BIOLOGICAL SAFETY POLICY

DEVENS ENTERPRISE COMMISSION, DEVENS, MASSACHUSETTS

Adopted _____

SECTION 1: AUTHORITY

This policy is adopted pursuant to the authority granted to local Boards of Health under Massachusetts General Laws, Chapter 111, Section 3 and any other applicable law, rule, regulation or policy.

SECTION 2: PURPOSE

To safeguard the health and welfare of the residents, general population at large, visitors, staff and employees of businesses in Devens, the Devens Enterprise Commission (DEC) hereby promulgates this policy governing the use of all Regulated Biological Agents, as defined herein, within Devens by specifying the practices to be used for constructing and handling of recombinant deoxyribonucleic acid (rDNA) molecules as well as organisms and viruses containing rDNA molecules within the Devens. These policies accomplish this by adopting these policies and the NIH Guidelines (see Section 3) as the primary standard of policy and (i) not permitting rDNA work requiring a high level (BL4 or higher as defined by NIH Guidelines) of containment; (ii) establishing local mechanisms to inform the DEC Board of Health of the initiation and status of rDNA work; and (iii) issuing local registrations or permits for the initiation or continuance of rDNA experiments. The use of biological agents requiring Biosafety Level 4 (BSL-4) containment is or greater is not permitted in Devens. Nothing contained herein or omitted shall be construed to limit DEC taking or not taking in its discretion action relative to Biological Safety.

SECTION 3: APPLICABILITY

These policies shall apply to any entity, institution, business, research facility (whether private or public) and all other similar entities of any nature, involved in or in any way undertaking any and all types of research or manufacturing involving Biological Agents in Devens. All research or manufacturing involving Regulated Biological Agents, as defined below, in Devens shall be undertaken only in strict conformity with the most recent edition or version of the "NIH Guidelines", CDC's "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," these policies as amended, other applicable laws, rules and regulations and all other health regulations as Devens may in its discretion promulgate. In the event of a conflict between standards or policies, the standard or policy providing, in the discretion of the DEC, the greatest level of public safety shall govern.

Any entity or Institution currently engaged or initiating activity in these regulated activities at the time of passage of these policies, shall be required to apply for and receive a permit on or before 6 months from the passage hereof and then annually in accordance with the permit procedures set forth herein.

For the purposes of this policy, clinical laboratories that exist in direct support of healthcare or veterinary services, unless these facilities are also engaged in research or production of biological

agents, are not required to comply with these permitting requirements, provided the same is confirmed by the DEC.

Educational institutions or groups utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at Biosafety Level 1 are not required to comply with these permitting requirements, provided the same is confirmed by the DEC.

SECTION 4: DEFINITIONS

The following terms are used in this policy as defined below.

Biological Agent: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance.

Biological Risk Group: Equivalent to the risk group for any biological pathogen as defined in *Risk Groups* (Subsection II-A-1) of the latest amendment of the NIH Guidelines (defined below), and as specified in the latest edition of the BMBL (defined below). Risk Group designation describes the natural risk to human health and the likelihood of transmission associated with the unaltered form of each biological agent.

Biosafety Level: Physical containment as defined in *Physical Containment Levels* (Appendix G-II) of the latest amendment of the NIH Guidelines (defined below) and the latest edition of BMBL (defined below).

BMBL: The current edition of the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) Publication No. 21-1112, entitled "Biosafety in Microbiological and Biomedical Laboratories."

Board of Health: The Devens Enterprise Commission (DEC) acting as the Devens Board of Health.

Clinical Laboratory: Healthcare facilities providing a range of laboratory procedures which aid physicians in carrying out the diagnosis, treatment, and management of patients.

Healthcare Facility: Places that provide healthcare including hospitals, clinics, outpatient care centers and specialized care centers, such as birthing centers and psychiatric care centers.

Institution: Any public entity or private entity (individual person or group, corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization) acting as a unit responsible for compliance with the requirements set forth in this policy.

Institutional Biosafety Committee (IBC): A committee established in accordance with Subsection IV-B-2 of the NIH Guidelines (defined below) and any applicable requirements of this policy. The IBC shall be the party responsible within an institution with regard to the implementation of this policy, with oversight by the DEC as described.

NIH Guidelines: The National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules published in the Federal Register of July 23, 1976, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee (RAC) within the National Institutes of Health (NIH).

Regulated Biological Agents: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that:

1. Is identified as a "Recombinant or Synthetic Nucleic Acid Molecules " in Section I-B (Definition of Recombinant or Synthetic Nucleic Acid Molecules) of the most recent revision of the NIH Guidelines (as defined above), or

2. Is classified as a Risk Group 3 or 4 agent in the NIH Guidelines or the BMBL (as defined above), or

3. Is identified as a "select agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 CFR 73.3, 73.4, 73.5, 73.6, 7 CFR 331.3 and 9 CFR 121.4, and the rulings made by the CDC and the USDA relative thereto, as such regulations and rulings may be amended from time to time. "Select agent" as used herein shall not include *de minimis* amounts of agents or toxins which are excluded from 42 CFR 73.00 et seq.

Veterinary Facility: Places that provide clinical care and/or laboratory support for healthcare of animals including hospitals, clinics, outpatient care centers, and specialized care centers such as dental or surgical facilities.

SECTION 5: PROFESSIONAL ADVISORY ASSISTANCE

The DEC, acting as the Board of Health for Devens, has responsibility, along with other appropriate entities, for enforcement of this policy, however, whenever the facts and circumstances deem necessary, the DEC shall be authorized to retain assistance from a professional consultant or consultants with appropriate professional and academic experience and training to support review and assessment of applications, documentation, inspections, and proposals. The salaries and expenses paid by the DEC for inspections, reviews, staff and consultants for work related to permits sought and/or issued under this policy shall be assessed to the applicants and/or holders of the permits made under this policy. This cost assessment is in addition to any established permit fee(s). Nothing contained in this policy or any action or inaction by DEC shall constitute a specific assurance of safety or assistance.

SECTION 6: GENERAL REQUIREMENTS

A. All Institutions proposing to use Regulated Biological Agents, unless specifically exempt herein, must obtain a permit from the DEC before commencing or continuing research, manufacturing, or other use of regulated biological agents, including bringing regulated biological agents onto Devens property.

B. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit applications and supporting documents as filed with said application and the terms of the permit. The use of regulated biological agents requiring BSL-4 or higher containment as described in the NIH Guidelines and the BMBL shall not be permitted in Devens.

C. Each institution applying for a permit under these policies shall establish and operate an Institutional Biosafety Committee (IBC) in accordance with NIH Guidelines and these policies unless specifically exempted.

D. Each institution seeking permit approval shall certify and attest in its application that it will comply with the NIH Guidelines, the biosafety standards established in the BMBL, all other applicable laws, rules

and policies and all other conditions set forth in this policies. Access for site inspection of facilities and pertinent records by the DEC or its designees upon reasonable notice, should it be deemed necessary by the DEC, is required by the DEC as a condition of permit approval. It is also a requirement of these policies and any applicable law, rule or policy that the institution cooperate with DEC and any other governmental entity in any activity related to these policies.

E. Institutions permitted pursuant to these policies shall file a report or reports to the DEC annually or more frequently if requested, and for permit renewal. This report, at a minimum, shall include copies of all IBC minutes for the previous year consistent with instructions below, certification that the entity is in compliance with this policy and the NIH Guidelines and BMBL, as well as all other applicable regulatory authorities, a report on any quality assurance and quality improvement efforts made during the previous year, and a complete roster of current IBC members. It shall be the responsibility and obligation of the institution to ensure that it is in compliance with all applicable laws, rules and policies.

F. Institutions permitted pursuant to these policies shall provide a written summary of any incidents or adverse event involving biological agents, toxins, or other hazardous materials (consistent with DEC's Water Resource Overlay District , 974 CMR 4.09 that may have resulted in an exposure within the facility, or in the release from the facility involving groundwater, wastewater, direct airborne release, or any improper disposal of potentially contaminated solid waste. This report shall be sent to the DEC as soon as it is feasible, but not more than seven days from the date of the incident.

SECTION 7: INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) REQUIREMENTS

A. Each institution applying to the DEC for a permit under these policies must form an Institutional Biosafety Committee (IBC), as defined by the NIH Guidelines. The IBC shall include as members representatives of the institution, DEC's Consultant the Fire Chief or their designees plus one additional community representative, appointed by the DEC, who is a resident of Devens.

B. Members of the IBC representing the DEC and community shall not have a conflict of interest in the applicant/permitted institution or in any institution in relevant competition. Guidance as to the Conflict of Interest law shall be sought in appropriate cases. Representatives shall be bound to the same provisions of non-disclosure and non-use of proprietary information and trade secrets as all other members of IBC, except to the extent necessary to alleviate any public health hazard or comply with its fiduciary obligations to the DEC and Devens. As used in these policies proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.

C. The IBC will provide to the DEC with the submission of a permit application a complete roster of all IBC members, including names, e-mail addresses and resumes or curriculum vitae (CVs). The DEC will be provided with an updated roster of IBC members, including resumes or CVs of new members, in a timely manner following any change in IBC membership.

D. The IBC will meet no less than once a year and further upon request. All minutes of the IBC meetings must be forwarded to DEC. The minutes of the IBC submitted at least annually to the DEC or when requested will include sufficient detail to allow the DEC and its staff or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined biosafety level and corresponding safety practices. All protocols reviewed and approved by the IBC within the previous year, including, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological

vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), the BSLs assigned after IBC review and the rationale or guidance document upon which the selected BSL was based.

E. The IBC, acting on behalf of an institution, shall review and approve all work involving regulated biological agents, assessing risk and biosafety policy in compliance with NIH Guidelines and BMBL, these policies or any applicable law, rule or policy in an ongoing manner. The IBC is responsible for assuring all work in the facility is and remains in compliance with the standards set forth in these policies and applicable laws, rules and policies at all times. The IBC will provide the DEC a description of each project or protocol as approved by the IBC, indicating the assigned biosafety containment level, in a format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project.

F. Information sent to the DEC may have essential proprietary information and trade secrets removed, however, the full text of meetings shall remain on file in the records of the institution and must be available for inspection at all reasonable times by any member of the IBC, the DEC, a professional consultant acting on behest of the DEC and any local, state or federal authority.

SECTION 8: REGISTRATION AND PERMITTING REQUIREMENTS

Low Risk Facilities (BSL-1) must register with the DEC and include:

(1) Name and curriculum vitae of a person in the organization familiar with the proposed rDNA research or use and the NIH Guidelines.

(2) A brief summary from the above-named person describing the proposed rDNA research or use and providing:

(A) A list of all of the institution's facilities within the City of Somerville, including the address and a description of the research or use of rDNA at each facility.

(B) Name and type of organisms (host/donor [foreign DNA]/vector) being used.

(C) Reference to the section of the NIH Guidelines where the rDNA research or use falls.

(D) If rDNA Molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.

(E) The scale (in liters) on which the organisms will be grown.

(F) An assurance that all rDNA research or use will be carried out following the NIH Guidelines, where applicable.

(G) Name of biological waste handler, if any, and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.

(H) Description of annual safety training and refresher training provided to laboratory staff.

The registration fee for a permit or annual renewal by the DEC shall be $_____, in addition to any other license or permit fees and staff and/or consultant costs.

All BSL-2 and BSL-3 Institutions subject to these policies shall obtain a permit from the DEC. Permit applications will be provided by the DEC. Application for permitting must be accompanied by a nonrefundable permit application fee. The application must include the following information and such further information as may be requested by the DEC, its agents, employees, officials or consultants:

A. Institution name and address.

B. Name(s) of corporate officer(s) authorized to sign the application and emergency contact information (including cell phone numbers and email addresses) for those individuals signing on behalf of the institution.

C. Name and emergency contact information (including cell phone numbers and email addresses) of the institution's designated official responsible for compliance with this policy. This is most often the designated biosafety officer, as defined in the NIH Guidelines.

D. An emergency response plan for the purpose of orienting Devens representatives, including but not limited to the DEC, Fire, and Police Departments, to the physical plant and to procedures to be utilized in the event of an emergency. This documentation must include the location of the facility on a local map, a plot plan showing the location of the permitted facility with all points of entry clearly indicated, and a floor plan showing the internal layout of the facility with specific biological containment and non-biological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated.

E. Designation of the appropriate biosafety levels (as defined in this policy) for all laboratory areas, which are consistent with the NIH Guidelines or BMBL for all IBC-approved protocols and any other applicable laws, rules and regulations.

F. Floor plans showing laboratory areas. All biosafety containment, biosafety levels, and designated waste storage areas should be indicated. Updated floor plans to reflect any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal and when updated.

G. Description of all organisms in use, and all protocols reviewed and approved by the IBC in the past year, in sufficient detail to allow the DEC and its Agents or professional consultants to understand the risk assessment and risk assignment process by which the IBC determined biosafety level and corresponding safety practices. Documentation must include, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), and the BSLs assigned after IBC review, with the rationale or guidance document upon which the selected BSL was based.

H. Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal and when updated.

I. An evaluation of the public health and environmental risks associated with all biotechnology-byproduct effluents generated by the facility and a determination of the applicability of conditions, including appropriate effluent treatment requirements for waste disposal, consistent with 105 CMR 480.

J. A treatment and/or monitoring plan and signed vendor agreement for systematic pest control management in laboratories, contiguous facilities and food service establishments (separately permitted by the Board of Health) in any and all facility buildings.

K. The institution’s health monitoring and surveillance plan for an appropriate medical surveillance program including oversight by an occupational health physician, or documentation of a signed medical surveillance agreement with a qualified provider. Plan must include consideration of workers from susceptible populations such as pregnant or immunocompromised.

L. Upon submission of a permit application, the applicants will present an overview of the use of all regulated biological agents during a regularly scheduled meeting of the DEC. The presentation shall include a general introduction of the institution, its mission, its research or production plans, a timeline of the use of rDNA or other biological agents, an overview of the applicant's biosecurity risk assessment and program, and a discussion of the facilities. Questions raised by the DEC during or subsequent to this the presentation must be addressed by the institution to the satisfaction of the DEC to be granted a permit.

M. The application fee for a permit or annual renewal by the DEC shall be $_____ or as otherwise determined by the DEC based on the project involved, in addition to any other license or permit fees and staff and/or consultant costs.

N. Acceptance of this permit is acknowledgement that it is the responsibility of the institution to properly decommission the facility at end of use. Upon moving or closing a facility permitted by the DEC under these policies, the institution commits to and will submit a report (with supporting documentation) to the DEC indicating that the facility was properly decommissioned; including, but not limited to, cleaning and sanitizing drain lines and tanks, removal of all hazardous materials and wastes and removal of all biological material and wastes. Upon receipt of this documentation,

O. The DEC may conduct further and/or a final inspection of the facility. All maintenance and laboratory safety records shall be made available to the DEC at the time of any inspection. Areas of particular interest to the DEC include:

A. General housekeeping and biological hygiene;

B. Physical separation and access control (BSL-2 and BSL-3 laboratories);

C. Proper signage indicating biosafety level and emergency contact information;

D. Proper equipment such as appropriate biosafety cabinets for meeting the biosafety level containment standards with performance ratings clearly indicated;

E. Proper general ventilation and hygiene facilities (e.g. sink) for the biosafety level;

F. Proper personal protective equipment in use by personnel (e.g. lab coat, gloves, eye protection).

G. Possession of all required federal, state, and local permits and approvals; and

H. Establishment of an appropriate medical surveillance program for all employees coming into contact with regulated materials.

P. Permit renewal applications must be submitted by November 30 each year, along with an annual Biosafety Report. This report shall include: 1) minutes from all IBC meetings held since the last annual report, 2) protocol summaries of all work approved or reviewed by the IBC since the last report, 3) an updated IBC membership roster with e-mail, home phone numbers, and home addresses for all members, and 4) any major changes to the biosafety manual or floor plans originally submitted during the initial application. Regardless of when issued, Permits are valid for one calendar year from January 1 through December 31.

SECTION 9: ADMINISTRATIVE APPROVAL AND FORMAL APPROVAL

Administrative approval may be granted provided that there are no significant deficiencies. Administrative approval may be appropriate when there are minor deficiencies identified by the DEC and the DEC determines that a subsequent site visit is unnecessary. Formal approval shall be contingent upon the Institution providing documentation to the DEC that such minor deficiencies have been resolved. Such documentation may be made in the form of a letter or e-mail indicating that the necessary steps shall have been taken to resolve such deficiencies. However, if significant deficiencies are discovered during the site visit, the SBC may conduct subsequent site visits to confirm that such deficiencies have been resolved to the satisfaction of the SBC.

Formal approval may be granted by the DEC once any deficiencies are resolved.

Section 10: AMENDMENTS AND THE "THREE YEAR RULE"

Any move to a new location, physical expansion of lab space within current facilities, creation of additional lab space at another location within Devens, increase in the containment level (BSL) for existing lab space, significant change of protocol (e.g. new work involving a different BSL agent, or addition of large scale activities), requires an amendment to a Permit. If an Institution seeks to amend a Permit, it shall contact the DEC and request to be placed on the agenda for a subsequent DEC meeting. If that Institution has already appeared before the DEC within the past three (3) years and the DEC determines that the proposed amendment represents a minor change under the permit (e.g. simple expansion at BSL-1), this requirement to appear may be waived. These minor amendments may or may not require a site visit and may be handled administratively.

SECTION 11: PROHIBITIONS AND EXEMPTIONS

A. The use of biological agents determined by the IBC to require BSL-4 or higher containment shall not be permitted in Devens.

B. Agents classified as a Risk Group 4 or higher in the NIH Guidelines or the BMBL shall not be permitted in Devens.

C. The IBC is responsible for completion of a comprehensive risk assessment to assign an appropriate containment level when one is not prescribed in the NIH Guidelines. The IBC risk assessment may be completed independently or in consultation with an outside agency or consultant.

D. Use of more than _____ gallons of live culture of any Regulated Biological Agent(s) shall not be permitted on site unless a variance is first obtained from the DEC.

E. Precautions and testing as requested by the DEC shall be followed in order to prevent the release of any viable biological organisms into the environment, of particular concern are contamination of the local aquifer, bodies of water or water source or aerosol releases, and to comply with all provisions of 105 CMR 480, *Minimum Requirements for the Management of Medical or Biological Waste.*

F. The institution shall report within 24 hours to an agent of the DEC, followed by a written report within 15 days to the DEC, any significant accident or risk of illness or major release to the environment related to the use of Regulated Biological Agents if that release constitutes a violation of 105 CMR 480 or of any law, rule or policy and/or involves the release of a viable and potentially infectious agent. An additional inspection of facilities and procedures may be deemed necessary by the DEC based upon its judgment of the nature and extent of the event.

SECTION 12: ENFORCEMENT

A. The DEC may require any institution permitted by these policies, at any time or on a schedule set by the DEC, to comply with water, effluent or soil testing, evaluation or other procedure to demonstrate conditions are in compliance with the health and safety needs of the community.

B. This policy shall be enforced by the DEC or its Agent.

SECTION 13: OTHER APPLICABLE PERMITS AND APPROVALS

Institutions applying for a Permit shall be responsible for obtaining all required federal, state, and local permits and regulatory approvals for the use of the Institution's facility. A Permit will not be withheld in the event that other permits are still being sought, but the DEC may request documentation that these Institutions have applied for such other permits. The Institution applying for a Permit shall be under a continuing obligation to notify the DEC of the refusal of any governmental or regulatory agency to issue such permit or approval. Failure to obtain any such required permit or approval may be grounds for the denial or revocation of a Permit.

SECTION 14: PENALTIES

Whoever violates any provision of this policy may be subject to penalties as follows:

A. If a designated agent of the DEC determines that a party has violated this policy, such agent may issue a written order ("Order") to the Institution (permit holder) and its designated agent to correct the offending deficiencies within a reasonable specified time.

B. Violation of any provision of this policy may subject the violator to a fine of $300.00 per day. In addition thereto, non-compliance with these policies may be enforced by non-criminal disposition by an agent of the DEC, with the first offense subject to a warning and each subsequent offense subject to a non-criminal disposition penalty of $300.00. Each day of violation shall constitute a separate and distinct offense.

C. In addition to a fine, an institution which violates any provisions of this policy, or persists being in noncompliance in activities covered under this policy, which pose an immediate threat to the public health or environment may be closed by the DEC. The DEC may utilize any and all enforcement tools, including but not limited to civil, criminal, non-criminal disposition and any other avenue.

D. An Institution to whom an order has been served pursuant to this policy may request a hearing before the DEC by filing a written petition requesting a hearing with the DEC within seven days after the day the order was served. Upon receipt of such petition, the DEC will set a time and place for such hearing not later than 30 days after the day on which the order was served. The DEC may postpone the date of a hearing for a reasonable time beyond such 30-day period, if in the judgment of the DEC the petitioner has submitted sufficient reason for such postponement.

E. The DEC may suspend or revoke a permit if it determines that the institution has failed to comply with this policy, or other applicable permit conditions. Suspension or revocation shall follow written notice and a hearing.

F. In the event the DEC or its agent determines there is an imminent threat to public health and safety it may suspend a permit immediately without prior notice. Any Institution thereafter may invoke a hearing

process to appeal said suspension. After a hearing, the DEC may affirm, modify or rescind said Order, or take any other action it deems warranted and appropriate.

SECTION 15: SEVERABILITY

Each provision of this policy shall be construed as separate to the end that if any part of it shall be held invalid for any reason, the remainder shall continue in full force and effect.

SECTION 16: WAIVERS

Waivers, in whole or in part, from these policies may be authorized by the DEC when, in its discretionary opinion, the enforcement thereof would do manifest injustice, provided that the decision of the DEC shall not conflict with the spirit of these policies or any minimum standards required by Federal, State or Local law; and provided that the applicant demonstrates to the reasonable satisfaction of the DEC that a sufficiently equivalent level of protection can be achieved. Any waiver granted by the DEC shall be in writing and shall be subject to such conditions as the DEC deems appropriate.

The DEC may suspend or modify these policies. A failure of the DEC to comply with these policies shall not result in a constructive grant of any relief and shall not preclude subsequent enforcement or action by the DEC.

SECTION 17. HEADINGS

The headings provided for in this document are for convenience only and shall not affect and interpretations of this document.

SECTION 18: EFFECTIVE DATE

This policy shall become effective upon publication pursuant to M.G.L. c. 111 §31.

Devens Enterprise Commission

[list members]