and Toxins

The lists generated by the CDC and APHIS consists of viruses, bacteria, fungi, and toxins. Also regulated by the CDC and APHIS are genetic elements and recombinants as well as specific types of experiments. The materials and experiments listed below must comply with all regulatory requirements and be registered with EHSS.

Criteria for Inclusion

The lists of select agents and toxins includes those biological agents and toxins identified by the CDC and APHIS as having the potential to pose a severe threat to human health, to animal health/products, or to plant health/products. The criteria used to develop the lists of select agents and toxins included:

- effect of exposure;
- degree of contagiousness;
- methods by which the agent or toxin is transferred;
- availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection; and
- any other criteria, including the needs of children and other vulnerable populations that are considered appropriate.

HHS Select Agent and Toxin List

- Abrin
- Cercopithecine herpesvirus 1 (Herpes B virus)
- *Coccidioides posadasii*
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyscirpenol
- Ebola viruses
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- Ricin
- *Rickettsia prowazekii*
- *Rickettsia rickettsii*
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- South American Haemorrhagic Fever viruses
    - Flexal
    - Guanarito
    - Junin
    - Machupo
    - Sabia
- Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses
    - Central European Tick-borne encephalitis
    - Far Eastern Tick-borne encephalitis
        - Kyasanur Forest Disease

  - Omsk Hemorrhagic Fever
  - Russian Spring and Summer encephalitis
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*

USDA Select Agent and Toxin Lists

Livestock

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian influenza virus (highly pathogenic)
- Bluetongue virus (exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- *Cowdria ruminantium* (Heartwater)
- Foot-and-mouth disease virus
- Goat pox virus
- Japanese encephalitis virus
- Lumpy skin disease virus
- Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
- Menangle virus
- *Mycoplasma capricolum /M.F38/M. mycoides capri* (contagious caprine pleuropneumonia)
- *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia)
- Newcastle disease virus (velogenic)
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (exotic)

Plant

- *Candidatus* Liberobacter africanus
- *Candidatus* Liberobacter asiaticus
- *Peronosclerospora philippinesis*
- *Ralstonia solanacearum*, race 3, biovar 2
- *Sclerophthora rayssiae* var. zeae
- *Synchytrium endobioticum*
- *Xanthomonas oryzae* pv. Oryzicola
- *Xylella fastidiosa* (citrus variegated chlorosis strain)

HHS/USDA Overlap Select Agent and Toxin List

- *Bacillus anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*

- *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- *Clostridium perfringens* epsilon toxin
- *Coccidioides immitis*
- *Coxiella burnetii*
- Eastern Equine Encephalitis virus
- *Francisella tularensis*
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Shigatoxin
- Staphylococcal enterotoxins
- T-2 toxin
- Venezuelan Equine Encephalitis virus

Genetic Elements/Recombinant Nucleic Acids/Recombinant Organisms List

- Nucleic acids that can produce infectious forms of any of the select agent viruses
- Recombinant nucleic acids that encode for the functional form(s) of any of the listed toxins if the nucleic acids:
  - can be expressed *in vivo* or *in vitro*; or
  - are in a vector or recombinant host chromosome and can be expressed *in vivo* or *in vitro*.
- Listed agents and toxins that have been genetically modified

Restricted Experiments List

Virginia Tech may not conduct the following experiments unless approval is received from the CDC and/or APHIS:

- Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
- Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50} < 100$ ng/kg body weight.

To apply for approval, a written request with accompanying scientific information must be submitted to the University Biosafety Officer. Upon review by the University Biosafety Officer, CDC and/or APHIS, a written decision granting or denying the request will be issued.

Exclusions

Specific Criteria

Any select agent or toxin that meet the following criteria is excluded from regulatory requirements.

1. Any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
2. Non-viable agents or nonfunctional toxins.

3. Select toxins under the control of a principal investigator, if the aggregate amount does not, at any time, exceed the amounts listed in Table 1.

Toxin	Amount (mg)	Toxin	Amount (mg)
Abrin	100.0	Saxitoxin	100.0
Botulinum neurotoxins	0.5	Shiga-like ribosome inactivating proteins	100.0
Conotoxins	100.0	Shigatoxin	100.0
Clostridium perfringens epsilon toxin	100.0	Staphylococcal enterotoxins	5.0
Diacetoxyscirpenol (DAS)	1000.0	T-2 toxin	1000.0
Ricin	100.0	Tetrodotoxin	100.0

Table 1. Excluded Toxin Quantities

Attenuated Strains

An attenuated strain of select agent or toxin may be excluded if it does not post a threat to public health, animal health/products, or plant health/products. In these cases, Virginia Tech may request a review by the CDC and/or APHIS to determine whether the attenuated strain poses a threat. If the CDC and/or APHIS determines it does not pose a threat, then that specific strain is excluded from regulatory requirements.

The current list of exempted attenuated strains (http://www.cdc.gov/od/sap/sap/exclusion.htm) is continually updated as the CDC and APHIS process exclusion requests. Check this list to see if your agent or toxin is excluded before you submit a written request.

Request for Exclusion Status Review

To request a review for exclusion status, a written request with accompanying scientific information must be submitted to the University Biosafety Officer. Upon review by the University Biosafety Officer, CDC and/or APHIS, a written decision granting or denying exclusion status will be issued.

If a review is favorable, exclusion status is effective upon notification by the University Biosafety Officer. If the excluded strain is manipulated such that virulence is restored or enhanced, then the strain is immediately subject to regulatory requirements.

If a review results in an adverse decision, Virginia Tech may request reconsideration. To request reconsideration, a written request stating all the facts and reasons why Virginia Tech thinks the CDC and/or APHIS decision was incorrect must be submitted to the University Biosafety Officer. Upon review by the University Biosafety Officer, CDC and/or APHIS, a written decision granting or denying the request for reconsideration will be issued along with the reasons why.

Federal Law Enforcement Seizure

Any select agent or toxin seized by a Federal law enforcement agency is excluded from regulatory requirements as long as safety and security of the material is maintained until it is either transferred to an approved facility or destroyed.

Exemptions

The regulations include exemptions for certain entities and situations. Even if an exemption applies, a Principal Investigator/Researcher/Supervisor using select agents and toxins must still declare their possession to the University Biosafety Officer and comply with university biosafety requirements presented in *Biosafety for Laboratory Workers*.

Diagnosis, Verification, or Proficiency Testing

Clinical or diagnostic laboratories and other entities that possess, use, or transfer select agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing are exempt provided that:

- the University Biosafety Officer is immediately notified by telephone, facsimile, or e-mail;
- a report (APHIS/CDC Form 4) is immediately prepared and submitted to the University Biosafety Officer;
- the select agent or toxin is secured against theft, loss, or release; and
- unless directed by the University Biosafety Officer, CDC, and/or APHIS, the agent or toxin is transferred to an approved facility or destroyed (i.e., autoclaved) within:
  - seven days after identification via diagnosis or verification; or
  - 90 days after receipt, if used for proficiency testing.

Exempted Products

Products containing select agents or toxins that are cleared, approved, licensed, or registered and being used in the manner intended by the following are exempt from regulatory requirements.

- Federal Food, Drug, and Cosmetic Act (21 USC 301 *et seq*.);
- Section 351 of Public Health Service Act pertaining to biological products (42 USC 262);
- Virus-Serum-Toxin Act (21 USC 151-159); or
- Federal Insecticide, Fungicide, and Rodenticide Act (7 USC 131 et seq.).

Investigational/experimental products containing select agents or toxins being used in an investigation authorized by any Federal Act may be granted exemption status.

- An application for exemption (APHIS/CDC Form 5) must be submitted to the University Biosafety Officer. Within 14 calendar days after receipt, and provided the application is complete, the CDC and/or APHIS will issue a written decision granting or denying the request.
- If the application is approved, the University Biosafety Officer must be notified when such approval is no longer needed. At that time, the exemption terminates.

Domestic or Foreign Health Emergency

In cases of domestic or foreign public or agricultural health emergencies, temporary exemption for an individual or entity may be granted for 30 days. Depending upon the type of emergency, a one-time extension of an additional 30 days may also be granted.

An application for exemption or extension (APHIS/CDC Form 5) must be submitted to the University Biosafety Officer. Upon review by the University Biosafety Officer, the CDC and/or APHIS, a written decision will be issued granting or denying the request.

Facility, Agent, and Personnel Registration

Each facility, select agent/toxin, and individual requiring access to select agents/toxins must be registered with and approved by the University Biosafety Officer. The University Biosafety Officer maintains Virginia Tech's registration with the CDC and/or APHIS. The university's registration is valid for a maximum of three years and renewal of its registration is based upon compliance history and any outstanding deficiencies.

Facility and Agent Registration

Application for Registration

Any Principal Investigator seeking approval for use of a select agent or toxin must complete an application package and submit it to the University Biosafety Officer. Once the application is received, the University Biosafety Officer will:

- review the application for completeness and contact the Principal Investigator if there are any questions; and
- submit the application to the CDC and/or APHIS for review and approval.

While the CDC or APHIS is reviewing the application, the University Biosafety Officer will:

- inspect the specified facilities to ensure proper biosafety levels are maintained and proper security measures are in place;
- provide the Principal Investigator with a list of required standard operating procedures, plans, documentation, or additional information that is required for approval; and
- work with the Principal Investigator to ensure all safety, security, and incident response plans are implemented.

The CDC and/or APHIS will:

- review the submitted information; and
- decide whether or not the information provided indicates the facility and related operations are sufficient to possess, use, and transfer select agents and toxins under Virginia Tech's registration.

The CDC and/or APHIS may request additional information or written plans and conduct a facility inspection prior to issuing an approval.

Approval of Registration

- The University Biosafety Officer will notify the Principal Investigator in writing if approval and permission to operate under Virginia Tech's registration is granted.
- Registrations are only valid for the specific select agents and toxins and the specific activities and locations indicated in the information provided on the application forms.

The time required for application review and registration approval varies depending upon the compliance deficiencies that may be identified during the process. If all safety, security, and incident response plans are completed and implemented and the facility meets biosafety level standards, the minimum time for processing is 12 weeks. It has been the university's experience that 5-6 months is a more realistic timeframe.

Denial of Registration

- If the CDC and/or APHIS deny approval, they will inform the University Biosafety Officer. The University Biosafety Officer will, in turn, inform the Principal Investigator. When deficiencies have been resolved, the Principal Investigator may again seek registration.
- The Principal Investigator may request a review of a decision denying approval status by submitting a written request for review to the University Biosafety Officer within 30 calendar days after the decision. The appeal must state the factual basis for the appeal. The University Biosafety Officer will then forward the appeal to the CDC and/or APHIS for review.

Amendments to Registration

- The University Biosafety Officer must be immediately notified of any intended updates or modifications to the information submitted in the application. This includes changes in:
  - personnel;
  - work locations;
  - protocols and procedures;
  - objectives of research; and
  - select agent and toxin strains.
- **The CDC and/or APHIS must approve intended modifications before they are implemented.**

Personnel Registration

Personnel must be registered with and approved by the University Biosafety Officer prior to being provided access to select agents or allowed unescorted access to select agent labs or animal rooms.

Application for Registration

- The Principal Investigator must notify the University Biosafety Officer as soon as possible of new personnel under their direction having a legitimate need to access select agents or toxins.
- **Each prospective select agent user must have the appropriate education, training, and/or experience to handle and manage select agents or toxins.** An initial screening (Appendix A) must be performed by the Principal Investigator and the University Biosafety Officer to determine if an individual's background is sufficient or if further education, training, and/or experience is needed.
- After the initial screening, the individual needing access must submit the required security risk assessment information (Appendix B) to the University Biosafety Officer.
- The University Biosafety Officer will request a unique identifying number from the CDC and/or APHIS for that individual.
- Once a unique number is assigned, the individual will be given a packet containing fingerprint cards and associated instructions. Fingerprints must be returned to the University Biosafety Officer for submission to the FBI.
- Security risk assessments generally take 8-12 weeks to complete.

Approval for Access

- The University Biosafety Officer will notify the individual and Principal Investigator of the security risk assessment results.
- In addition to the security risk assessment, an individual must also complete university and lab-specific training prior to receiving full approval and access privileges.
- Access approval is valid for a maximum of five years.

Denial of Access

The University Biosafety Officer will notify the individual and Principal Investigator if an individual's access approval is denied. The individual and Principal Investigator may appeal the denial by submitting a written request stating the factual basis for the appeal to the University Biosafety Officer within 30 calendar days after the decision.

Termination of Access

- The Principal Investigator must immediately notify the University Biosafety Officer if an individual plans to leave the university or no longer requires access to select agents or toxins.
- An individual's access privileges will be terminated if the individual is reasonably suspected by any Federal law enforcement or intelligence agency of:
    - committing a crime punishable by more than one year in jail;
    - knowing involvement with an organization that engages in domestic or international terrorism or with any other organization that engages in intentional crimes of violence; or
    - being an "agent of a foreign power."
- An individual's access privileges will be terminated if it is determined such action is necessary to protect public health and safety.

Security and Incident Response

Security Requirements

Risk Assessment

- Each research group, in conjunction with the University Biosafety Officer, must conduct a systematic risk assessment in which threats are defined, vulnerabilities are examined, and risks associated with these vulnerabilities are minimized with a security systems approach.
- Documentation of security risks and steps taken to minimize these risks should be included in the laboratory's written security plan.

Written Security Plan

- Each research group must develop and maintain a site-specific written plan or summary of security measures adopted to prevent unauthorized access of a select agent or toxin. The CDC/NIH guidelines for lab security and emergency response planning (Appendix C) must be used when developing the plan.
- The plan must:
    - include a description of each security risk identified during the assessment phase;
    - at a minimum, adopt the university security requirements;
    - contain a description of any security measures that are specific to their particular facility or research;
    - be submitted to the University Biosafety Officer as part of the application package; and
    - be reviewed by the University Biosafety Officer and Principal Investigator on an annual basis, after any incident, and after any drill or exercise.
- Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.

Inventory and Access Control Requirements

Inventory and Access Control at the Point of Storage

- Each select agent user or group of users must maintain a current and accurate inventory of each select agent and toxin (including viral genetic elements and recombinant nucleic acids, and recombinant organisms) held in long-term storage.
- The inventory records (Appendix D) for each select agent must include the following:
    - name and characteristics of the agent (e.g., strain designation GenBank Accession number);
    - storage location information (e.g., building, room, and freezer);
    - quantity acquired, the source, and the date of acquisition;
    - when moved from storage and by whom and when returned to storage and by whom;
    - the purpose of use;

- when applicable, the quantity transferred, the date of transfer, the sender, and the recipient (this includes transfers within a facility between approved individuals); and
- a written explanation of any discrepancies.

- The inventory records for each toxin must include the following:
  - name and characteristics;
  - storage location information (e.g., building, room, and freezer);
  - quantity acquired, the source, and the date of acquisition;
  - initial and current quantity amount (e.g., milligrams, milliliters, grams)
  - purpose of use, quantity used, date of use, and person accessing the toxin;
  - when moved from storage and by whom and when returned to storage and by whom including quantity amount;
  - when applicable, the quantity transferred, the date of transfer, the sender, and the recipient (this includes transfers within a facility between approved individuals);
  - if destroyed, the quantity of toxin destroyed, the date of such action, and by whom; and
  - a written explanation of any discrepancies.
- Inventory and storage access records must be:
  - located near the storage area and kept secure;
  - maintained by the laboratory for at least three years;
  - reviewed weekly by the laboratory supervisor for any discrepancies; and
  - provided to the University Biosafety Officer or other regulatory agency during an inspection.

Access Control at the Point of Entry into Secure Area

- An entry/exit record (Appendix F) must also be maintained for each secure area. This record must include the:
  - name of each individual entering the area, including the names of escorted individuals (e.g., visitors, Physical Plant personnel, contractors, CDC/APHIS inspectors);
  - date and time the individual(s) entered the area; and
  - date and time the individual(s) exited the area.
- Entry/exit records must be:
  - placed on the entry door leading to the secure area or right inside the entry door;
  - maintained at least three years; and
  - provided to the University Biosafety Officer or other regulatory agency during an inspection.

Personnel Security Requirements

- All personnel having a legitimate need for accessing select agents or toxins or areas in which these materials are stored must be registered with and approved by the University Biosafety

Officer prior to being provided access. Procedures for registration and approval are described in the Personnel Registration section.

- **While the FBI is conducting its security risk assessment, an individual is allowed to work in a secure area ONLY if an approved individual accompanies them at all times. In addition, the individual may not manipulate select agents or toxins but may observe an approved individual manipulate them.**
- All visitors, maintenance personnel, and other individuals not approved for access must be escorted in secure areas at all times by an approved individual.

Physical Security Requirements

At a minimum, laboratories possessing select agents and toxins must implement the following security measures:

- Select agents and toxins must be stored and used in areas separated from public use and access areas.
- All doors to laboratories or storage areas that contain select agents and toxins must be lockable (via key, card key, key pad, biometric device, or a combination of any of these measures). If key locks are used, they must be keyed "direct to control."
- A record of the distribution of keys, card keys, combinations, or codes to approved individuals must be maintained by the Principal Investigator. The date of issue, access information (e.g., building, room, freezer), and date of key return must be logged and a signed agreement describing the requirements for possessing the key must be maintained.
- Quarterly visual key checks must be conducted and documentation must be maintained with the key distribution log
- Any loss of key or card key (i.e., any key that cannot be accounted for within 24 hours) or compromise to combinations or codes will require "rekeying" of the secure area(s). The University Biosafety Officer must be notified immediately of any loss or compromise of keys, combinations, passwords, etc.
- Combinations and codes must be changed following any staff changes. A rekeying of the secure area must occur if the vacating staff does not return their key within 48 hours of termination of service to Virginia Tech.
- No sharing of keys or combinations among approved individuals or among approved and non-approved individuals is permitted. Anyone that shares their means of entry into a secure area with another individual will be denied entry into the secure areas until an investigation is complete. Termination of access privileges may occur.
- All laboratories and storage areas containing select agents and toxins must remain locked except when entering or exiting.
- All visitors, maintenance personnel, or other individuals not approved for access must be escorted in secure areas at all times by an approved individual.
- Equipment used to store or process select agents and toxins (e.g., freezers, refrigerators, cabinets, incubators, shakers) must be lockable and remain locked unless removing or replacing the select agent or toxin.
- All unexpected or suspicious packages must be inspected by visual or noninvasive means before they are brought into, or removed from, areas where select agents are stored or used.

- Suspicious persons or activities must be immediately reported to the Virginia Tech Police and the University Biosafety Officer.

Information Security Requirements

- Information related to select agents and toxins (e.g., inspection reports; application information; transfer documentation; safety and security information; notifications of releases, loss, or thefts; and research results) is not subject to the Freedom of Information Act (5 USC 552).
- Specific security requirements must be developed by each research group and documented. Each research group must establish policies for access, use, storage, and transfer of sensitive files and data. These should be included the site-specific written security plan.
- Paper Storage Systems
    - All paperwork associated with select agents and toxins (e.g., transfer documents, application information, list of individuals approved for access) must be kept confidential and in a secure location (e.g., locked filing cabinet).
    - Only approved individuals may have access to select agent and toxin information.
- Computer Information Systems
    - Individuals must comply with Virginia Tech's Acceptable Use and Administration of Computer and Communication Systems policy requirements.
    - An Information Technology Security Awareness session is available to Virginia Tech employees by contacting Wayne Donald at wdonald@vt.edu.
    - Review General Recommendations for Technology Security developed by the Information Technology Security Office at Virginia Tech.

Incident Response Requirements

Written Incident Response Plan

- Each research group must develop and maintain an incident response plan to address site-specific procedures for managing:
    - the theft, loss, or release of a select agent or toxin;
    - inventory discrepancies;
    - security breaches;
    - severe weather and other natural disasters;
    - workplace violence;
    - bomb threats;
    - suspicious packages; and
    - emergencies (e.g., fire, gas leak, explosion, power outage).
- The plan must contain the following information:
    - the hazards associated with the use of select agents and toxins;
    - any hazards associated with response actions that could lead to a spread of a select agent or toxin;

- emergency contact information;
- personnel roles and lines of authority and communication;
- planning and coordination with local emergency responders;
- procedures to be followed by employees performing rescue or medical duties;
- emergency medical treatment and first aid;
- list of personnel protective and emergency equipment, and their locations;
- site security and control;
- procedures for emergency evacuation (including type of evacuation, exit route assignments, safe distances, and places of refuge); and
- decontamination procedures.

- The written plan must be submitted as part of the application package.
- The plan must be reviewed by the University Biosafety Officer and Principal Investigator and revised as necessary:
  - at least annually;
  - after any drill or exercise; and
  - after any incident.
- Drills or exercises must be conducted at least annually with local emergency responders and approved personnel to test and evaluate the effectiveness of the plan. Drills must provide for a debriefing and question and answer session so issues may be discussed and improvements made to incident procedures.

Incident Response Requirements

- An incident response coordinator must be designated for each research group. This person should have the responsibility and authority to implement requirements of the site-specific incident response plan.
- All non-emergency incidents must be immediately reported to the University Biosafety Officer. All emergencies must be immediately reported to the Virginia Tech Police and then the University Biosafety Officer.
- Each entry door into a secure area must list emergency contact information to include:
  - name(s) of designated emergency contact(s);
  - office location(s);
  - work and home phone numbers; and
  - university emergency contact information.

Notification of Theft or Loss

- Any theft or loss must be immediately reported to the University Biosafety Officer. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.
- The following information must be reported:

- name of select agent or toxin and any identifying information;
- an estimate of the quantity lost or stolen;
- an estimate of the time during which the theft or loss occurred;
- the location from which the theft or loss occurred; and
- the list of Federal, State, or local law enforcement agencies to which a report was made.

- A completed APHIS/CDC Form 3 must be presented to the University Biosafety Officer and APHIS/CDC within seven calendar days.

Notification of Release

- Any release causing occupational exposure or release occurring outside primary barriers of the biocontainment area must be immediately reported to the University Biosafety Officer. If the University Biosafety Officer is not available, contact the Virginia Tech Police.
- The following information must be reported:
  - name of select agent or toxin and any identifying information;
  - an estimate of the quantity released;
  - an estimate of the time and duration of the release;
  - the location from which the release occurred;
  - the environment into which the release occurred (e.g., in building or outside of building, waste system);
  - number of potentially exposed individuals;
  - actions taken to respond to the release; and
  - hazards posed by the release.
- A completed APHIS/CDC Form 3 must be presented to the University Biosafety Officer and APHIS/CDC within seven calendar days.

Biosafety

Written Biosafety Manual

- Each research group must develop and maintain a biosafety plan that addresses the risk and resulting containment procedures for working with select agents and toxins and any animals infected with these agents or toxins. Completion of Part B of the university biosafety plan, *Biosafety for Laboratory Workers*, satisfies this requirement and must be submitted with the application package.
- The biosafety manual must be reviewed by the University Biosafety Officer and Principal Investigator and updated as necessary:
    - at least annually;
    - after any drill or exercise; and
    - after any incident.
- Drills and exercises must be conducted at least annually to test and evaluate the effectiveness of the manual.

Laboratory Safety Requirements

Infectious Biological Agent Research

All laboratories handling infectious biological agents must comply with:

- Part A: University Policies and Procedures in Virginia Tech's *Biosafety for Laboratory Workers*;
- Virginia Tech's Bloodborne Pathogens Program; and
- the requirements listed for the appropriate biosafety level in the CDC/NIH *Biosafety for Microbiological and Biomedical Laboratories (current ed)*.

Toxin Research

All laboratories handling toxins and hazardous chemicals must comply with the requirements specified in:

- Virginia Tech's *University Chemical Hygiene Plan*; and
- *Appendix I: Guidelines for Work with Toxins of Biological Origin* in the BMBL.

Recombinant DNA Research

All labs working with recombinant DNA must comply with the requirements listed in the NIH Guidelines.

Vertebrate Animal Safety Requirements

Infectious Biological Agent Research

All animal handling associated with biological agent research must comply with:

- the university requirements as implemented by the Institutional Animal Care and Use Committee;
- the appropriate animal biosafety level requirements listed in the CDC/NIH *Biosafety for Microbiological and Biomedical Laboratories (4th ed)*; and

- requirements specified in *Guide for the Care and Use of Laboratory Animals*.

Toxin Research

All animal management for toxin agent research must comply with:

- the university requirements as implemented by the Institutional Animal Care and Use Committee; and
- requirements listed in *Appendix I: Guidelines for Work with Toxins of Biological Origin* in the BMBL.

Recombinant DNA Research

All recombinant DNA research using animals must comply with the requirements listed in the NIH Guidelines.

Plant Biocontainment Requirements

In developing a biocontainment plan, the following must be considered:

- Containment Facilities and Safeguards for Exotic Plant Pathogens (Newman Library Call No. SB979.5 .C66 1998); and
- A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes (http://www.isb.vt.edu/cfdocs/greenhouse_manual.cfm)

Recombinant DNA Research

All recombinant DNA research using plants must comply with the requirements listed in the NIH Guidelines.

Training

Approved Individuals

- Each individual approved for access to select agents and toxins must be trained on all aspects of program requirements. The University Biosafety Officer provides training on all university requirements and each Principal Investigator must provide research-specific training.
- **Each individual must be trained PRIOR to being granted access to select agents.**
- An annual refresher must be provided by the University Biosafety Officer (for university requirements) and by the Principal Investigator (for research-specific requirements).
- A record (Appendix G) must be maintained to document an individual's training and must include:
    - individual's name;
    - date of training;
    - topics covered during the training; and
    - methods used to verify that the individual understood all the requirements for working with select agents and toxins.

Non-approved Individuals

- Non-approved individuals who must enter secure areas with an escort must be made aware of the hazards associated with select agents and toxins, security requirements, and emergency response procedures prior to entering the area.
- A record (Appendix H) must be maintained to document an individual's training and must include:
    - individual's name;
    - date of training;
    - topics covered during the training; and
    - methods used to verify that the visitor understood the information.
- For frequent visitors (i.e., ≥ once a month), the initial training documentation may be dated and signed each time the individual must be escorted rather than using a new form each time. However, if any changes to the hazards, security requirements, or emergency response procedures occur, the visitor must be retrained and new documentation maintained.
- For infrequent visitors (i.e., < once a month), a new training and information session must occur each time with documentation maintained.

Transfers

Transfer of select agents and toxins may only occur between entities that are approved to possess, use, and transfer the particular agent or toxin to be transferred.

Prior to Transfer

- An APHIS/CDC Form 2 must be completed and sent to the University Biosafety Officer.
- Other appropriate permits must be obtained by the recipient:
  - USDA Permit – for the interstate movement of a select agent per 7 CFR Part 330 and 9 CFR Part 122. Permit applications are available at http://www.aphis.usda.gov/forms/index.html
  - USDA and/or HHS Import Permit – for the importation of select agents per 7 CFR Part 330.200, 9 CFR Part 122.2, and 42 CFR Part 71.54
    - USDA permit applications:
      - Plant Pathogens - http://www.aphis.usda.gov/forms/index.html
      - Livestock Pathogens - http://www.aphis.usda.gov/vs/ncie/
    - HHS permit application for human pathogens is available at http://www.cdc.gov/od/ohs/biosfty/imprtper.htm
  - US Department of Commerce Export Permit – for the export of select agents and toxins. Licensing information is available at http://www.bxa.doc.gov/Licensing/index.htm.
- The CDC and/or APHIS must review and approve the transfer. If approved, the CDC and/or APHIS will issue a transfer authorization number that is valid for 30 days after issuance.

Receipt of Select Agents and Toxins by Virginia Tech

- All transfers must be coordinated through the University Biosafety Officer. The University Biosafety Officer must be notified at least three working days in advance that the Sender is ready to ship the select agent or toxin to Virginia Tech.
- The University Biosafety Officer must receive all select agents and toxins for Virginia Tech personnel. No direct deliveries to the lab are permitted.
- Deliveries must be addressed to:

  Charlotte Waggoner
  Responsible Official
  Environmental, Health and Safety Services
  459 Tech Center Drive
  Blacksburg, VA 24061 MS 0423
  (540) 231-5864

- Upon receipt, the University Biosafety Officer will:
  - visually inspect the package for leaks or damage;
  - deliver the package to an approved individual and to a secure area;
  - ensure that the material is entered into the lab's Acquisition Log; and

- notify the Sender and CDC/APHIS within two business days of receipt that the package arrived.

- If the select agent or toxin is not received within 48 hours of the expected delivery time, the package received is leaking or otherwise damaged, or if the amount received differs from that indicated by the Sender, the University Biosafety Officer must immediately notify the CDC and/or APHIS as well as the Sender.

Transfer of Select Agents and Toxins from Virginia Tech

- Anyone offering a package for shipment by a commercial carrier must be trained. The University Biosafety Officer is trained and must review all shipments of select agents and toxins.

- The packaging, labeling, and required shipping documentation must comply with the Department of Transportation regulations (http://www.myregs.com/dotrspa/) and the International Air Transport Association (IATA) guidelines since most shipments are handled by air courier.
  - The IATA publication, *Infectious Substances and Diagnostic Specimens Shipping Guidelines* is available for purchase from IATA.
  - The World Health Organization (WHO) publishes *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens* which are applicable to the transport of infectious substances and diagnostic specimens both nationally and internationally. The CDC and IATA requirements for proper packaging and labeling mirror the WHO guidelines.

- Transfer of select agents and toxins must be by USPS Registered First-Class Mail with return receipt or an equivalent system (e.g., FedEx) that allows for tracking.

Intra-entity Transfers

Transfers of select agents and toxins between approved individuals within an approved facility operating under the same registration are exempt from completing an APHIS/CDC Form 2 provided that for each transfer:

- the Principal Investigator maintains a chain-of-custody record (≥ 3 years) that includes the:
  - name of select agent or toxin,
  - amount of agent or toxin transferred,
  - date of transfer;
  - sender and recipient names; and
  - reason for the transfer.

- and, the movement of the agent or toxin is conducted under the supervision of an approved individual and the University Biosafety Officer approves the transfer.

Records

- All records related to select agent possession, use, and transfer must be maintained for at least three years and promptly presented upon request to the University Biosafety Officer and governmental officials.
- Records that must be maintained include:
    - Facility and agent application documentation
        - Current lab layout diagrams
        - Denial, revocation, or suspension appeal documentation
    - Current list of approved individuals
    - Inventory acquisition logs
    - Inventory access logs
    - Entry/exit Logs
    - Security Plan
        - Key distribution logs
        - Rekeying documentation
        - Quarterly visual checks documentation
        - Drills/exercise documentation
        - Annual review documentation
    - Incident Response Plan
        - Incident debriefing documentation
        - Drills/exercise documentation
        - Annual review documentation
    - Biosafety Plan
        - Risk assessments
        - *Biosafety for Laboratory Workers* Part B: Lab-specific Policies and Procedures
        - Drills/exercise documentation
        - Annual review documentation
    - Annual facility verification documentation
    - Training records
        - Approved individuals
            - Initial training
            - Annual refresher
        - Non-approved individuals

- Transfer documentation
- Inspection documentation
    - Reports
    - Plans for correcting deficiencies
    - Documentation of corrected deficiencies
- Notifications of theft, loss, or release

Inspections

Purpose of Inspections

Surveys of labs, animal rooms, and work areas associated with the labs are designed to ensure:

- the facility used to manage and house select agents and toxins is acceptable and maintained at the required biosafety level;
- proper equipment and safety procedures are used to work with the select agents and toxins;
- security and incident response measures are satisfactory;
- records and written plans are maintained; and
- deficiencies are resolved in a timely manner.

Inspection Frequency

- The University Biosafety Officer will conduct periodic surveys (at least annually) throughout the lab's registration period. They may be announced or unannounced.
- The CDC and/or APHIS may, without prior notification, inspect any facility where select agents and toxins are used or stored and all associated records.
- Any amendment (e.g., addition of a new room for research, addition of new select agent or toxin) to an approved area's registration may be contingent on inspection and submission of additional information (e.g., risk assessments, biosafety plans, training records).

Inspection Components

During surveys, the University Biosafety Officer and regulatory agencies will review:

- compliance with appropriate facility design criteria;
- appropriateness of biosafety level used to manage select agents;
- security policies and procedures;
- incident response procedures;
- safety procedures;
- training procedures;
- completeness of security risk assessments;
- the availability and proper use of safety equipment;
- the management of transfers of select agents;
- all documentation related to the management of the facility and select agents (e.g., log books, training records, operations manuals, transfer documents, prior inspection reports); and
- notification procedures for theft, loss, release, changes in personnel, changes in research activities, or changes in facility operations.

"Passing" a Laboratory Inspection

The University Biosafety Officer and the CDC and/or APHIS will use the appropriate regulation or university program requirements as a guide during surveys. **Your lab or work area should conduct**

periodic self-audits using these regulations and requirements as a guide as well to ensure that all equipment and procedures, as well as the facility itself, are capable of handling the agent(s) you are managing. Any self-audits should be documented and maintained for at least three years.

If your research involves use of…	Use these as a guide to compliance
Live select agent bacteria, viruses, fungi or rickettsiae	Biosafety for Microbiological and Biomedical Laboratories (BMBL) Virginia Tech's *Biosafety for Laboratory Workers* Virginia Tech's Bloodborne Pathogens Program
Recombinant DNA, genetic elements, or inactivated agents	NIH Guidelines
Toxins of biological origin	Virginia Tech Chemical Hygiene Plan NIH Guidelines (if the toxin work involves working with recombinant DNA or intact toxin producing organisms) Appendix I: Guidelines for Work with Toxins of Biological Origin (contained in the BMBL)
Animals "infected" with any of the above materials	*Guide for the Care and Use of Laboratory Animals* And, if applicable, depending upon the research material… ❑ Biosafety for Microbiological and Biomedical Laboratories (BMBL) ❑ Virginia Tech's *Biosafety for Laboratory Workers* ❑ *Appendix I: Guidelines for Work with Toxins of Biological Origin* ❑ NIH Guidelines
Plant Pathogens	❑ Containment Facilities and Safeguards for Exotic Plant Pathogens (Robert R. Kahn and S.B. Mathur eds., 1999) – Newman Library Call No. SB979.5 .C66 1998 ❑ A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes (Patricia L. Traynor ed., 2001) ❑ NIH Guidelines

Table 2. Compliance Guides

Resources

People

Laboratory Safety Division

- Co-Director, Bernadette Mondy; (540) 231-8758 or bmondy@vt.edu
- University Biosafety Officer, Charlotte Waggoner; (540) 231-5864 or ren@vt.edu
- University Chemical Hygiene Officer, Donald Conner; (540) 231-7611 or dcon@vt.edu
- Hazardous Materials Manager, Frank Imperatore, (540) 231-2982 or imperato@vt.edu

Occupational Safety and Health Division

- Co-Director, Zack Adams; (540) 231-5985 or mailto:adamsz@vt.edu
- Industrial Hygienist (Physical Hazards), Albert Moore; (540) 231-3080 or noise@vt.edu
- Industrial Hygienist (Chemical Hazards), Anca Bejan; (540) 231-2509 or ab4@vt.edu
- Industrial Hygienist (Biological Hazards), Sarah Owen; (540) 231-4034 or sowen@vt.edu

Radiation Safety Division

- Co-Director, Doug Smiley; (540) 231-5364 or smileydc@vt.edu

On-line Information

General Biosafety

- *Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th edition*, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm
- Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, CDC /NIH; http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm
- Virginia Tech Bloodborne Pathogens Program; http://www.ehss.vt.edu/Programs/OHIH/BBP/bbpprogram.htm
- Risk Group Classifications for Infectious Agents, American Biological Safety Association (ABSA); http://www.absa.org/resriskgroup.html
- Material Safety Data Sheets for Infectious Agents (Health Canada); http://www.phac-aspc.gc.ca/msds-ftss/index.html

Importation of Etiologic Agents

- Importation Permits for Etiologic Agents, CDC; http://www.cdc.gov/od/eaipp/
- Interstate Movement or Importation of Animals, Animal Products, and Biologics (VS Form 16-3 and possibly VS Form 16-7), APHIS, USDA; http://www.aphis.usda.gov/vs/ncie/
- Interstate Movement or Importation of Plant Pests (PPQ Form 526), APHIS, USDA; http://www.aphis.usda.gov/ppq/permits/

Exportation of Etiologic Agents

- Export of Etiologic Agents of Humans, Animals, Plants, and Related Materials, Department of Commerce Bureau of Industry and Security; http://www.bis.doc.gov/ComplianceAndEnforcement/index.htm

Transportation and Transfer of Etiologic Agents

- Interstate Shipment of Etiologic Agents, CDC; http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
- Hazardous Materials Regulations, Department of Transportation (DOT); http://www.access.gpo.gov/nara/cfr/waisidx_04/49cfrv2_04.html
- International Air Transportation Association (IATA); http://www.iata.org/index.htm
- Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens, World Health Organization (WHO); http://www.who.int/csr/resources/publications/biosafety/WHO_EMC_97_3_EN/en/

Recombinant DNA Work

- NIH Guidelines for Research Involving Recombinant DNA Molecules. 2002; http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

Animal Care and Use

- Occupational Health and Safety in the Care and Use of Research Animals. National Academy Press (NAP), 1997; http://www.nap.edu/catalog/4988.html
- Guide for the Care and Use of Laboratory Animals. National Academy Press, 1996; http://www.nap.edu/readingroom/books/labrats/
- Institute for Lab Animal Research; http://dels.nas.edu/ilar_n/ilarhome/

Glossary

Access means the state of having possession or the ability to gain possession of a select agent or toxin.

Alternate Responsible Official is the person designated to act on behalf of the Responsible Official (RO) if the RO is unavailable.

Animal and Plant Health Inspection Service (APHIS) the Department of Agriculture's agency delegated the responsibility of oversight of facilities using, possessing, or transferring select agents and toxins that pose a threat to animals or plants.

Biological agent Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such mircroorganism or infectious substance, capable of causing:

- death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
- deterioration of food, water, equipment, supplies, or material of any kinds; or
- deleterious alteration of the environment.

Biosafety Development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agents to workers, other persons, and the environment.

Biosecurity Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.

Bioterrorism Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.

CDC Centers for Disease Control and Prevention, the Department of Health and Human Service's agency delegated the responsibility of oversight of facilities using, possessing, or transferring select agents and toxins that pose a threat to humans.

CFR Code of Federal Regulations, the federal government's official "books" for the publication of federal regulations.

Department means a distinct specialized division or functional component of Virginia Tech such as the Fralin Biotechnology Center or the Virginia-Maryland Regional College of Veterinary Medicine.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent or toxin provided that such analysis is directly related to protecting the public health and safety, animal health or animal products, or plant health or plant products.

EHSS Environmental, Health and Safety Services, Virginia Tech's department charged with oversight and administration of health and safety programs.

Entity means any governmental agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may use, transfer or receive a select agent.

Laboratory means a worksite at a single geographic location where laboratory use of select agents occurs under the direct supervision of a single principal investigator/researcher.

Long-term storage means placement in a system designed to ensure viability for future use, such as a freezer or lyophilized materials.

Overlap select agent or toxin means a biological select agent or toxin that is considered a threat to humans as well as animals and plants and is therefore regulated by the CDC as well as APHIS.

Possession means the ability to carry, use, or manipulate.

Permit A written authorization by the USDA or CDC to import or move biological agents or toxins.

Principal Investigator is a Virginia Tech employee responsible for the operations and associated researchers of a laboratory or group of laboratories.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Researcher is a Virginia Tech employee conducting research in a laboratory or group of laboratories under the direction of a Principal Investigator who is responsible for the daily operations of a laboratory or group of laboratories.

Responsible Official means a Virginia Tech employee with the authority and responsibility to ensure that the requirements of the select agent regulations are met, on behalf of Virginia Tech. The Responsible Official for Virginia Tech is the University Biosafety Officer.

Risk A measure of the potential loss of a specific biologic agent of concern, on the basis of the probability of occurrence of an adversary event, effectiveness of protection, and consequence of loss.

Secure area means any area (e.g, laboratory, animal holding room) that contains a select agent or toxin.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) listed by the CDC and/or APHIS.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples used for diagnosis, verification, or proficiency testing.

Threat The capability of an adversary, coupled with intentions, to undertake malevolent actions.

Threat assessment A judgment, based on available information, of the actual or potential threat of malevolent action.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

Unit means a subdivision of a department such as Veterinary Medicine – Center for Molecular Medicine and Infectious Disease (CMMID).

University Biosafety Officer is the individual within Environmental, Health and Safety Services (EHSS) assigned the responsibilities associated with the title of Responsible Official as described in the Responsibilities section.

USDA United States Department of Agriculture, the agency that is responsible for ensuring a safe food supply.

Verification means the demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

Vulnerability An exploitable capability, security weakness, or deficiency at a facility. Exploitable capabilities or weaknesses are those inherent in the design or layout of the biologic laboratory and its

protection, or those existing because of the failure to meet or maintain prescribed security standards when evaluated against defined threats.

Vulnerability assessment A systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.

Appendix A: Personnel Registration – Initial Screening

VirginiaTech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Select Agent and Toxin Program
Personnel Qualifications Screening

Name:	**Principal Investigator:**
Phone:	**Email:**
SELECT AGENTS/TOXINS TO BE USED:	
RESEARCH PROJECT TITLE AND BRIEF OBJECTIVES:	
FORMAL EDUCATION: **Degree(s) Earned/Dates/Institution(s)** **Relevant Classes/Labs Completed and Grade Received**	
RELEVANT WORK EXPERIENCE: **Job Title/Company/Dates Employed/Responsibilities**	
RELEVANT TRAINING: **Course(s)/Dates/Institution**	
PROFESSIONAL MEMBERSHIPS/CERTIFICATIONS:	

Virginia Tech EHSS Form (8-2005)
Personnel Qualification Screening

Appendix B: Personnel Security Risk Assessment Forms

Virginia Tech
VIRGINIA POLYTECHNIC INSTITUTE
AND STATE UNIVERSITY

Environmental Health and Safety Services
459 Tech Center Drive, Blacksburg, Virginia 24061 MS 0423
(540) 231-5864 Fax (540) 231-3944

To: Prospective Select Agent User

From: Charlotte Waggoner, University Biosafety Officer

Subject: Select Agent Security Risk Assessment Information

Date: Effective February 2005

Instructions:

1. Fill out *Section III: Individual Information* on page 2. Leave #15 blank. If you check "yes" on question 16g, you must complete the *Foreign Born Information* on page 3.
2. Read *Section IV: Consent* on page 4.
3. Complete the *Virginia Tech USA Patriot Act Compliance Status* form on page 5. This form will be kept in-house while the FBI completes its security risk assessment.
4. Make sure to sign and date pages 2, 4, and 5.
5. Fill in the information on page 6. This is used to prepare the cards needed for fingerprinting.
6. Make a copy of the forms for yourself if you want. Copies will be maintained at the health and safety office.
7. Return the originals to Charlotte Waggoner (mail code 0423).

If you have any questions or problems with the form, please contact Charlotte Waggoner at ren@vt.edu or 540-231-5864.

Thank you.

Section III: Individual Information

8. Full Name (Last, First, Middle) 8a. Aliases/Maiden Name:	9. Date of Birth (Month, Date, Year)	10. Social Security Number
11. Residence Address: (No., Street, City, State, Zip Code)		12. Sex ☐ Male ☐ Female
13. Place of Birth (City, State or Foreign Country) *If not born in the United States please complete questions on page 3 titled Foreign Born Information.	14. Race: ☐ Black or African ☐ Asian/ Native Hawaiian or other Pacific Islander	☐ White ☐ Hispanic or Latino ☐ American Indian or Alaska Native
15. Unique Identifier Number (Supplied by APHIS or CDC):		
16. Certifications (All questions must be answered "Yes" or "No" in the box provided) *Title 18 Section 1001 of the U.S. Code provides that knowingly falsifying or concealing a material fact is a felony that may result in fines or imprisonment for not more than 5 years or both.		
16a. Are you under indictment or information in any court for a felony, or any crime, for which the judge could imprison you for more than one year? ☐ Yes ☐ No	16b. Have you been convicted in any court for a crime, for which the judge could have imprisoned you for more than one year, even if you received a shorter sentence including probation? Yes ☐ No	
16c. Are you a fugitive from justice? ☐ Yes ☐ No	16d. Are you an unlawful user of any controlled substance (as defined in Section 102 of the Controlled Substance Act [21 U.S.C. 802])? ☐ Yes ☐ No	
16e. Have you ever been adjudicated as a mental defective or been committed to any mental institution? ☐ Yes ☐ No	16f. Are you an alien illegally or unlawfully in the United States? ☐ Yes ☐ No	
16g. Are you an alien who has been lawfully admitted for permanent residence or a naturalized citizen? If yes, please complete page 3 of the application. ☐ Yes ☐ No	16h. Have you been discharged from the Armed Services of the United States under dishonorable conditions? ☐ Yes ☐ No	
I certify that the above answers are true, correct and complete. I understand that the making of a false oral or written statement is a crime.		
Signature:	Date:	

2 of 6

Foreign Born Information

(This page must be completed by any individual answering "YES" to question 16g of page 2)

1. Country of Citizenship:

2. Mothers's Full Name:

3. Fathers's Full Name:

4. Date of Entry to the United States:

5. Place of Entry:

6. Immigration Status at Entry:

7. Current Immigration Status:

8. Date Status Expires, if Applicable:

9. Alien Number or Admission Number (9-11 digits):

Alien registration numbers are issued by the Bureau of Immigration and Customs Enforcement for individuals who are granted permanent legal resident or a naturalized citizen status in the U.S. Other situations that individuals would have an alien registration number include the following: Employment Authorization cards, Temporary Resident cards, Border Crossing cards, I-94 or Visa numbers. If this number is not available please provide an explanation. If born to US citizen serving a military or diplomatic post in a foreign country please provide a copy of the US born abroad birth certificate

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Section IV: Consent

By signing this form, I hereby authorize the U.S. Department of Justice to obtain any information relevant to assessing my suitability to access, possess, use, receive or transfer select agents and toxins from any relevant source, including, but not limited to, individuals, public sources, and government sources. This information may include, but is not limited to, biographical, financial, law enforcement and intelligence information.

I further authorize any individuals having information pertinent to such an assessment to release such information to a duly accredited representative of the U.S. Department of Justice. The authorization set forth in this paragraph is valid for five (5) years from the date on which this form is signed.

I further authorize the U.S. Department of Justice to disclose any records, results or information relating to, or obtained in connection with, my security risk assessment to: the U.S. Department of Agriculture; the Department of Health and Human Services; any agency contractors assisting in the determination of risk; and responsible officers or other appropriate personnel of pertinent entities.

I further authorize the release of records, results or information relating to, or obtained in connection with my security risk assessment to any law enforcement or intelligence authority or other federal, state or local entity with relevant jurisdiction where such information reveals a risk to human, animal and/or plant health or national security.

I further authorize disclosure of records results or information relating to, or obtained in connection with my security risk assessment to organizations or individuals, both public and private, if deemed necessary, in the sole discretion of the U.S. Department of Justice, to elicit information or cooperation from the recipient for use in assessing my suitability to access, possess, use, receive or transfer select agents and toxins.

I further authorize release of records, results or information relating to, or obtained in connection with my security risk assessment to laboratories, universities, individuals, or other entities, both public and private, responsible for making security assessments, employment and/or licensing determinations and suitability or security decisions when the information is relevant to an assessment of my suitability to access, possess, receive, use, or transfer agents or toxins

I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecution or other legal action.

PRINTED NAME _____ DATE _____

SIGNATURE _____

Virginia Tech
USA PATRIOT ACT COMPLIANCE STATUS

Purpose: All individuals identified as having a legitimate need for access to select agents must not be a "restricted person" as defined in the USA Patriot Act of 2001. A "restricted person" is prohibited from possessing, receiving, shipping, transporting, and accessing select agents at Virginia Tech.

The information provided below will be used by Virginia Tech to document an individual's self-declared compliance status with the Act. This is an interim step while the FBI conducts its security risk assessment for the individual.

Directions: Answer the following questions to determine whether you are considered a "restricted person" under the USA Patriot Act:

		Yes	No
1.	Are you under indictment in any court for a felony, or any crime, for which the judge could imprison you for more than one year?	☐	☐
2.	Have you been convicted in any court for a crime, for which the judge could have imprisoned you for more than one year, even if you received a shorter sentence including probation?	☐	☐
3.	Are you a fugitive from justice?	☐	☐
4.	Are you an unlawful user of any controlled substance?	☐	☐
5.	Have you ever been adjudicated as a mental defective or been committed to any mental institution?	☐	☐
6.	Are you an alien illegally or unlawfully in the United States?	☐	☐
7.	Have you been discharged from the Armed Services of the United States under dishonorable conditions?	☐	☐
8.	Are you an alien who has been lawfully admitted for permanent residence or a naturalized citizen?	☐	☐

If you answered "Yes" to any of the questions #1-7, you are considered a "restricted person" under the USA Patriot Act and are prohibited from possession, receipt, shipment, and transportation of select agents at Virginia Tech. Please contact your Principal Investigator or supervisor and Personnel Services to discuss alternative research/work options.

- I have read and understand the purpose of this questionnaire.
- I understand that if I declare myself a "restricted person" that I am not permitted to possess, receive, transport, ship, or have access to select agents at Virginia Tech.
- I understand that an FBI security risk assessment will be performed which could change my compliance status with the Act and my ability to conduct research/work with select agents.
- I have been given an opportunity to ask questions regarding this document.

I certify that I ☐ am ☐ am not a "restricted person".

Signature:_____ Date:_____

Printed Name:_____

Supervisor/Principal Investigator:_____

Sign and return this document to Charlotte Waggoner, University Biosafety Officer
Mail Code 0423

Virginia Tech EHSS Form (02-2005)
USA Patriot Act Compliance Status

Fingerprint Card Information

Last Name: _____

Height: _____(in feet and inches)

Weight: _____(in pounds)

Hair Color:
- ❑ Blond
- ❑ Brown
- ❑ Black
- ❑ Red
- ❑ Gray
- ❑ Bald
- ❑ Other _____

Eye Color:
- ❑ Blue
- ❑ Black
- ❑ Brown
- ❑ Green
- ❑ Hazel
- ❑ Other _____

Work Address: _____

Work Phone Number: _____

Campus Mail Code: _____

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Appendix C: Security and Incident Response Guidelines

Recognize that laboratory security is related to but different than laboratory safety.

- Involve both safety and security experts in evaluation and development of recommendations for a given facility or laboratory.
- Review safety policies and procedures on a regular basis.
- Management should review policies to ensure that they are adequate for current conditions and consistent with other facility-wide policies and procedures.
- Lab supervisors should ensure all lab workers and visitors understand security requirements and are trained and equipped to follow established procedures.
- Review safety policies and procedures whenever and incident occurs or a new threat is identified.

Control access to areas where biologic agents or toxins are used and stored.

- Laboratories and animal care areas should be separate from the public areas of the buildings in which they are located.
- Laboratory and animal care areas should be locked at all times.
- Card-keys or similar devices should be used to permit entry to laboratory and animal care areas.
- All entries (including those by visitors, maintenance workers, repairmen, and others needing one-time or occasional entry) should be recorded, either by the card-key device (preferable) or by signature in a logbook.
- Only workers required to perform a job should be allowed in laboratory areas, and workers should be allowed only in areas and at hours required to perform their particular job.
- Access for students, visiting scientists, etc., should be limited to hours when regular employees are present.
- Access for routine cleaning, maintenance, and repairs should be limited to hours when regular employees are present.
- Freezers, refrigerators, cabinets, and other containers where stocks of biological agents, hazardous chemicals, or radioactive materials are stored should be locked when they are not in direct view of workers (e.g., when located in unattended storage areas).

Know who is in the laboratory area.

- Facility administrators and lab personnel should know all workers. Depending upon the biological agents involved and the type of work being done, a background check and/or security clearance may be appropriate before new employees are assigned to the laboratory area.
- All workers (including students, visiting scientists, and other short-term workers) should wear visible identification badges. Identification badges should include, at a minimum, a photograph, the wearer's name, and an expiration date. It may be useful to use colored markers or other easily recognizable design symbols on the identification badges to indicate clearance to enter restricted areas (e.g., BSL-3 labs, animal care areas).
- Guests should be issued identification badges, and escorted or cleared for entry using the same procedures as for regular workers.

Know what materials are being brought into the laboratory area.

- All packages should be screened (e.g., visual check) before being brought into the laboratory area.
- Packages containing specimens, bacterial or virus isolates, or toxins should be opened in a safety cabinet or other appropriate containment device.

Know what materials are being removed from the laboratory area.

- Biological materials/toxins for shipment to other laboratories should be packaged and labeled in conformance with all applicable local, federal, and international shipping regulations.
- Required permits (e.g., PHS, DOT, DOC, USDA) should be in hand before materials are prepared for shipment.
- The sender should know the recipient or receiving facility, and the sender should make an effort to ensure that materials are shipped to a facility equipped to handle those materials safely.
- Hand-carrying of microbiological materials and toxins to other facilities is rarely appropriate. If biological materials or toxins are to be hand carried on common carriers, all applicable regulations must be followed.
- Contaminated or possibly contaminated materials should be decontaminated before they leave the laboratory area. Chemicals and radioactive materials should be disposed of in accordance with local, state, and federal regulations.

Have an emergency plan.

- Control of access to laboratory areas can make an emergency response more difficult. This must be considered when emergency plans are developed.
- An evaluation of the laboratory area by appropriate facility personnel, with outside experts if necessary, to identify both safety and security concerns should be conducted before an emergency plan is developed.
- Facility administrators, lab directors, principal investigators, lab workers, safety personnel, and facility security officials should be involved in emergency planning.
- Police, fire, and other emergency responders should be informed as to the types of biological materials in use in the laboratory areas, and assisted in planning their responses to emergencies in the laboratory areas.
- Plans should include provision for immediate notification of (and response by) laboratory directors, laboratory workers, safety personnel, or other knowledgeable individuals when an emergency occurs, so they can deal with biosafety issues if they occur.
- Laboratory emergency planning should be coordinated with facility-wide plans. Such factors as bomb threats, severe weather, earthquakes, power outages, and other disasters should be considered when developing laboratory emergency plans.

Have a protocol for reporting incidents.

- Lab directors, in co-operation with safety and security officials, should have policies and procedures in place for reporting and investigation of incidents or possible incidents (e.g., undocumented visitors, missing chemicals, unusual or threatening phone calls).

Appendix D: Inventory Acquisition Log

VirginiaTech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Select Agent and Toxin Inventory Acquisition Log

This is to certify that the record has been filled as of _____ (mm/dd/yy).

_____
Signature

Building, Room Number, and Storage Location: _____

Directions: Using a pen, LEGIBLY write in the information below for new select agent or toxin added to long-term storage (i.e., a system designed to ensure viability for future use, such as a freezer or lyophilized materials). You may use an initial for your first name, but you must write out your last name. For organisms, quantities should be indicated by the number of containers, vials, or tubes. For toxins, quantities should be indicated in specific units of weight or volume (e.g., mg, g, ml, etc.).

Select Agent or Toxin (name and characteristics such as strain designation or GenBank Accession number)	Date Acquired (mm/dd/yy)	Quantity Acquired	Source	Name of Individual Adding to Inventory

Once filled, a copy of this form must be maintained in a secure location and presented for validation upon request.

Record Verification:

Date: (mm/dd/yy)	Designated Individual (Signature)	Date: (mm/dd/yy)	Designated Individual (Signature)

Virginia Tech EHSS Form (6-2005)
Select Agent and Toxin Inventory Acquisition Log

Appendix E: Inventory Access Log

VirginiaTech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Select Agent and Toxin Inventory Access Log

This is to certify that the record has been filled as of _____ (mm/dd/yy).

_____
Signature

Building, Room Number, and Storage Location: _____

Directions: Using a pen, LEGILBLY write in the information below for EACH access to a select agent or toxin held in long-term storage (i.e., a system designed to ensure viability for future use, such as a freezer or lyophilized materials). You may use an initial for your first name, but you must write out your last name.

Select Agent or Toxin (name and characteristics such as strain designation or GenBank Accession number)	Date Removed from Storage (mm/dd/yy)	Quantity Removed (toxins only)	Date Returned to Storage (mm/dd/yy)	Quantity Returned (toxins only)	Purpose of Use	Name of Individual Accessing Inventory

A copy of this form must be maintained in a secure location and presented for validation upon request.

Record Verification:

Date: (mm/dd/yy)	Designated Individual (Signature)	Date: (mm/dd/yy)	Designated Individual (Signature)

Virginia Tech EHSS Form (6-2005)
Select Agent and Toxin Inventory Access Log

Appendix F: Entry/Exit Log

VirginiaTech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Select Agent Use or Storage Area
Entry/Exit Log

Building and Room Number: _____

Directions: Using a pen, LEGILBLY write in the information below for EACH entry into the select agent area. You may use an initial for your first name, but you must write out your last name. If the person is a visitor, indicate this by putting a "V" in the appropriate box. The visitor's escort must be indicated by putting an "E" in the appropriate box next to his/her name. Approved individuals should leave this box blank. All visitors must receive training on biosafety and security requirements of this area and documentation must be maintained.

Once filled, a designated person authorized to verify records must sign off that the record is complete.

Date (mm/dd/yy)	Name	Visitor = V Escort = E	Time of Entry	Expected Time of Exit	Actual Time of Exit	Comments
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	
			am pm	am pm	am pm	

A copy of this form must be maintained in a secure location and presented for validation upon request.

Record Verification:

Date: (mm/dd/yy)	Designated Individual (Signature)

This is to certify that the record has been filled as of _____ (mm/dd/yy).

Signature

Virginia Tech EHSS Form (6-2005)
Select Agent Use/Storage Area Entry/Exit Log

Appendix G: Approved Individual Training Record

Date: _____

Time: _____

Initial ☐ Refresher ☐

Instructor: _____

VirginiaTech
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Select Agent and Toxin Program
Record of Training

Name: _____

Job Title: _____

Supervisor/Lab: _____

Department: _____ **Mail Code:** _____

Email Address: _____ **Phone:** _____

Training Topics:
- Program and Regulatory Overview
- Responsible Parties
- Select Agent and Toxins List (Regulated and Exempt)
- Registration and Inspections
- Safety Requirements
- Security Requirements
- Incident Response
- Transfers
- Training
- Recordkeeping

Method Used to Verify Understanding of Material: (check all that apply)
- ☐ Question and Answer
- ☐ Written Test
- ☐ Hands-on exercises

This is to certify that I have completed the above training, understand the requirements, and will follow all established procedures for working with select agents and toxins.

_____ _____
Employee Signature Date

_____ _____
Instructor Signature Date

A copy of this record must be maintained with the individual's other training records for at least three years after the date of training. This record must be made available upon request for verification.

Virginia Tech EHSS Form (6-2005)
Select Agent and Toxin Program Record of Training

Appendix H: Non-approved Individual Training Record

Appendix I: Checklist for Compliance

Facility, Agent, and Personnel Registration

Inspection Item	N/A	YES	NO
An application form has been completed and submitted to the UBO.			
If using an agent, the exemptions list has been checked online.			
If using toxins, the toxin quantity exemptions have been checked online.			
A list of all individuals requiring access to select agents and toxins has been given to the UBO (this includes laboratory and animal care staff).			
The application is submitted at least 12 weeks prior to any anticipated possession, use, or transfer of select agent or toxin.			
A preliminary inspection has been conducted by the UBO to verify information provided on the application form before submission to the CDC/APHIS for review.			

Biosafety

Inspection Item	N/A	YES	NO
If using biological select agents, the work being conducted complies with the requirements listed in Virginia Tech's *Biosafety for Laboratory Workers*: o Completion of a risk assessment o Development of a biosafety manual o Proper use of signs and labeling o Medical surveillance program is in place o Training of lab and animal staff o Availability and required use of engineering controls o Availability and required use of personal protective equipment o Work practices o Decontamination procedures development o Accidents, spills, and emergency reporting o Waste management procedures o Transportation and transfer of biological agents			
If using biological select agents, the work being conducted complies with the appropriate biosafety level requirements listed in the CDC/NIH *Biosafety for Microbiological and Biomedical Laboratories.*			
If using biological toxins, the work being conducted complies with the requirements of the Virginia Tech *Chemical Hygiene Plan* and the *Guidelines for Work with Toxins of Biological Origin* (Appendix I in the BMBL).			
If working with recombinant DNA, the work complies with the requirements listed in the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*			

Inspection Item	N/A	YES	NO
If animals are used, all work complies with the requirements: o of the appropriate animal biosafety level listed in the CDC/NIH *Biosafety for Microbiological and Biomedical Laboratories*, o listed in *Guidelines for Work with Toxins of Biological Origin* (in the BMBL), o specified in the *Guide for the Care and Use of Laboratory Animals*, and o *NIH Guidelines for Research Involving Recombinant DNA Molecules*			
The Principal Investigator has developed lab specific procedures and safety precautions to address all requirements.			
The Principal Investigator and the animal care supervisor have developed animal handling procedures and safety precautions.			

Security and Incident Response

Inspection Item	N/A	YES	NO
A security risk assessment has been conducted and documented.			
A written security plan has been developed that, at a minimum, adopts the university security requirements.			
The written security plan is annually reviewed by the UBO and lab supervisor(s).			
An inventory of each select agent and toxin in our possession has been conducted.			
A log of access of select agents and toxins from storage is maintained.			
An entry record is maintained for each lab and animal room containing select agents and toxins			
Each individual requiring access has submitted a Virginia Tech Patriot Act Compliance Form and an FBI 961 Form to the UBO.			
Each individual requiring access has been fingerprinted.			
Each individual requiring access has been officially notified by the UBO that they are approved to access select agents and toxins.			
All visitors to areas where select agents and toxins are located are escorted and logged in the entry record.			
Select agents are stored and used in areas separate from public use and access.			
All doors to labs and animal rooms are lockable.			
All doors to labs and animal rooms remain locked except when entering or exiting.			
A key distribution record is maintained.			
Quarterly visual key checks are conducted and documented.			
No sharing of keys is permitted.			
Containers used to store select agents and toxins remain locked when not in the direct view of an approved individual.			
All unexpected or suspicious packages are inspected before they are brought into a secure area.			
Suspicious activities or persons are immediately reported to the Virginia Tech Police.			
A system for notification of loss, theft, or release is implemented.			

All information (paper and computer) related to select agents and toxins is maintained in a secure manner and only accessed by approved individuals.			

Incident Response

Inspection Item	N/A	YES	NO
All emergencies are immediately reported to the Virginia Tech Police.			
All emergency incidents are reported to the UBO within 24 hours of the incident.			
Each entry into a secure area must list emergency contact information.			
An emergency response plan has been developed for plausible events.			
A backup location for storage of cultures and animals has been identified.			
An annual mock drill or exercise is conducted.			
An annual information and training session is coordinated for the local emergency response groups.			
Emergency response procedures are reviewed annually by the UBO.			

Transfers

Inspection Item	N/A	YES	NO
For each transfer, a Form 2 is completed.			
Deliveries to Virginia Tech are processed by the UBO and then delivered to an approved individual.			
Import permits are obtained as required.			
Export permits are obtained as required.			
Transfer of select agents and toxins is made by registered mail or other system that allows for tracking.			
All individuals responsible for packaging and shipping infectious agents and toxins have been trained.			

Training

Inspection Item	N/A	YES	NO
All approved individuals are trained upon assignment and annually thereafter.			
Non-approved individuals entering secure areas are informed of the hazards and security requirements. Documentation is maintained.			

Records

Inspection Item	N/A	YES	NO
All documentation related to the possession and use of select agents and toxins is maintained for at least three years. This includes: o Training records o Entry and access records o Risk assessments o Key distribution logs and any rekeying information o All written procedures and protocols o Security, safety, and incident response plans o List of approved individuals o Application forms and information			
A copy of all pertinent university programs is readily available in the secure area(s) and work-specific information is included: o *Chemical Hygiene Plan* o *Biosafety for Laboratory Workers* o *Exposure Control Plan*			
A copy of the following is available in the secure areas*:* o *Biosafety for Microbiological and Biomedical Laboratories* o *NIH Guidelines for Research Involving Recombinant DNA Molecules* o *Guide for the Care and Use of Laboratory Animals*			
An annual review of all SOPs and written operations manuals and plans is performed by the principal investigator, lab director, animal care supervisor, and UBO			