

SELECT AGENT POLICY

1.0 PURPOSE

- 1.1 To provide a safety and security policy for CDC/USDA-defined Select Agents in research, teaching, and clinical environments at the University of Illinois at Chicago.
- 1.2 To ensure UIC entity compliance with all local, state and federal regulations for the possession, use, transfer, and destruction of Select Agents.

2.0 SCOPE

- 2.1 This policy applies to all University of Illinois at Chicago faculty, staff, hosted visitors, students, visiting researchers, volunteers, outside contractors and laborers working at UIC sites, and employees of firms working at UIC facilities.

3.0 REFERENCES

- 3.1 7 Code of Federal Regulations Part 331, Possession of Select Agents
- 3.2 9 Code of Federal Regulations Part 121, Agricultural Bioterrorism Protection Act of 2002; Possession Use and Transfer of Select Agents and Toxins.
- 3.3 42 Code of Federal Regulations Part 73: Possession Use and Transfer of Select Agents and Toxins
- 3.4 49 Code of Federal Regulations Part 72: Interstate Shipment of Etiological Agents
- 3.5 CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 4th Edition (May 1999)
- 3.6 US Public Law 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- 3.7 University of Illinois at Chicago, Environmental Health and Safety Office *Biohazard Safety Program Manual 2003*

- 3.8 CDC/USDA *Guidance Document For Application for Laboratory Registration for Possession, Use and Transfer of Select Biological Agents and Toxins*, MB No. 0920-0576, OMB No. 0579-0213
- 3.9 Bioterrorism Preparedness and Response Act FBIO Information Form FD-961
- 3.10 CDC Select Agent Program *FAQ for New Regulation* at <http://www.cdc.gov/od/sap/faq.htm>.
- 3.11 *Morbidity and Mortality Weekly Report*, “Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents.” December 6, 2002/ Vol. 5, No. RR-19.
- 3.12 Public Law 107-56, USA Patriot Act
- 3.13 29 Code of Federal Regulations 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories.

4.0 DEFINITIONS

- 4.1 **Biohazardous material** - Any material containing biohazardous organisms in sufficient quantity that if exposed to this material, a susceptible host may become infected or can have an adverse reaction.
- 4.2 **Biohazardous organism** - Includes all bacteria, fungus, parasites, rickettsia, virus, and prions that exhibit sufficient virulence and quantity to cause an adverse reaction or infection in a susceptible host, human or animal.
- 4.3 **Biohazardous waste** - Any waste material that has come in contact with human blood, other body fluids such as saliva, vaginal secretions, cerebrospinal, synovial, pleural, amniotic, and peritoneal fluids; this is also inclusive of any other body fluids, excretions, secretions, unfixed tissue or organs, skin from living or dead humans, cell or tissue cultures, organ cultures, culture medium or similar solutions, blood, organs and tissue from experimental animals infected with any human pathogen.
- 4.4 **Biological Product** - A product prepared in accordance with regulations that govern the manufacture of vaccines, reagents, etc.
- 4.5 **Biosafety Cabinet (BSC)** - A device enclosed (except for necessary exhaust purposes) on three sides, top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used.

- 4.6 **Biosafety Level** - A safety categorization defined in the BMBL, used in biological research, teaching, and production assigning microorganisms into one of four safety category levels according to risk. Each level designates laboratory practices, techniques, safety equipment, and lab facilities required to work with a specific microorganisms.
- 4.7 **Biosafety Officer** - A UIC EHSO staff person responsible for the Biohazard Safety Program at UIC. This individual has biosafety expertise and experience to oversee and address all biosafety issues and technical questions.
- 4.8 **Cell Cultures** - Human or animal cells propagated out of an organism.
- 4.9 **Containment** - A method for safely confining and controlling infectious agents, and the material containing them.
- 4.10 **Decontamination** - A process or treatment from sterilization to simple cleaning with soap and water that renders a medical device, instrument, or environmental surface noninfectious.
- 4.11 **Diagnostic Specimens** - Any human or animal material including but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids, which the shipper reasonably believes may contain an etiologic agent and that is being shipped for purposes of diagnosis.
- 4.12 **Disinfection** - A form of decontamination on inanimate objects (work surfaces, equipment, etc.), that reduces pathogenic non-sporeforming microorganisms, but not all microbes, to a level where a susceptible host will not be infected
- 4.13 **Gene Therapy** - The delivery of exogenous DNA to mammalian cells to cause the expression of this material thereby altering the cells phenotype.
- 4.14 **Institutional Biosafety Committee (IBC)** - A committee that reviews and approves/denies recombinant DNA activities.
- 4.15 **Institutional Review Board (IRB)** – an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. An IRB has the authority to approve, require modifications in (to secure approval), or disapprove research, and serves an important role in the protection of the rights and welfare of human research subjects.
- 4.16 **Knockout** - The deletion of the phenotypes rendered by the inactivation (gene knockout) of various physiologic molecules, which are normally presented. These unexpressed phenotypes are then bred into animals, to be utilized for research.

- 4.17 **Principal Investigator (PI)** - A faculty member or guest member, who is assigned laboratory space in order to conduct research.
- 4.18 **Recombinant DNA**- Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from replication of those synthetic DNA molecules.
- 4.19 **Responsible Official/Alternate Responsible Official (RO/ARO)** – Individuals designated by the UIC Vice Chancellor for Administration to have the authority and be responsible for ensuring UIC compliance with the Select Agent Title 42 CFR Part 73 regulations.
- 4.20 **Risk Group** - The safety level to which an organism is assigned, from 1 through 4, and corresponding to the number of the Biosafety level.
- 4.21 **Select Agents** - Specifically regulated pathogens and toxins as defined in Title 42, CFR, Part 73, including pathogens and toxins regulated by both DHHS CDC and USDA (i.e., overlapping agents or toxins).
- 4.22 **Select Agent Biosafety** - Can be any one of the four levels, but typically requires BSL-3 or BSL-4 due to the infectious nature of the materials.
- 4.23 **Select Agent 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.
- 4.24 **Threat** - The capability of an adversary, coupled with intentions, to undertake malevolent actions.
- 4.25 **Threat assessment** - A judgment, based on available information, of the actual or potential threat of malevolent action.
- 4.26 **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.
- 4.27 **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.

5.0 PROCEDURE

- 5.1 Select Agent Registration - No Select Agent/Toxin may be obtained, transferred, destroyed or used, without consultation with the EHS Office and Responsible Official/ARO for registration and reporting.
 - 5.1.1 See <http://www.cdc.gov/od/sap> and <http://www.aphis.usda.gov/vs/ncie> for the most recent list of Select Agents and Toxins.
 - 5.1.2 Some conditions do not require SA registration with the CDC or USDA. When the PI controlled inventory of regulated toxins is below the legal government registration quantity, no government notification of possession, or FBI security check of PI and staff is necessary. The RO/ARO can identify the quantity for the specific toxin involved. This does not exclude the PI from maintaining a Select Agent inventory for EHSO tracking.
 - 5.1.3 If the organism is a select agent, but is of a strain deemed non-reportable by the CDC or USDA, no government notification of possession, or FBI security check of PI and staff is necessary. The RO/ARO can identify the strain for the specific agent involved. These are called “Exclusions”.
 - 5.1.4 CDC Form 0.1319/APHIS Form 2044 Application for Laboratory Registration for Possession, Use, and Transfer of Select Biological Agents and Toxins must be completed under the guidance of the RO/ARO as an amendment to the UIC entity registration with CDC/USDA.
 - 5.1.5 CDC Form 0.1317/APHIS Form 2042 Request for Exemption of Select Biological Agents and Toxins may be completed and submitted for these agents if they are being used for investigational purposes with justification indicating that the agent would not be capable of jeopardizing safety or public health. This should not be confused with Exclusions, which are attenuated agents excluded by CDC/APHIS from registration due to their strain etc. as above.
 - 5.1.6 The Laboratory Director must inform the RO/ARO when a Select Agent/Toxin is isolated at the facility and assist in completion of CDC Form 0.1318/APHIS Form 2040 Report of the Identification of a Select Biological Agent or Toxin in a Clinical or Diagnostic Laboratory.
 - 5.1.7 Botulinum neurotoxin is only considered a select toxin under the Select Agent regulations when the amount under the control of a physician exceeds 0.5 mg. Additionally, all dermatology clinics using FDA-approved botulinum toxin preparations in accordance with labeling instructions are excluded from the requirements to register under the Select Agent regulations and DO NOT need to submit a letter to CDC or USDA to declare exemption from registration with the Select Agent Program.

- 5.2 A multi-disciplinary risk assessment and threat analysis of lab and work procedures must be performed initially, reviewed yearly, and updated with any change in protocol or procedure.
 - 5.2.1 Multidisciplinary team members at UIC are the EHSO Biosafety Officer, the EHSO Industrial Hygienist, the UIC Police, the PI, facilities management, information technology staff, scientific staff and others as appropriate.
 - 5.2.2 The risk assessment and threat analysis is defined against the vulnerabilities of the specific laboratory to determine the necessary components of a facility security plan and system and a facility safety plan.
 - 5.2.3 The UIC EHSO Select Agent Program Laboratory Security Plan and UIC EHSO Select Agent Program Laboratory Safety Risk Assessment checklists are recommended for use in these assessments.
- 5.3 Security Plans and Policies must be established.
 - 5.3.1 Each specific laboratory must have an initial and annually-reviewed comprehensive security plan the covers physical security, data and IT system security, personnel policies, access control, SA accountability, SA handling, emergency plans and reporting mechanisms.
 - 5.3.2 The security plan must be periodically tested for effective performance, ranging from checks of keys, locks and alarms to a full-scale laboratory exercise.
 - 5.3.3 Security clearances that include FBI background investigations and fingerprint records are required for all personnel planned to have access to Select Agents.
 - 5.3.3.1 The RO/ARO provides the permission to release information forms FD 961 Bioterrorism Preparedness and Response Act FBI Information Form to each individual and submits these to the FBI.
 - 5.3.3.2 The RO/ARO provides FBI fingerprint forms to a licensed police agency such as the UIC Police for proper fingerprinting of each individual. The agency sends the completed fingerprint forms to the FBI.
 - 5.3.3.3 The RO/ARO receives notification of security clearance approval/denial and notifies the PI/Supervisor.

- 5.3.3.4 Persons refusing to sign permission for release of information or to submit to fingerprinting shall be denied access at all times to any Select Agent/Toxin and sensitive data.
- 5.3.3.5 Persons entering Select Agent areas who do not have clearance must be escorted and monitored by authorized personnel.
- 5.3.4 All persons approved for access to Select Agents/Toxins must wear visible identification badges that include a photograph, name and expiration date. Escorted visitors must also have identification badges, but without the photograph.
- 5.3.5 Procedures must be in place for reporting and removing unauthorized persons.
- 5.3.6 Security plans must include control of data access, such as files, notes, computers and servers.
- 5.4 All areas where Select Agents are in use or stored must have controlled access and monitoring.
 - 5.4.1 Methods may include key or electronic locking pass keys, key pad combinations, lock-boxes, and video surveillance cameras.
 - 5.4.2 The UIC Police should be consulted for security device recommendations.
 - 5.4.3 Select Agents/Toxins not in direct view of an approved laboratory worker must be kept locked in their freezers, cabinets or other storage containers.
 - 5.4.4 All Select Agent/Toxins areas must have all entries recorded for visitors, maintenance workers, and others needing one-time or occasional entry.
 - 5.4.5 Escort procedures and training must be provided for routine cleaning, maintenance, contractor work and repairs.
 - 5.4.5 Select Agents/Toxins must not be stored in a common freezer or refrigerator in a communal storage area or in a common equipment room
- 5.5 A system of Select Agent/Toxin accountability must be established.
 - 5.5.1 An inventory log of Select Agents must maintained under the authority and accountability of the PI/Supervisor. This log is required for quantification of toxins or strains of viable organisms.
 - 5.5.2 The PI/Supervisor is required to inform the RO/ARO or Biosafety Officer of the Select Agent/Toxin inventory at the 10th of each month.

- 5.5.3 The EHSO shall maintain a secure database with monthly updates of Select Agent project status and inventories.
- 5.5.4 In the event a quantity of designated toxin reaches the predetermined volume requiring registration, the transfer of additional toxin shall be denied by the RO/ARO until the registration forms and process are completed.
- 5.5.5 Under no circumstances may a Select Agent/Toxin be destroyed by the PI/Supervisor. Discontinuing the use of an agent shall be reported to the RO/ARO for CDC notification and permission for destruction.
- 5.5.6 Select Agent/Toxin destruction shall be performed by the EHSO after CDC/USDA approval and in accordance with a chain-of-custody witnessed protocol.
- 5.5.7 Written procedures must be in place in the event of theft, loss or release of the SA to notify the RO or a RO, UIC Biosafety Officer, and UIC Police immediately.
- 5.5.8 Select Agent/Toxin transfer, consumption and receipt must be recorded immediately in the laboratory inventory log.
- 5.5.9 Required permits and manifests for shipped and received agents must be retained for inspection e.g., granted by the U.S. Public Health Service, USDA, DOT, U.S. Department of Commerce, and IATA.
- 5.6 Select Agent/Toxin Shipping, Receiving and Transfer procedures must be followed.
 - 5.6.1 Purchase or transfer of agents must be requested using an APHIS Form 2041 Report of Transfer of Select Biological Agents and Toxins/CDC EA-101 Transfer of Select Agent that is approved and signed by the RO/ARO.
 - 5.6.2 All incoming Select Agents/Toxins must be shipped to the UIC central receiving area address at: _____
 - 5.6.3 Cleared and trained UIC receiving personnel shall deliver all incoming Select Agents/Toxins to the EHSO centralized agent receiving area to maximize safety and minimize security hazards associated with damaged or unknown packages.
 - 5.6.4 Following EHSO inspection and approval, the PI/Supervisor shall be notified of arrival followed by EHSO delivery of the package to an authorized laboratory worker and a signed receipt.

- 5.6.5 All transfers of Select Agents/Toxins internal to UIC or external must have the signed approval of the RO/ARO prior to any transfer.
- 5.6.6 The shipping RO/ARO and receiving RO/ARO control the transfer of all Select Agent requests to include reports to CDC/USDA.
- 5.6.7 All researchers receiving SA materials must be notified in writing of the risks associated with these materials and the safety practices needed to handle them.
- 5.7 Additional approvals may be required before a Select Agent/Toxin can be used.
- 5.7.1 If research encompasses Select Agent recombinant DNA manipulation, protocols must be submitted to and approved by the Institutional Biosafety Committee and UIC Biosafety Officer.
- 5.7.2 If Select Agent research involves animals, the protocol must be submitted to and approved by the Animal Care Committee and UIC Biosafety Officer.
- 5.7.3 If Select Agent research involves human trials, then a protocol must be submitted to and approved by the IRB and UIC Biosafety Officer.
- 5.8 Each laboratory conducting Select Agent/toxin work must have written laboratory-specific biosafety practices and procedures.
- 5.8.1 These must be completed prior to commencement of work.
- 5.8.2 They must contain practices and procedures set forth in the UIC Biosafety Program Manual modified into the laboratory-specific, agent-specific practices and procedures.
- 5.8.3 They must include a written protocol response to adverse incident reporting such as spills, needle sticks, or other mishaps.
- 5.8.4 They must include an emergency response plan with:
- A notification list with names and phone/pager numbers
 - Supervisors First Report of Accidental Injury and Illness
 - Biosafety Level 3 Spill Protocol
 - Procedure for theft, loss or release of the SA/toxins.
 - Electrical blackout procedure
 - Lab fire procedure
 - Tornado, earthquake, or other disasters

- Reporting procedure to include the RO (Alternate RO), and Biosafety Officer
- 5.8.5 The RO/ARO and the Biosafety Officer must be notified immediately, if any significant problems, violations of SA biosafety practice, releases, spills or other laboratory accidents with potential SA biohazard exposure occurred.
 - 5.8.6 Workers are required to observe and monitor the work practices and procedures of others in the laboratory with any action considered to be a protocol violation reported to the lab manager or PI.
 - 5.8.7 If a serious failure to follow the UIC Biosafety Manual guidelines occurs, placing persons at risk, the incident must be reported to the PI or the UIC Biosafety Officer.
 - 5.8.8 The EHSO must orient the Chicago Fire Department and other external emergency response agencies to these emergency plans and procedures.
 - 5.8.9 The PI must ensure that the emergency phone numbers for key authorized persons are posted on the outside of the facility door in accordance with UIC laboratory signage requirements.
 - 5.8.10 The EHSO is responsible for verifying that the RO or ARO has notified DHHS/CDC or APHIS using CDC Form 0.1316/APHIS Form 2043 Report of Theft, Loss, or Release of Select Biological Agents and Toxins, if select agents/toxins are found missing, release outside of the laboratory, involved in exposures, or misused, and that the appropriate state and local public health authorities have been advised.
- 5.9 Occupational Health Surveillance must be provided for all persons who perform SA work.
 - 5.9.1 Each person must be offered serologic testing when they begin work and at least once a year thereafter.
 - 5.9.2 The UIC Biosafety Officer, RO(ARO) and University Health Services must be notified immediately, if a person is known to or suspected of having acquired an infection resulting from work in or around the laboratory.
 - 5.9.3 It is the responsibility of the PI to screen the health status of visitors/workers for increased risk of acquiring infection or for whom exposure and resulting infection might be unusually hazardous e.g., immuno-compromised persons, pregnancy prior to entry of the lab.

- 5.9.4 Hepatitis B vaccinations must be offered by the department to all PI's and all employees working with primary human or primate tissue and tissue cultures.
- 5.10 All persons with access to Select Agents must receive training on the laboratory security and the Select Agent organisms or toxins in use.
 - 5.10.1 Training must include :
 - Biosafety or other health and safety policies
 - Practices and procedures to be followed for this research
 - Laboratory-specific security procedures and requirements
 - Design features that make up the secondary SA Biohazard containment.
 - Certificate for the trainee
 - A written lesson plan
 - A signed attendance sheet
 - A participant signed agreement to comply
 - 5.10.2 Each person must be trained prior to beginning work, when a procedure or policy changes, and yearly thereafter.
 - 5.10.3 Training content must be reviewed and approved by the UIC Biosafety Officer and RO/ARO.
 - 5.10.4 Periodic performance security testing of keys, locks, alarms, and evacuation exercises with date, description and participant signatures logged must be done.
 - 5.10.5 Visitors and maintenance personnel are to be advised of the potential risks, required practices, and procedures that they must follow as well as instructed about the signs and symptoms of infection or exposure conveyed through written material or as a computerized presentation.
 - 5.10.6 When working with human blood, blood products, body fluids, tissue, and tissue cultures, employees and PI's must attend yearly Bloodborne Pathogen training, provided by EHSO or an EHSO approved trainer.
- 5.11 Any item removed from the SA laboratory but not considered to be hazardous waste must be decontaminated before removal.
 - 5.11.1 Items may be wiped down with a disinfectant or sealed in a bag and autoclaved.
 - 5.11.2 Each person will decontaminate his/her own work surfaces (e.g., benches, sinks, doors, handles, etc.) immediately after each use and immediately after any contamination with viable material.

- 5.11.3 The floors must be clean and in good repair, cleaned at least weekly under supervision and immediately after contamination with any viable material.
- 5.11.4 The autoclave must be close to the SA investigational lab (within 100 ft for BSL 2 and in the ante room for BSL 3 and 4).
- 5.11.5 All waste from a viable organism (infectious, trash, etc.) SA lab facility must be autoclaved by the end of each day and before it leaves the building.
- 5.11.5 All waste from a toxin SA lab facility must be treated with an equal quantity of a mixture that contains 2.5% NaOCl and 0.25 M NaOH. This treatment should last 4 hours. After the 4 hours, test the pH and adjust the pH to 7.0 with 0.1M HCl. After final pH adjustment, the mixture can be poured down the drain and recorded on the inventory log. (Toxins and Select Agents may not be discarded or destroyed in this fashion until CDC/USDA approval is received and the EHSO chain of custody destruction protocol is activated.)
- 5.11.6 Each laboratory must post clear instructions on how SA waste will be handled.
- 5.11.7 Cleaning and maintenance are to be supervised by authorized personnel and performed only during normal work hours.
- 5.12 The laboratory facility must meet all physical requirements listed in the BMBL in accordance with the Biosafety Level (1-4) appropriate for the Select Agent/Toxin to be used.
 - 5.12.2 The physical components of the laboratory facility, such as ventilation, filtration, sanitation, and security devices are to be maintained in proper working order.
 - 5.12.3 If the ventilation system or other physical containment component of the laboratory fails, work in the SA lab facility must be halted. Facilities Management and the UIC Biosafety Officer must be contacted to help determine corrective actions.
 - 5.12.4 At the time the SA facility must be closed for maintenance, repair or decommissioning, a laboratory clearance inspection must be performed by the UIC Biosafety Officer before the work may commence or a new occupant is installed.
 - 5.12.5 Routine maintenance of the SA lab that affects ventilation or containment must be scheduled with EHSO at least two weeks in advance.

- 5.12.6 Weekly tests must be performed by laboratory personnel to verify the required negative pressure for each room in the SA facility. (This test can be performed using a strip of tissue held in the opening of door held slightly ajar). All readings must be logged and kept on file to show that this test is being performed.
- 5.12.7 Special containment systems such as an exhaust HEPA filtration system must be tested and certified to meet National Sanitation Foundation Standard 49 no less than annually.
- 5.12.8 The PI must keep a log of all maintenance conducted by non-laboratory staff when the SA lab facility has NOT been closed for maintenance.

The log must record:

- type of work/maintenance completed (with enough detail so those unfamiliar with the work can reconstruct the sequence of work/maintenance events),
- date of entry and names of workers,
- start time,
- completion time,
- disinfection technique for contaminated tools,
- special personal protective equipment required to protect the workers (e.g., boots, heavy gloves, face shield etc.),
- work order number, and
- mode of disinfection or other steps taken to protect maintenance workers.

5.12.9 Select Agent/Toxin laboratory areas must be separate from public areas of the building.

5.13 Personal Protective equipment must be endorsed by the Environmental Health and Safety Office (EHSO).

5.13.1 All persons who enter the SA laboratory must wear all required personal protective equipment identified for that specific facility. This can include:

- wraparound gown
- gloves
- eye protection
- shoe covers
- head covers
- sleeve protectors
- face shields

- respirators - such as N-95's, Powered Air Purifying Respirators, full face respirators, air-pressurized suits with air-line supplied air.

5.13.2 *All respirators must be fit-tested by EHSO personnel prior to use.*

5.13.3 *Respirator users must have a medical review and approval from UHS prior to the fit-testing and wearing of the equipment.*

5.13.4 The staff must receive documented training in the use of the PPE supplied

5.13.5 Whenever potentially infected animals or tissues are in the SA laboratory and not contained in biosafety cabinets, all persons must be provided with (and required to wear) a HEPA-filtered respirator or pressurized suits.

5.13.6 No person shall leave the SA laboratory, while wearing clothing designated for wear inside the facility.

5.13.7 Distinctive protective clothing (clearly different from protective clothing used in nearby areas) shall be provided to the laboratory staff for their use inside the facility.

5.13.8 Many Select Agent toxins are not listed for glove compatibility. In the case of no attainable information, utilize the assumption that most of the biotoxins are large molecular weight chemicals capable of being metabolized by human cells, and should not be volatile, are water soluble, and none have solvent characteristics.

5.13.9 Latex or nitrile materials should not be affected by SA toxins and solvent resistant gloves are not needed, but gloves should be impervious to the toxin and medium in which the toxin is contained.

5.13.10 When working with a dry form of toxin, Anti-Static gloves need to be worn.

5.14 All manipulations of viable SA's are to be performed in a biosafety cabinet. All manipulations of nonviable Select Agents/Toxins are to be performed in a fume hood or Class II B 1 or 2 biosafety cabinet.

5.14 Precautions - Cell cultures, human tissue cultures, recombinant DNA, transgenics, and gene therapy shall have the following precautions observed:

5.14.1 All human and primate established or primary cell lines, blood, blood products, body fluids, tissues, and tissue cultures are considered biohazardous. Work on these specimens are considered as risk group 2 (Appendix A) and carried out in BSL - 2 laboratories (Appendix B).

5.14.2 If a cell culture contains a known etiological agent, oncogenic virus, or amphotropic packaging system, containment must be the same as recommended for that agent.

5.14.3 BSL 2 or greater is necessary for the following cell lines:

- Cell lines derived from lymphoid tissues
- All mycoplasma containing cell lines

5.14.4 No one shall work with cells derived from themselves, or from a first degree relative, due to the possibility that a host immune system may not provide adequate protection, if challenged by a pathogen or vector involved in research of these cells.

6.0 DOCUMENTATION

6.1 CDC Form 0.1319/APHIS Form 2044 Application for Laboratory Registration for Possession, Use, and Transfer of Select Biological Agents and Toxins.

6.2 CDC Form 0.1317/APHIS Form 2042 Request for Exemption of Select Biological Agents and Toxins

6.3 CDC Form 0.1316/APHIS Form 2043 Report of Theft, Loss, or Release of Select Biological Agents and Toxins

6.4 CDC Form 0.1318/APHIS Form 2040 Report of the Identification of a Select Biological Agent or Toxin in a Clinical or Diagnostic Laboratory.

6.5 APHIS Form 2041 Report of Transfer of Select Biological Agents and Toxins.

6.6 CDC EA-101 Transfer of Select Agent

6.7 UIC EHSO Select Agent Program Laboratory Security Plan

6.8 UIC EHSO Select Agent Program Laboratory Safety Risk Assessment

6.9 UIC EHSO Biological Agent Chain of Custody/Destruction Record

6.10 FD 961 Bioterrorism Preparedness and Response Act FBI Information Form

7.0 RESPONSIBILITIES

7.1 The Responsible Official/Alternate Responsible Official

7.1.1 Developing and implementing safety, security and emergency response

plans in accordance with § 73.10—§ 73.12;

- 7.1.2 Allowing only approved individuals to have access to select agents or toxins in accordance with § 73.8 and § 73.11;
- 7.1.3 Providing appropriate training for safety, security and emergency response in accordance with § 73.13;
- 7.1.4 Transferring select agents or toxins in accordance with § 73.14;
- 7.1.5 Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with § 73.13;
- 7.1.6 Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with § 73.15.
- 7.1.7 The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with § 73.6.

7.2 EHSO/Biosafety Officer

- 7.2.1 Conducting Select Agent/Toxin laboratory inspections with results provided to the RO/ARO.
- 7.2.2 Obtaining monthly Select Agent/Toxin inventory reports with results provided to the RO/ARO.
- 7.2.3 Maintaining a secured Central Receiving facility with a certified biosafety cabinet.
- 7.2.4 Maintaining a secured Database on its isolated server for Select Agent/Toxins recordkeeping and information tracking.
- 7.2.5 Providing/assisting with required Training programs.
- 7.2.6 Providing guidance on selection of Biosafety Level selection and requirements.
- 7.2.7 Providing assessment of facility ventilation and chemical fume hood face velocities, PPE, facility design, spill response, work practices, and other health and safety issues as appropriate.
- 7.3.8 Providing respirator fit-testing.

7.3 Principal Investigator

- 7.3.1 Ensuring completion of a multidisciplinary risk and threat assessment;
- 7.3.2 Ensuring completion and installation of facility security plans;
- 7.3.3 Ensuring training, practice and enforcement of Select Agent/Toxin physical security;
- 7.3.4 Ensuring security of data and electronic technology systems;
- 7.3.5 Providing essential information for security screening of personnel;
- 7.3.6 Writing and instituting policies for access and safe work practices specific to the laboratory and animal areas;
- 7.3.7 Maintaining accountability and inventory records for the Select Agent/Toxin at all times.
- 7.3.8 Coordinating with the RO/ARO for receipt of agents into the laboratory, and transfer or shipping of select agents from the laboratory;
- 7.3.9 Notifying the RO/ARO and EHSO for destruction of agents/toxins.
- 7.3.10 Maintaining and posting laboratory-specific emergency response plans.
- 7.3.11 Reporting of incidents, unintentional injuries, and security breaches.
- 7.3.12 Recording all entries into these areas, including entries by visitors, maintenance workers, service workers, and others needing one-time or occasional entry.
- 7.3.13 Limiting routine cleaning, maintenance, and repairs to hours when authorized employees are present and able to serve as escorts and monitors.
- 7.3.14 Establishing procedures and training for admitting repair personnel or other contractors who require repetitive or emergency access to select agent areas.
- 7.3.15 Ensuring visitors are issued identification badges, including name and expiration date, and escorted and monitored into and out of select agent areas.
- 7.3.16 Ensuring procedures are in place for reporting and removing unauthorized persons.

7.4 UIC Police

- 7.4.1 Providing expertise on security needs.

7.4.2 When feasible, obtaining and sending in fingerprints to the FBI.

7.5 University Health Services

7.5.1 Providing expertise and counseling on work-related exposures.

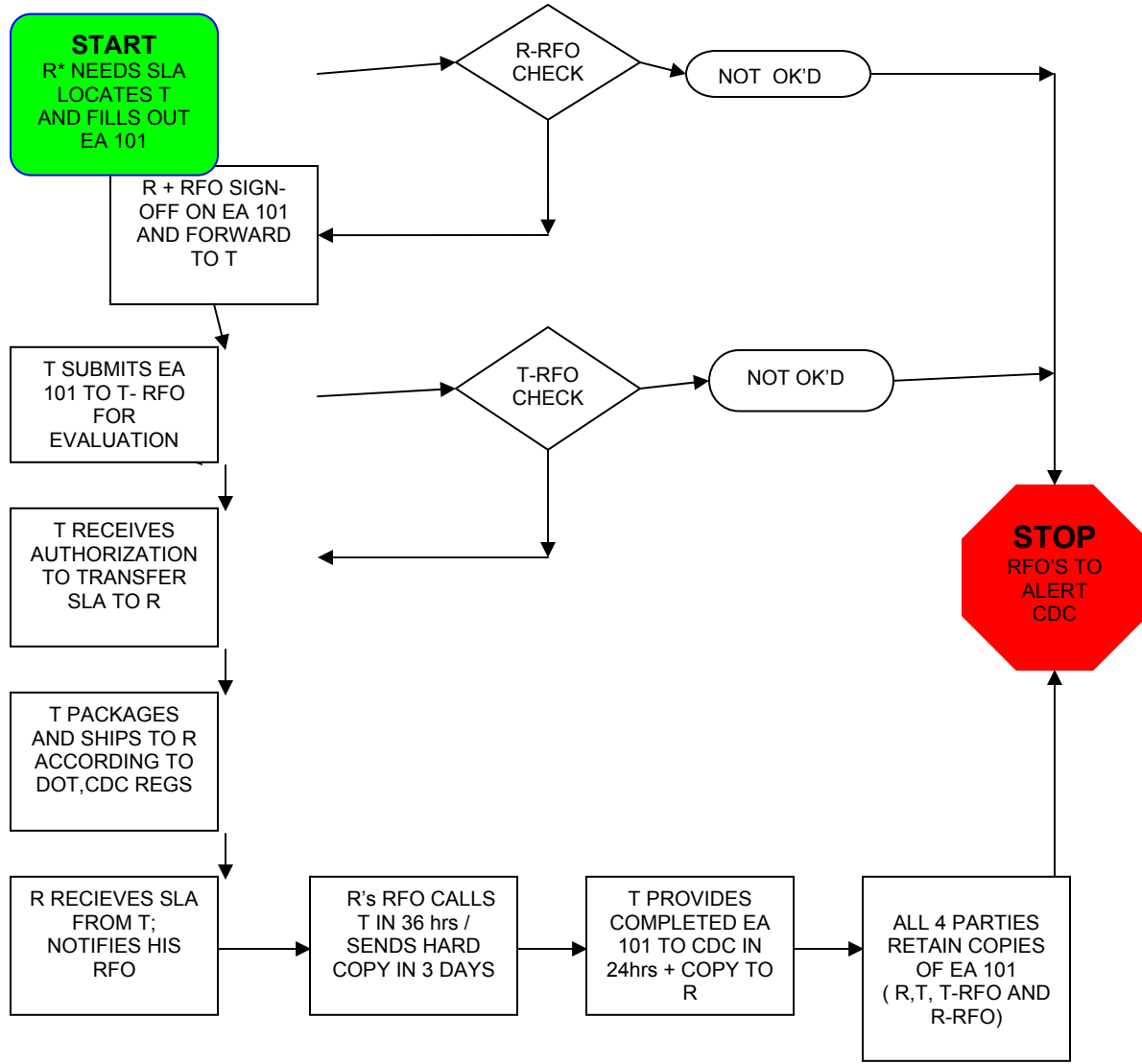
7.5.2 Providing preventive and baseline services as appropriate and available for Select Agents/Toxins.

7.6 University of Illinois at Chicago Administration

7.6.1 Appointing the Responsible Official and Alternate Responsible Official

8.0 APPROVALS

8.1	<u>Diane L. Hodges</u>	<u>10/31/03</u>
	Associate Vice Chancellor for Administration	Date
8.2	<u>Marilyn L. Hau</u>	<u>10/16/03</u>
	Director of Environmental Health and Safety	Date



R* = REQUESTOR
 RFO = RESPONSIBLE FACILITY OFFICIAL
 SLA = SELECT LIST AGENT
 T = TRANSFERROR
 DOT = DEPT. OF TRANSPORTATION

SELECT AGENT TRANSFERS BETWEEN FACILITIES:
 REPORTING REQUIREMENTS UNDER CDC'S LR/SAT REGS
 PGH 11/2002