

Culture of Safety at Boston University's Research Enterprise

In March 2010, the Associate Vice President for Research Compliance (AVPRC) appointed a Task Force on Biosafety to review the safety program at Boston University and to make recommendations on how the *culture of safety* at BU can be enhanced. The task force with representation from a broad spectrum of BU stakeholders (see Appendix-I-F), reviewed various aspects of the programs at Boston University and issued its final report on July 1, 2010. In formulating its recommendations, the task force reviewed practices at other institutions, including those of Industry, to identify best practices to enhance BU safety programs.

While the task force noted that “*over the past several years, Boston University and Boston Medical Center have significantly enhanced their safety programs,*” it also identified a number of areas in which the modification of existing practices, or the introduction of new practices, would significantly improve the *culture of safety* at BU. These recommendations, when fully implemented, will build upon the safety programs currently in place and establish the *culture of safety* as a fully integrated component of BU activities.

The task force also recognized the importance of enhancing safety at the National Emerging Infectious Diseases Laboratory (NEIDL) and made additional recommendations in the NEIDL Specific Addendum. This addendum includes additional recommendations that establish more stringent criteria at the NEIDL with enhanced monitoring and safety requirements where *safety first* is the key component of its operations. The recommendations of the task force were accepted by the AVPRC and were distributed and discussed at various research leadership forums that included the following participants:

- The BUMC and the University Provosts;
- BUMC Provost's meeting (Deans, Associate Deans, VPR, Associate Provosts, etc.);
- SOM Executive Committee (Department Chairs, Vice Deans, etc.);
- Institutional Biosafety Committee;
- NEDIL Leadership (Director, Associate Directors and Core Directors);
- Safety Program Leadership.

The key recommendations were targeted towards enhancements in programmatic areas that include:

- Active adoption of a *culture of safety* as a core value at every level.
- Inclusion of a commitment to safety as a condition of employment for all those engaged in research and as a key factor in annual Performance Appraisals.
- Written confirmation by all individuals engaged in research that they have been adequately trained and that they will follow the safety requirements.
- New procedures for the temporary or permanent removal of the privileges of individuals who violate health and safety requirements.
- Clear indication that while safety is a shared responsibility of each individual working in a laboratory, ultimately Principal Investigators bear full responsibility for safety in their laboratories.
- Appointment of a Laboratory Safety Coordinator who is specifically responsible for implementing day-to-day safety requirements in the laboratory.

- Enhancements in the operation of the Institutional Biosafety Committee (IBC) operations and its membership to ensure expertise and support for all applications for work that could be reviewed.
- Appointment of a Chief Safety Officer at the NEIDL with full oversight responsibility on all safety aspects of the NEIDL and with the authority to halt any operations that are judged to present a health and safety hazard, or are in violation of regulatory or policy requirements.
- Appointment of a NEIDL Safety Committee with a specific charge for the review of all aspects of safety the NEDIL.
- Recruitment of a communication specialist to assist in developing campus wide and NEIDL-specific *culture of safety* communication plans.

The implementation plan outlined in this document was developed based on discussions with various stakeholders. The plan includes additional recommendations that were suggested during the discussions and considered to be important for the enhancement of the *culture of safety*.

Note: the text in **blue font** is the actual text of the committee's recommendation.

Section-I: Campus-wide Implementation Plan

1. Role of the Leadership

The Biosafety Task Force report identified the role of leadership as a critical factor in the success of the *culture of safety*. While safety in an institution is the responsibility of each individual, it is important to identify clearly the “executive who owns the program” and who has overall responsibility for safety. Boston University (BU) and Boston Medical Center (BMC) have assigned this responsibility the Associate Vice President for Research Compliance (AVPRC), who is responsible for all non-financial research compliance matters, including health and safety.

Recommendation: The task force recognized that “while the culture of safety is the responsibility of each and every individual in the organization; the leadership of the institution must particularly be engaged in and support the culture of safety. Deans and Department Chairs must continue to demonstrate an active commitment to ongoing safety and promote that commitment by holding the culture of safety as a core value of their operations. They must regularly and consistently communicate the importance of safety in their laboratories and demonstrate the value and respect they have for the safety of people who work under their supervision. This will help ensure that the culture of safety cascades down through the organization.”

Action: The senior leadership has fully embraced the implementation of a *culture of safety* at BU and has demonstrated its support of programs established to develop a safe work environment at BU. This support, as noted in the task force report, has resulted in the enhancements of the safety program at BU over the past four years. BU President Robert A. Brown has amplified the commitment in the President's Statement of Commitment, which stated that: “*Boston University is fully committed to protecting the environment and maintaining healthy and safe campuses.*”

The President's Statement of Commitment in Environmental Health and Safety has been widely distributed throughout the University and is prominently on the [Environmental Health and Safety home page](#). This statement is the foundation for the specific policies presented in the Policy Manual and for the supporting plans, guidelines, and work practices at BU. Furthermore, this statement broadly addresses safety in all aspects of University operations and has implications far beyond those addressed in the laboratory setting.

The continued support of the leadership at every level is critical to maintaining and enhancing the *culture of safety* at BU. The report was distributed to the BUMC Provosts Group (Deans, Associate Deans, Associate Vice Presidents, Associate Provosts, etc.) and the SOM Executive Committee (Department Chairs, Associate Deans, etc.) for discussion and to solicit input toward developing the final implementation plan.

2. Laboratory Safety

Recommendation: The Task Force recommends that each laboratory be required to designate a “Laboratory Safety Coordinator” (LSC) who along with the PI will be responsible for day-to-day oversight and implementation of safety activities and communication in the laboratory. Further, the LSC will serve as the liaison between their laboratory and the Office Environmental Health and Safety (EHS). The Task Force also recommended specific requirements for the role of the LSC.

Action: Each Principal Investigator (PI) is required to submit (as applicable):

- An application for use of Biological Agents to the Institutional Biosafety Committee (IBC) for approval prior to any use;
- An application for use of radioactive materials to the Radiation Safety Committee (RSC) for approval prior to any use; and,
- A chemical inventory with annual updates.

As part of the protocol review and approval process, each PI is asked to nominate an individual as the Laboratory Safety Coordinator (LSC). Where groups of PIs are using a common laboratory, they may nominate a single individual as the LSC. The roles and responsibilities of the LSC were defined in an e-mail on March 18, 2010 that was sent to the research community requesting such appointments (see Appendix-I-A).

Role of Environmental Health and Safety (EHS)

The committee recognized the critical role of EHS in the establishment of the *culture of safety* and maintaining a safe work environment. The Director of Research Safety acts as the Chief Safety Officer for all matters pertaining to research safety at BU and BMC and in this role leads the programs necessary to support the continued success of the *culture of safety*.

Recommendation: The Task Force recommended that a key role that EHS must play in the culture of safety is developing a strengthened safety partnership with the user community and to provide the training, oversight, and mentoring of the LSC in all phases of laboratory safety.

Action: To meet this goal, EHS has designated a Safety Specialist from its staff to each PI, group of PIs, or department. This assignment has been made in a manner that best matches the specific activities in the laboratory or the department (e.g., biomedical research, undergraduate chemistry labs, etc.) with the expertise of the Safety Specialist (e.g., biosafety, chemical safety, etc.). The designated individuals are specifically responsible for acting as a single point of contact with their assigned laboratories and serve as the liaison between the researchers and laboratory staff and EHS to strengthen and enhance the safety programs at BU. Similar assignments have been made for non-laboratory areas (e.g., facilities).

Facilities Management and Public Safety liaisons have been identified for each building and those individuals, along with the EHS liaison, will coordinate with the user representative (LSC or others) to ensure timely and consistent communication and education on safety at BU. The specific activities of the EHS-designated individuals are described in Appendix-I-B.

Recommendation: The Task Force also recommended that EHS work with the PIs and LSCs to develop new tools including training materials, safety updates or other pertinent tools for the laboratories to use as the safety culture is enhanced.

Action: EHS, working with a representative group of LSC, has developed an LSC [tool kit](#) to assist them in their role. The web-based [tool kit](#) has been widely publicized among the LSCs and will be updated regularly to reflect changes in the programs.

3. Role of Laboratory Safety Coordinator (LSC)

Recommendation: The Task Force envisioned that the LSC will serve a critical function in the overall structure and monitoring of safety practice at the institution and play a crucial role in achieving an enhanced culture of safety. The committee also envisioned that the LSCs will coalesce around the notion

that a culture of safety can be significantly enhanced by group discussion of safety concerns recommended that the LSCs as a group conduct regular meetings on safety enhancement issues designed to improve the overall safety in all BU laboratories.

Action: The following additional actions have been taken in ensure the full adoption of the task force recommendations:

- EHS has established regularly scheduled meetings with the LSCs at both the Charles River and the Medical Campuses. The meetings are structured to include discussions of current issues, common problems identified during inspections and program reviews, any incidents or near misses, and other pertinent information. Meetings involving general safety topics are held regularly and include representatives from Facilities Management and Public Safety.

4. Institutional Biosafety Committee Review and Recommendations

4.1. IBC Committee Membership

Recommendation: The Task Force strongly recommends that appointments to the IBC be restructured and that the Provost, in consultation with senior academic leadership and department chairs should make all appointments to IBC. The IBC chair will provide guidance on the expertise that the committee needs and the Provost will consider those when seeking nominations and making appointments.

Action: This recommendation addresses an important issue related to appointments to faculty Oversight Committees and should be extended to appointments for all search oversight committees. The Associate Vice President for Research Compliance (AVPRC) has worked with the Provosts to implement this recommendation by:

- Providing a list of the oversight committee membership requirements to the Provosts no later than July 1 of each year. The list includes:
 - The committee name;
 - Membership requirements, noting areas of specialization;
 - A determination whether administrative members should be appointed to provide expertise on a particular issue (i.e., emergency response, facility, public safety, communication or other areas as deemed appropriate); and,
 - Terms of the appointment.
- If the nomination of new committee members is required during the term of the committee (e.g., due to the resignation of a current member), the AVPRC will ask the Provosts for assistance with naming a replacement.

Recommendation: The Task Force stated that as the institution looks toward the opening of new laboratories at the BSL-2 and BSL-3 and BSL-4 levels (at the NEIDL), additional faculty with proper expertise be added to the IBC.

Action: Currently, the IBC reviews all BSL-2 and BSL-3 research protocols and the committee membership enhancement discussed above provides the full staffing and expertise needed for the

IBC. As NEIDL approaches obtaining final approval for BSL-4 work, the AVPRC, in consultation with the IBC, will identify the specific additional BSL-4 expertise required for review of the protocols. Once the needs have been identified, the AVPRC will work with the NEIDL scientific leadership to identify membership from the NEIDL scientific community engaged in BSL-4 research. As recommended by the task force, external expert reviewers may be recruited as needed.

4.2. Review of Applications

Recommendation: The Task force noted that the current application review by the IBC is unnecessarily slow, the process is not interactive, and is over burdened. These shortfalls may be remedied by the full transition to Research Information Management System (RIMS), which should facilitate the review process. The Task Force urged the Office of Research Compliance to meet with the IBC to review the mission of the committee and identify areas for improvement with the goal of final approval of most protocols being achieved within one cycle of IBC meeting.

Action: The Office of Research Compliance (ORC) initiated the following steps to implement these recommendations:

- IBC office has started utilizing the RIMS-IBC module for submittal of electronic applications. The second phase of the deployment includes online review and approval, which is in the final stages of design and testing.
- The Director of Research Safety, in consultation with the IBC, reviewed the current protocol pre-review process, and recommended improvements in the approval process. This includes enhancements to the current safety and risk assessment pre-reviews, which will provide the IBC with additional information on safety equipment, inspection results, training status of users, etc., to assist with the approval process.
- The IBC reviewed the task force report at its July 2010 meeting and the AVPRC attended the August 2010 IBC meeting to discuss the report.
- ORC coordinates the activities of the oversight committees with those of the Office of Sponsored Programs (OSP) to ensure that the approval requirements for proposals submitted for funding are clearly identified at an early stage and that PIs are appropriately contacted to assist with timely approvals.

4.3. NEIDL-Related Protocols

Recommendation: As the NEIDL approaches approval for research, the Task Force recommends that NEIDL Core Directors meet with the IBC to conduct a series of short training sessions using the individual protocols for training exercises. In this way, the IBC members could become more accustomed to the types of experiments that will be performed.

Action: The training program has already started with the NEIDL director making a presentation to the IBC on the overall mission and the scientific and research agenda of the NEIDL. Additional presentations were scheduled for the August and September 2010 IBC meetings. The AVPRC will work with the IBC chair to develop continuing interactions as NEIDL gets closer to operating at BSL-4 research.

Recommendations: The Task Force noted that certain experimental protocols may be extremely sensitive (e.g., Dual Use Research of Concern (DURC) or those associated with select agents, necropsy of non-human primates). In such cases, the IBC must strike a balance between transparency and the protection of individual investigators and regulatory requirements for maintaining security of the select agents. The Task Force recognizes that these can be very complex and sensitive issues to resolve and recommends that a subcommittee of the IBC be appointed to focus on reviewing these applications in complete detail.

Action: This recommendation has been in place since 2009 when the AVPRC, in consultation with the IBC members, Research Safety staff, Office of General Counsel (OGC), and Corporate Communications/ Community Relations representatives developed a format for posting IBC minutes on the [IBC website](#). The minutes include the summary of research projects, as well as the committee deliberations and decisions.

5. Dual Use Research of Concern (DURC)

Recommendation: The Task Force report indicated that the general view of the Institutional Biosafety Committee (IBC) is that the IBC should not be the primary reviewer for DURC but, along with other institutional safety committees, lab inspections, etc. it should act as a safety net by identifying projects that have the potential for DURC. The PI should be responsible for disclosing DURC research to the institution. The Task Force further recommended that an institutional policy be developed for consideration and reporting of research with potential for DURC that is clearly outlined and communicated to all researchers. The National Institutes of Health has developed a DURC screening survey (Appendix II of the Task Force Report), and the Task Force recommends that a similar screening tool be adopted for Boston University.

Action: A BU ad hoc Advisory Committee on Dual Use Research of Concern (DURC) was convened in 2009 and its final report was submitted July 2, 2009. The ad hoc committee recommended that Boston University (BU) and Boston Medical Center (BMC) carry out a two-stage plan in anticipation of federal regulations.

- The first stage involves the initiation of education and training programs for faculty and staff. An awareness presentation is being prepared to be presented at various open forums to inform the impacted research community at BU of the:
 - Types of research that may fall under DURC;
 - Proposed National Science Advisory Board for Biosecurity (NSABB) recommendations; and,
 - Recommended review process.

Additional information materials (e.g., brochures, web-based materials, etc.) were also prepared for the research community and can be found on the [BU DURC website](#).

- The second stage involves the development of a formal policy and process in compliance with federal regulations after such regulations have been officially proposed. The final BU policy and the structure of the review will be based on the recommendations of NSABB. The IBC has adopted a series of screening questions that are part of the new RIMS-based IBC application.

- The chair of the ad hoc Committee on DURC and the Director of Research Safety met with the IBC at their July 2010 meeting to discuss the ad hoc committee recommendations.
- The Director of Research Safety, working with the ad hoc committee on DURC, developed and implemented an initial awareness program for the faculty and staff by October 1, 2010. This has included attendance in departmental meetings by the chair of the ad hoc committee and/or Director of Research Safety to present the awareness program and to engage the research community in a discussion of Dual Use Research of Concern.

6. Enforcement

The task force recognized that the current enforcement mechanisms embedded in existing oversight committee activities provide adequate provisions for enforcing any variances from established policies and procedures (see Appendix-I-D for a sample from IBC). The task force discussion indicated that there is a need for enhancements in the implementation of the current provisions. These were included in the Human Resources Subcommittee below and have been incorporated in the implementation plans. EHS, working with the oversight committees, will revise the categories of violations listed in Appendix-C to identify those infringements that are considered as a category of “zero defects,” which constitute major violations. Examples of such infringements would include:

- Training is considered a mandatory requirement for all individuals working in a laboratory environment before they start their work. Each individual is required to sign the User Certification Form (Appendix-I-C), which is also certified by the PI, that the required training has been completed. Therefore, an individual who is working without appropriate training will be considered as being in violation of a key requirement, which will be considered a major violation.
- Safety training includes detailed instructions in the safe practices and use of appropriate Personal Protective Equipment (PPE) such as gloves, laboratory coats, etc. Therefore, violations of such requirements will also be considered to be major.

Action: While the current oversight procedures are deemed adequate, additional enforcement actions that include disciplinary action and inclusion of safety as a condition of employment as well as an element in an individual’s Annual Performance Evaluation are included in the implementation plans described below.

7. Human Resources Subcommittee

The task force recognized that as the University continues to strive to foster a working environment that protects health according to the highest standards of safety and security, each faculty, staff, and trainee must be responsible for the safety consequences of what they do or fail to do. To meet this objective, the task force made the following recommendations:

Recommendation: All laboratory personnel must attend safety training as specified by EHS or oversight committees (e.g. IBC) for their laboratory assignment. Additionally they are required to sign a written personal commitment to laboratory safety that acknowledges that failure to follow safety guidelines may result in loss of laboratory privileges and possible disciplinary action including loss of employment (See Appendix-IV of the Task Force Report).

Action: Existing BU policies mandate that all laboratory personnel (i.e., employees and students) must attend safety trainings prior to starting work in the laboratory and also complete periodic refresher

trainings. Additional training is required when new hazards are introduced into the laboratory (e.g., the addition of a new biological agent). All individuals listed on a protocol are required to sign a written User Certification Form (see Appendix-I-C for a sample from IBC). The Director of Research Safety and his/her staff review the records and ensure that all laboratory personnel have received appropriate training and that they have signed the User Certification Forms.

Recommendation: The annual reviews and process for promotion should include explicit criteria on laboratory personnel's support of and participation in safe laboratory practices.

Action: the AVPRC, working with the Associate Vice President for Human Resources, reviewed this recommendation and developed procedures for incorporating a specific safety evaluation section in the annual employee performance evaluation to approach these procedures broadly so that safety expectations are reflected inside and outside of laboratory spaces. The following statement is also included in the new BU Performance Appraisal Forms (Appendix-I-E):

"Safety: Adheres to safe practices when performing assigned tasks; plans work procedures with safety concerns in mind and maintains a safe work environments; actively supports a culture of safety and encourages others to do so; attends training programs as appropriate; recognizes and reports unsafe conditions and actively works to remedy them."

The Medical Campus Provost has added safety as a review factor for deans, chairs, and center directors effective next review cycle.

Recommendation: The Task Force recognizes that incidents can occur for several reasons. An incident may be truly an accident, it may result from inadequate training, or employee lack of knowledge of procedure or it may result from willful violation of safety policy. Thus, any disciplinary action will be commensurate with the seriousness of the incident.

Action: The current enforcement plans have corrective actions embedded in them that, depending on the type, the severity, the extent and the circumstances of the event, include the permanent removal of the employee's privileges to work with hazardous materials (see Appendix-I-D). Once an individual's privileges for working with hazardous materials have been permanently removed, it is the responsibility of the PI to decide whether the individual may continue to work for a project without working with hazardous materials. If it is determined that the individual may not continue with existing assignments, then the PI will work with HR to implement appropriate action(s), including termination. The current Committee Oversight and Enforcement procedures will continue to be used as the basis for determining the disciplinary actions.

Recommendation: When an incident occurs, an Independent Review Committee should be appointed by the Associate Vice President for Research Compliance to conduct a thorough review, identify its root causes, and recommend corrective and disciplinary actions. A report of the Independent Review Committee should be provided to the laboratory PI and Department Chair. It will be the responsibility of the PI and Chair to work with Human Resources and/or appropriate academic officials when disciplinary action is indicated.

Action:

- The AVPRC will follow the recommendation of the task force in the event of any accident by appointing an Independent Review Committee (IRC) to investigate the accident. The specific charge of the IRC will depend on the nature of the incident; however, at the minimum it will include:

- A clear determination of what happened;
 - Identification of the root cause of the incident (e.g., human error, equipment malfunction);
 - Contributing factors (e.g., lack of training, lack of adherence to established policies and procedures, lack of experience, unapproved procedures, etc.);
 - Any interim action required to address similar situations (e.g., immediate training of individuals engaged in similar activities, halting of certain activities while investigations are ongoing, etc.);
 - Long term corrective actions to prevent the potential reoccurrence of the problem;
 - Disciplinary actions to be taken.
- The findings of the investigation of all accidents or near misses and any corrective actions recommended will be summarized in clearly defined documents and be distributed among the research community for lessons learned. Depending on the nature of the incidents, interim actions may be taken to alert those who are conducting similar types of research or procedures.

8. Communications Subcommittee

The task force recognized the critical importance of effective safety-related communications between EHS, oversight committees, the LSC, the PI, and faculty, staff, and trainees. To ensure an effective communication process, the task force made the following recommendations:

Recommendation: [A communications specialist should be hired to develop and implement an ongoing strategic plan to communicate safety programs to researchers in biological laboratories.](#)

Action: AVPRC has worked, and continues to work, with Corporate Communications in the development of its comprehensive communication plan.

Recommendation: [A protocol for reporting incidents to the internal audience at BU as well as the outside community including the neighborhood associations and the press will be developed by a subcommittee consisting of representatives from BU community relations, administration, EHS and the scientific community and a representative from the Community Liaison Committee \(CLC\).](#)

Action: The Executive Director of Research Compliance has developed a comprehensive notification matrix which uses the email and voice mail systems (Send Word Now). This includes external constituencies (e.g., Boston Public Health Commission-BPHC).

Recommendation: [A Laboratory Safety Hot Line should be established that allows faculty, staff, and trainees to report safety concerns to EHS without fear of retribution.](#)

Other Actions:

- a. In order to improve communication with the laboratories, EHS, working with the laboratories, established a “safety center” in each lab. This is a clearly marked designated shelf space in each laboratory where health and safety-related materials (e.g., safety logbooks, manuals, informational newsletters, safety notices, etc.) are placed for easy access.

- b. In order to improve communication with all areas of the University, The Office of Research Compliance updated all web pages to provide easier access to information, services, and University policies related to safety.
- c. During the discussion of the task force report with the research leadership (i.e., Provosts, BUMC Deans and the Associate Provosts, Department Chairs, etc.) the following additional recommendations were made:
- A fully embraced [culture of safety](#) requires an integrated approach that includes enhanced safety programs, communication, and cultural change management strategies. This was achieved by using “change management experts” for program development.
 - The *culture of safety* discussion includes the principle that any member of the team, including the most junior, must identify unsafe practices and can stop research in a lab, if appropriate, until the unsafe practice is corrected.
 - Activities of all oversight committees were reviewed to identify duplicative efforts which might be contributing to different interpretations of safety policies and procedures. Once identified, the duplicative efforts were eliminated—with the primary responsibility assigned to a single committee—or fully coordinated.
 - The Office of Research Safety has developed a system for tracking its findings during routine inspections. The system became operational July 1, 2010 and the results of these inspections are used as a matrix to evaluate the overall effectiveness of the safety programs and enhancements in the culture of safety. Trending of the data showing continual improvements in adherence to safety requirements, attendance in training, reductions in incidents or near misses. These factors are used as indicators of overall improvements.
 - The information from the trending is also used as focus of mandatory refresher training required for all laboratory workers.

Appendix-I-A: Memo to the Principal Investigators (PIs) to Appoint a Laboratory Safety Coordinator

The following message was sent to all PIs with research activities at BU and BMC.

Unsafe practices in the laboratory can result in exposure to hazardous materials or serious injuries. Prior to beginning work, every laboratory employee must know the potential hazards of the material with which they will work, identify and use appropriate personal protection, and implement specific laboratory practices to prevent exposure. It is expected that every laboratory worker follow and practice safe procedures at all times to ensure a safe laboratory environment.

The Principal Investigator (PI) has the primary responsibility for all aspects of health and safety in their laboratories. However, the PI may delegate day-to-day safety program implementation and oversight to an individual designee named as Laboratory Safety Coordinator (LSC) or Laboratory Manager (LM). This designee, along with the PI, then becomes responsible for day-to-day oversight of safety in the laboratory.

Role of Laboratory Safety Coordinator or Laboratory Manager

The LSC or LM serves an important function in the overall structure of safety at the institution and plays a crucial role in creating a full culture of safety. They act as facilitators in helping the establishment of a *culture of safety* within their laboratories and act as a conduit for communications between the laboratory personnel and EHS.

The following are key requirements of the role of LSC or LM:

- The PI must:
 - Determine and identify the specific responsibilities that he/she is delegating to the LSC or LM, and delegate them in writing.
 - Ensure that the LSC or LM function is delegated to another person should the incumbent leave and inform Environmental Health and Safety (EHS) of the new LSC or LM designee.
 - Clearly inform all individuals working in his/her laboratory that the LSC or LM has been given responsibility and authority to represent the PI in matters related to the role of EHS and oversight of the health and safety in the laboratory. This includes the LSC or LM's *ability to review and suspend any laboratory operations that he/she believes to be unsafe or in violation of the institutional requirements* and work with EHS to make the necessary corrections or improvements.
- The LSC or LM must be knowledgeable in laboratory operations and relevant safety requirements and will serve as the primary laboratory contact for issues related to chemical hygiene, biological, and radioactive materials.
- The PI and designated LSC or LM are responsible for implementing applicable policies and directives and taking other action, as required, assuring that the personnel and operations that they supervise comply with applicable requirements. These include:
 - Taking positive action to determine and reduce, to as low as reasonably achievable, the accidents and incidents associated with their operations;
 - Informing employees of the safety hazards associated with their work;
 - Instructing employees in safe work methods;
 - Keeping individuals performing specific tasks apprised of the most recent procedures and trained in implementation;
 - Ensuring that work is performed in a safe manner and in accordance with regulatory and institutional requirements;

- Working with EHS to determine best safe practices and procedures;
- Working with EHS to ensure that all members of the laboratory complete their required training in a timely manner;
- Ensuring that all deficiencies identified by EHS or other regulatory inspectors are addressed and corrected within the time required;
- Ensuring that the laboratory has adopted, completed, and made lab-specific the Chemical Hygiene Plan, Exposure Control Plan, and Biosafety Manual as applicable;
- Ensuring that the laboratory has access to MSDS;
- Ensuring that the chemical inventories are completed and updated as necessary;
- Ensuring that hazardous materials are disposed of appropriately;
- Ensuring that all Standard Operating Procedures (SOPs) for all laboratory procedures are approved by the appropriate LSC and are current. Ensuring that SOPs include appropriate safety instructions such as personnel protective equipment to be used, special precautions for any infectious agents or highly hazardous chemicals, instructions to perform procedures with appropriate safety equipment such as a fume hood, biological safety cabinet, or sealed centrifuge;
- Training personnel on agent specific hazards; appropriate laboratory safety procedures and techniques; safe use and operations of all equipment; recognizing other hazards in the workplace; and dealing with emergencies, including potential exposure, accidents, or spills;
- EHS will work with the LSC or LM to develop tools, including training materials, safety updates, or other pertinent information for the laboratories. It is the shared responsibility of the LSC or LM (along with the PI) to ensure that all workers in the laboratory read, understand, and comply with those materials;
- Ensuring that all equipment (i.e., fume hood, Biosafety cabinet, centrifuge, etc.) are appropriately maintained, tested, and/or certified; and,
- Informing the PI and/or EHS of any incidents or problems that need attention.

Appendix-I-B: Role of Environmental Health and Safety (EHS)

As stated previously, EHS plays a critical role in the development and maintenance of a *culture of safety* at BU. The Research Safety director acts as the Chief Safety Officer for all matters pertaining to safety in research laboratories and is responsible for the development of programs that will provide for a safe work environment.

In order to assist the laboratories with establishing their comprehensive safety programs and to further enhance the *culture of safety*, EHS has assigned a Safety Specialist to work with each PI, group of PIs sharing laboratory space, or a department or administrative unit on campus. This specialist will work closely with the PI and the Laboratory Safety Coordinator (LSC) to provide:

- Safety-related information;
- Act as a safety mentor for the LSC and others in the laboratory;
- Training;
- Technical expertise in safety;
- Review of Standard Operating Procedures (SOPs) for safety requirements;
- Assistance with the review of protocols submitted to the oversight committees (e.g., IBC);
- Interpretation of regulatory requirements;
- Performing period inspections and audits.

Appendix-I-C: User Certification Form

All individuals working in a laboratory are required to sign the following User Certification Form for each protocol submitted to the Oversight Committees in which they are a named participant.

I certify that:

- I have attended the required OEHS Laboratory Safety Training and refresher training.
- I have been provided training specific to the laboratory by the PI and LSC as well as any required agent specific training identified in the protocol.
- I have read and understood the protocol-specific safety requirements and the laboratory SOPs.
- I understand and will follow all laboratory safety procedures at all times.
- I will report any incidents or safety concerns to my supervisor immediately.

If you need additional information, please contact Research Safety at (617) 638-8830.

Note: Violations of health and safety requirements are considered as serious infractions that may result in suspension and/or termination of the protocol and/or an individual's privileges to work with hazardous materials.

First Name, MI	Last Name	Date	Signature

PI Certification:

All individuals in the laboratory have completed the required trainings listed above.

Signature: _____

Date: _____

Appendix- I-D: Institutional Biosafety Committee Oversight Program

As stated in Section-8, above, the Oversight Committees have established comprehensive oversight programs. The following is an example of the IBC oversight program as described in the Appendix U of the BU Biosafety Manual.

Oversight Program

Various regulatory agencies with oversight of research activities involving the use of etiologic agents or recombinant DNA, funding agencies, and BU and BMC policies require that a comprehensive, ongoing inspection and audit program be in place to review the compliance record of the users and the facility.

This includes:

- The review of procedures to ensure compliance with the terms of approved protocols (e.g., biological materials, animals);
- Inventory controls;
- General facility conditions;
- Training of individuals engaged in research;
- Other specific mandates required by the particular agency or IBC.

Oversight

The IBC has responsibility for the oversight program that will fall under one of the three broad categories defined below:

Inspections

Inspections are conducted because of a specific issue or concern and could be prompted by receipt of a complaint, request from a regulatory agency, or the Institutional Oversight Committee. All these instances will be investigated in accordance with the protocols established by IBC and the results will be reported to the IBC.

The IBC's chair or the vice chair and the Associate Vice President for Research Compliance (AVPRC) will be notified immediately at the initiation of any inspection. Upon notification, the IBC chair or vice chair will review the nature of the event leading to the investigation and determine whether any immediate action is required.

Such actions might include, but are not limited to:

- Establishment of a subcommittee to participate in the inspection or to discuss the violation before the next convened full committee meeting.
- Temporary suspension of activities or closure of the facility.
- Other actions as necessary.

Audits

Audits are part of the routine quality control program during which staff conduct ongoing audits of approved protocols.

The frequency, extent, and content of the audits will vary depending on the specific protocol being audited and will be developed by the IBC and the Biosafety Officer (BSO).

At the end of each audit, the staff will:

- Discuss their findings with the PI or the alternate responsible person named in the protocol when appropriate. The discussion will include any corrective actions needed.
- Send, within five working days, the PI or the alternate responsible person a written report describing any findings, corrective actions required, and the deadline for a written response.
- Determine, upon receipt of the responses from the PI, whether a follow-up visit is necessary to conclude the audit. In the event of failure by the PI to respond to the report in a timely manner, staff will contact the PI by phone or in person.
- Determine the type and severity of the findings and corrective actions taken.
- Report the findings to the committee.

Lab Review

Reviews are site visits conducted to observe certain procedures or activities and may be requested by the IBC or the PI. In general, the purpose of these reviews is to observe an activity (e.g., a PI is starting a procedure that he or she has not conducted before) and provide feedback to the IBC or a PI. Depending on the nature of the request, these reviews are often excellent forums for training and may or may not require a formal report to the IBC.

IBC Review and Enforcement

At the conclusion of an inspection or audit, the BSO, or designee, will report the findings to the IBC, or the subcommittee if one was appointed, for review and action. The report will include any corrective actions taken or in progress.

The IBC will review the findings and determine the appropriate corrective actions depending on a number of factors, such as the severity of the infractions, nature of the violation, or the history of PI and/or laboratory compliance.

In general, the IBC views the violations as:

- *Major deviations*: These have the potential for causing health or safety problems and may include deviations such as failure of monitoring; departure from approved protocol; use of unapproved biological agents; unauthorized removal of agents; repeat history of violations within the laboratory, etc.
- *Moderate Deviations*: These are those that are typically first-time deviations that are either major administrative deviations, or have a likelihood of causing minor health and safety problems and may include personnel qualified but not added to protocol, missing inventory records, quality control not performed in a timely manner, etc.
- *Minor Deviations*: These are generally of the type that are administrative in nature and have insignificant potential for causing health or safety problems and may include incomplete records.

Enforcement

In any category, the PI will be given a deadline to respond to the IBC report with an explanation of the reason for failure and plans for correction and/or protocol modification, as necessary.

Note: The PI has an opportunity to present his or her case to the full IBC should he or she so desire.

After review of the inspection report and the PI's response, and after reviewing the facts surrounding the violation, the IBC will take appropriate corrective action and may impose sanctions.

This action may range from, but is not limited to:

- Requiring more frequent laboratory inspections and/or monitoring;
- Mandated additional training;
- Requiring the PI and/or authorized users to retake the user certification test;
- Permanent termination of the protocol;
- Placing the PI on probation for a period;
- Removing certification of certain individuals who were responsible for a major violation including repeat offenders;
- Suspension of the approval of the protocol.*

** Only the IBC can authorize reinstatement. In making a finding regarding reinstatement, the IBC will consider the PI's corrective actions (taken or planned) and the results of an additional inspection.*

Note: The IBC and BSO have been given full authority to suspend any activity that is judged to be:

- Working on unapproved procedures, agents, or locations;
- A clear violation of the approved protocol or regulatory requirements;
- Have adverse health or environmental impacts.

Notification

At the initiation of any inspections, the following notifications must be made immediately:

- AVPRC, who will initiate any internal leadership or agency notification necessary;
- IBC chair or vice chair, who will determine immediate actions required;
- Occupational Health Officer, if there is a potential for employee exposure. The Occupational Health Officer will initiate relevant health agency notifications.

Appendix-I-E: BU Performance Appraisal form

Employee Name: _____ Job Title: _____
Evaluator Name: _____ Unit/Department: _____
Date of Appraisal: _____ Performance Evaluation Period: _____

PURPOSE OF PERFORMANCE APPRAISALS

The written performance appraisal is a formal assessment of the employee's job performance over a specified period of time based on performance expectations identified by the supervisor and shared with the employee. Informal performance assessment is an on-going aspect of effective supervision and communication and the written performance appraisal should not replace day-to-day supervision and communication.

Goals and Accomplishments

Did the employee achieve the goals as outlined in the prior year's evaluation? Yes ___ No ___

COMMENTS:

General Performance Categories

Exceeds Expectations: Employee's performance is clearly above average. Accomplishments are significant and above the standard of the job responsibilities

Meets Expectations: Employee's performance meets all essential job requirements. Accomplishments are in accordance with the standards of the position.

Below Expectations: Employee's performance requires some improvement to make full contribution to the department and job in order to meet the standards of the position.

Not Applicable: General performance category does not apply to position held by employee.

Performance Factors *				
	Exceeds Expectations	Meets Expectations	Below Expectations	Not Applicable
Job Knowledge				
Decision Making And Problem Solving				
Work Quality/Productivity				
Leadership				
Dependability				
Communication				
Interpersonal Relationships				
Safety				
OVERALL RATING				

Supervisor's comments:

Goals for next year:

Areas of improvement:

Supervisor's Signature _____ Date _____

Department Head or Designee's Signature _____ Date _____

Employee's Signature _____ Date _____

Performance Factors*

Job Knowledge

Understands job duties and responsibilities. Understands and adheres to the department's and University's policies and procedures.

Decision Making and Problem Solving

Demonstrates sound judgment in making decisions and solving problems. Gathers and analyzes relevant data and develops and implements workable solutions.

Work Quality/Productivity

Produces a sufficient volume of work to meet job requirements and meets deadlines. Demonstrates accuracy and thoroughness. Meets position and organizational objectives. Identifies ways to improve and promote quality. Applies feedback to improve performance. Monitors own work to ensure quality.

Leadership

Ability to motivate direct reports and others to fulfill unit goals and the University's mission. Develops and communicates a clear vision of the future environment and provides direction on what needs to be done to ensure long-term success. Champions methods, procedures, or systems that have the greatest potential for maximizing efficiency and effectiveness. Provides staff with specific feedback and coaching to improve performance and to assess development opportunities.

Dependability

Demonstrates dependability on the job and is responsive to the needs of the department. Schedules time off in advance, begins work on time, and keeps absences within guidelines. Ensures that work responsibilities are covered when absent. Arrives at meetings and appointments on time.

Communication

Demonstrates competence in expressing ideas verbally and in writing. Actively listens to suggestions and feedback from others and responds appropriately. Presents information clearly and concisely and is able to communicate effectively in all situations.

Interpersonal Relationships

Develops and maintains effective working relationships with colleagues, superiors, and, where appropriate, faculty, students, and external constituents. Demonstrates a professional demeanor at all times.

Safety

Adheres to safe practices when performing assigned tasks. Plans work procedures with safety concerns in mind and maintains a safe work environments. Actively supports a culture of safety and encourages others to do so. Attends training programs as appropriate. Recognizes and reports unsafe conditions and actively works to remedy them.

Appendix-I-F: Committee Membership

John Nash, *Co-Chair*
Chief Operating Officer
National Emerging Infectious Diseases Laboratories
Boston University

John Murphy, *Co-Chair*
Professor, Department of Medicine
Infectious Diseases Section

Ara Tahmassian, Ph.D.
Associate Vice President for Research Compliance
Boston University and Boston Medical Center

Greg Viglianti, Ph.D.
Associate Professor, Department of Microbiology
Boston University School of Medicine

Linda Hyman
Professor
Associate Provost, GMS

Katharine Bossart, Ph.D.
Research Assistant Professor, Department of
Microbiology
Boston University School of Medicine
Associate Director, Collaborative Core,
National Emerging Infectious Diseases Laboratories

Manuel Monteiro
Director, Human Resources
Boston University

Ron Morales
Director of Research Safety
Office of Environmental Health & Safety
Boston University

Frank Gibson
Associate Professor of Medicine
Section of Infectious Diseases
Past-Chair, IBC

Erika Geetter, Esq.
Office of the General Counsel
Boston University

John Tonkiss, Ph.D., SM (NRCM), CBSP
Associate Director High and Maximum Containment
Safety
National Emerging Infectious Diseases Laboratories
Boston University Medical Campus

Ellen Berlin
Director of Corporate Communications
Boston Medical Center/Boston University Medical
Campus

Larry Vintinner
Asst. Director for facility Management Operations
LASC Administration

Andrew Henderson
Associate Professor of Medicine
Infectious Diseases Section

George Snowdon
Director of Human Resources
Boston University Medical Campus

Celeste Rich
Lab Manager
Biochemistry

Sunyoung Oh
Post Doc Fellow
Pathology and Lab Medicine

Robert Moore
Ph.D Candidate
Boston University

Human Resources Subcommittee

John Nash
Manuel Monteiro
Erica Geetter
John Tonkiss

IBC Subcommittee

Andrew Henderson
Katherine Bossart
Greg Viglianti
Frank Gibson
John Murphy
John Tonkiss

Communications Subcommittee

Ellen Berlin
John Nash
Ron Morales
John Tonkiss

Mark S. Klempner, M.D.
Conrad Wesselhoeft Professor of Medicine
Director, National Emerging Infectious Diseases
Laboratories Institute Boston University Medical
Campus

Administrative Support: Tracy Bastien

Section-II: Implementation of the NEIDL Specific Recommendations

1. Introduction

In March 2010, a Task Force on Biosafety was appointed to review the safety program at Boston University and to make recommendations on how the *culture of safety* at BU can be enhanced. The task force recognized the enhanced importance of the *culture of safety* in the National Emerging Infectious Diseases Laboratory (NEIDL) and added a NEIDL Specific Addendum to its report issued on July 1, 2010.

A detailed implementation plan for the campus-wide recommendations described in Section-I, are also applicable to the NEIDL. This section establishes the additional or enhanced actions for the NEIDL Specific recommendations.

As the task force noted in its introduction to the addendum: “*while the recommendations in this report are applicable to all operations of the institution including the NEIDL; the Task force recognizes the need for more enhanced safety requirements at the NEIDL, which are contained in this Addendum. At the NEIDL, safety requirements apply to all individuals who enter the facility, including researchers, administrative staff, support staff (e.g. Public Safety, Facilities) as well as visitors and temporary contractors.*” The implementation of these recommendations will build upon the efforts that have been underway in preparing for the opening of the NEIDL and establish the *culture of safety* as a fully integrated component of the NEIDL activities.

The implementation plan has been developed following extensive discussions by the NEIDL leadership and follows the recommendations of the task force report’s addendum on the NEIDL and:

- Identifies the key recommendations of the task force;
- Action plan outlining measure to be taken for the implementation of the recommendation;
- A timeline for the implementation date;
- Matrices (where applicable) for measuring the success of the action plan.

The Associate Vice President for Research Compliance, in conjunction with the NEIDL leadership, will also establish a mechanism for the tracking of the implementation timelines and review of the matrices to ensure their timely implementation. This will include a comprehensive record of all corrective action plan details and procedures established for their implementation.

2. Role of the Leadership

Recommendation: The Task Force report states that “*While the culture of safety is the responsibility of each and every individual in the organization; the leadership of the institution, must particularly be engaged in and support the culture of safety...They must regularly and consistently communicate the importance of safety in their laboratories and demonstrate the value and respect they have for the safety of people who work under their supervision. This will help ensure that the culture of safety cascades down through the organization*”.

Action: The leadership of the NEIDL (i.e., the NEIDL Director, the Associate Directors, and the Core Directors) have fully embraced the importance of a *culture of safety* at the NEIDL and have continued this commitment and support during the design and construction of the facility as well as during the continuing preparation for the opening of the NEIDL. This commitment to safety is embedded in the mission of the NEIDL: “*To establish a research facility with the highest attention to community and laboratory safety and security.*”

The NEIDL leadership will continue to emphasize its commitment to safety at all times, specifically:

- All individuals working at the NEIDL are, and will continue to be, required to attend safety training before they start their activities at the NEIDL. This is extended to research staff as well as to the administrative and support personnel.
- Adherence to a *culture of safety* will be an integral part of the position descriptions and performance evaluation of the NEIDL staff.
- Safety will be incorporated into all operations as part of their Standard Operating Procedures (SOPs) and will be emphasized in all laboratory and other staff meetings.
- As part of the assessment of new hires, a *safety first* environment will also be a pre-employment hiring evaluation criteria.
- All offer letters will include a statement on the importance of the *culture of safety* at the NEIDL. The NEIDL offer letters currently state: “*By agreeing to this appointment you are acknowledging a personal commitment to participating in the NEIDL culture of safety initiative. This involves demonstrating an active commitment to ongoing safety initiatives and holding the culture of safety as a core value of your operations.*”
- Employee performance evaluations will include a specific section on the adherence to the *culture of safety*.

3. Safety Committee:

Recommendation: the Task Force recommended that in addition to the existing Oversight Committees (e.g. IBC, Laboratory Safety committee, Radiation safety Committee) the NEIDL should establish a Safety Committee. The Safety Committee should be responsible for advising the Leadership (BU and the NEIDL) and the Associate Vice President for Research Compliance on matters, which affect the safety of employees and the community at the NEIDL.

Action: The Associate Vice President for Research Compliance, in consultation with the BUMC Provost, will appoint a Safety Committee with representatives from various scientific and administrative cores to fulfill this recommendation. Appendix-II-A provides the details of the charge, reporting and operating procedures for the NEIDL Safety Committee.

4. The Chief Safety Officer (CSO)

Recommendation: The Task Force recommended that a position of Chief Safety Officer be established and given full responsibility for ensuring that all aspects of the safety programs at the NEIDL are being implemented and followed.

Action: With the full support of the NEIDL leadership, the Director of Research Safety is appointed as the Chief Safety Officer at NEIDL. The CSO, reporting to the Associate Vice President for Research Compliance also acts as the director of the NEIDL Environmental Health and Safety and Training Simulator Core. In addition, Associate Directors for Maximum Containment (BSL-4) and High Containment (BSL-3) have been appointed.

Appendix-II-B describes the roles and responsibilities of the CSO.

5. Laboratory Safety Coordinators

Recommendation: The Task Force Report has recommended that each PI appoint a Laboratory Safety Coordinator (LSC).

Action: Each NEIDL PI will be required to appoint a LSC. The LSC will work closely with the CSO and EHS in the implementation of the *culture of safety* at the NEIDL. PIs that share laboratory space may appoint a single LSC for their operations.

The roles and responsibilities of the LSC at NEIDL are outlined in Appendix-II-C and will be conveyed to the LSC in writing. The NEIDL leadership has determined that trainees may not serve as the LSC in any NEIDL laboratory.

6. Communication of the *Culture of Safety*

Recommendation: the Task Force highlighted the importance of communication as a key aspect of a successful implementation. It also recommended that the NEIDL employ a communications specialist to develop and implement a NEIDL specific strategic plan to communicate the safety program to researchers in the laboratories, support staff, trainees, and visitors on an ongoing basis.

Action: Corporate Communications has been participating to identify the audience(s), develop targeted messages, and deliver those messages using a variety of communication vehicles in a consistent, timely, and efficient manner. The specific role and activities of the Communication Specialist is described in Appendix-II-D.

7. Human Resources

Recommendation: the Task Force recommended that each NEIDL hire be required to sign a document indicating knowledge and acceptance that he/she will be working in a safety first environment and that any violations of safety procedures will be subject to review and disciplinary action.

Action: The current Boston University's Laboratory User Certification Form is modified for use at the NEIDL (see Appendix-E). The BU-wide form is used for laboratory personnel; however, due to the enhanced importance of safety at the NEIDL, the revised form applies to laboratory, support (e.g., facilities), and administrative employees at NEIDL.

Note: The NEIDL has defined the term "NEIDL hire" used by the task force as "each person who is hired to work, or is working, in the NEIDL, regardless of the actual source of hire (e.g. BU-CRC, BUMC, BMC, etc.)."

NEIDL offer letters include the following statement: "By agreeing to this appointment you are acknowledging a personal commitment to participating in the NEIDL culture of safety initiative. This involves demonstrating an active commitment to ongoing safety initiatives and holding the culture of safety as a core value of your operations."

- All current NEIDL employees are required to complete the User Certification Form.
- Faculty Promotions:
 - Faculty promotions are typically determined by the heads of departments and centers. NEIDL will be able to reflect upon a person's history of safety compliance and convey the information to the appropriate Department Chair or Center Director.
 - Provost of the Medical Campus has included adherence to a *culture of safety* and promoting and upholding a commitment to safety as an evaluation criteria for the BUMC deans, chairs, and center directors.

Recommendation: The Task Force recommended that job descriptions for NEIDL employees require a commitment to a safe laboratory environment as a primary responsibility. This commitment would be demonstrated by participation in safety training and practice, and compliance will be reflected in the individual's annual performance review.

Action: The AVPRC, working with Human Resources, will develop appropriate language that will be added to all job descriptions and performance evaluations for current and future NEIDL employees.

Recommendation: The committee recommends that if a NEIDL employee is involved in a laboratory incident that results from carelessness or a deliberate disregard for laboratory safety or security policy, that employee will lose his/her NEIDL laboratory or access (e.g. for support personnel) privileges and be remanded to the appropriate department or school for further action.

Action: The AVPRC working with the CSO, Public Safety, and the NEIDL leadership will implement this recommendation, when applicable.

8. Operations

Recommendation: The Task Force recommended that the Chief Safety Officer (CSO), or designee, review the safety requirements before the SOP is put into operation to ensure that adequate safety measures have been incorporated into the operations.

Action: This task is included as a responsibility of the CSO as described in Appendix-II-B and a sample SOP template is included in Appendix-II-F. All NEDIL SOPs must be submitted to the CSO, or his/her designee, for review and approval of safety related requirements.

9. Inspections and Reviews

Recommendation: The Task Force recommended that an enhanced inspection and review program be implemented in the NEIDL.

Action: The CSO will modify the existing BU oversight program to include both formal documented routine inspections in accordance with the policies and procedures developed by the oversight committees, as well as informal frequent walkthroughs of the laboratory areas to observe the adherence to safe practices.

Appendix-II-A: NEIDL Safety Committee

Introduction

The NEIDL, like other BU and BMC laboratories, has a responsibility to provide a safe and healthy work environment for faculty and staff and to protect the community from all potential hazards associated with its operations. To meet this obligation, in addition to the existing oversight committees (e.g., IBC, Laboratory Safety Committee, Radiation Safety Committee); the NEIDL is establishing a Safety Committee that will be responsible for the oversight of the safety issues at NEIDL.

Charge of the NEIDL Safety Committee

The NEIDL Safety Committee is responsible for representing the safety concerns of the NEIDL employees; reviewing the safety activities at the NEIDL; and for providing oversight of the ongoing development and management of the *culture of safety*.

The NEIDL Safety Committee augments the activities of the existing BU oversight committees and recommends additional safety policies for review and approval by the NEIDL leadership to enhance the current safety programs at the NEIDL.

The specific charge to the committee includes:

- Evaluation, monitoring, and analysis of safety issues intended to reduce the risk of personnel injury and property damage in the NEIDL.
- Review and investigation of safety and health issues raised by NEIDL employees or administrators, and recommending solutions for these issues as well as follow-up and reporting for compliance.
- Review reports of potential physical hazards and practices, injuries or illnesses, and actual losses, and make recommendations for actions as well as follow-up and reporting.
- Review the results of routine inspections and walkthroughs conducted in the NEIDL; evaluate the efficacy of the safety measures in place; and recommend strategies for any enhancements needed.
- Initiating and overseeing regularly scheduled emergency and evacuation drills.
- Other safety-related issues that the committee deems appropriate for review.

Members of the NEIDL Safety Committee act as a:

- Liaison between the committee and their constituent groups.
- Resource for training, explanation of safety requirements, and a means for communicating Safety Committee activities and other information to members of their constituent groups.

Subcommittees

The chair of the NEIDL Safety Committee may appoint permanent or ad hoc subcommittees to focus on specific issues. Permanent subcommittees will operate in the same manner as the NEIDL Safety Committee with similar recordkeeping requirements and will forward their minutes and reports to the chair for inclusion on the agenda of the NEIDL Safety Committee.

Due to the importance of safety for BSL-3 and BSL-4 research, permanent safety subcommittees will be appointed for each group. These subcommittees will be chaired by a PI from BSL-3 and BSL-4 laboratories respectively and its membership will include all LSC, representatives of other research staff from the respective BSL groups, CSO, and the support staff (e.g., animal core, facilities). The subcommittees will provide their reports and updates to the NEIDL Safety Committee, as described above.

Membership

- The NEIDL Safety Committee will include representatives of the NEIDL leadership, scientific, and administrative cores with each core director nominating one member from their core for the membership of the NEIDL Safety Committee.
- The Chief Safety Officer will be the chair of the NEIDL Safety Committee
- Additional permanent or ad hoc members from the BU or BMC community will be appointed.

Ex-Officio Member: The NEIDL Director is an ex-officio member of the NEIDL Safety Committee.

The NEIDL Safety Committee reports to the Associate Vice President for Research Compliance who, in consultation with the BUMC Provost, will make the final membership appointments.

Meetings

The NEIDL Safety Committee will meet monthly, and immediately in the event of a safety event. The chair may also call for meetings that are more frequent if the circumstances require.

Record Keeping

The Safety Committee will maintain written records of its activities, including:

- Agenda items.
- Minutes of its meetings that include:
 - A summary of the discussions;
 - Its findings; and,
 - Action items including:
 - The individual(s) responsible for the action items;
 - Timelines for completion; and,
 - Date completed.

The committee will forward a copy of its minutes and action items to the BUMC Provost and the Associate Vice President for Research Compliance.

The membership and the date, time, and location of the Safety Committee meetings will be distributed to the members of the NEIDL community.

Authority

The NEIDL Safety Committee has full responsibility for the oversight of safety at the NEIDL and has the authority to suspend any operations that it deems unsafe or to remove the access privileges of any individual pending a full investigation.

NEIDL Operations Committee

In addition to the NEIDL Safety Committee, an Operations Committee has been appointed which is responsible for the review of safety-related issues on a daily basis. The role of the committee is to review facility, security, equipment, and operational aspects of maximum and high containment operations each day and determine whether there are issues that must be resolved prior to start of any work.

Membership

The membership of the NEIDL Operations Committee:

NEIDL Director
Chief Safety Officer
Maximum Containment Safety Officer
High Containment Safety Officer
Director of NEDIL Facilities Core

Authority

Each member of the committee has the authority to stop an operation that in his or her opinion presents a safety risk.

Appendix-II-B: Roles and Responsibilities of the NEIDL Chief Safety Officer

The Boston University Director of Research Safety, reporting to the Associate Vice President for Research Compliance, is the individual responsible for all aspects of health and safety for the research community at Boston University (BU) and Boston Medical Center (BMC). This individual also acts as the Chief Safety Officer (CSO) for the NEIDL with overall responsibility for the NEIDL health and safety programs.

The CSO is also the director of the NEIDL Environmental Health and Safety and Training Simulator Core.

Note: The CSO has direct access to the BUMC Provost for reporting of safety-related issues.

Responsibilities

Working closely with the research and administrative cores and BU Oversight Committees, the CSO is responsible for:

- Fostering and implementing a *culture of safety* at the NEIDL in a manner that recognizes safety as a top priority at the NEIDL.
- Acting as the regulatory subject matter expert and providing analysis of the local, state, and federal regulatory requirements and their impact on the NEIDL.
- Acting as the liaison between the NEIDL Safety Committee and BU Oversight Committees.
- Acting as a liaison between the NEIDL and regulatory agencies (e.g., BPHC, CDC, BED, etc.).
- Acting as the Responsible Official (RO) for the purpose of the CDC Select Agent Registration and oversight.
- Reviewing and approving all Standard Operating Procedures (SOPs) to ensure that all operations have incorporated adequate safety measures. CSO may delegate the review of SOPs to other Health and Safety Core members with expertise to review such matters.
- Working with the NEIDL leadership and Safety Committee, establishes goals, strategies, plans, rules, procedures, and programs to improve the *culture of safety* throughout the NEIDL.
- Developing matrices for various safety activities within the NEIDL and providing regular reports of these activities to the Safety Committee.
- Reporting all accidents and near misses to the Associate Vice President for Research Compliance and NEIDL Director, and participating in all accident and near miss investigations.
- Overseeing the implementation of any corrective actions or programmatic changes, recommended by any Independent Accident Review Committees appointed to review accidents.
- Chairing the NEIDL Safety Committee.
- Overseeing the safety inspections, compliance audits and surveys, and acting as a liaison with regulatory agencies.
- Overseeing all safety trainings, emergency drills, and safety awareness campaigns.

Qualifications

- Minimum requirement is a B.S. degree in occupational safety, microbiology, general sciences, or a related field.
- Extensive work experience in occupational health and safety or environmental health in a research-intensive university with at the minimum both select and non-select agents at the BSL-3 level.
- Experience in effectively establishing a *culture of safety*.

- Certification in a related field.
- Demonstrated written and verbal communication skills.
- Must have extensive knowledge of local, state, and federal regulations governing health and safety.
- Must have proven record of working with all levels of employees (e.g., faculty, staff, students, senior leadership) internal to the institution as well as external vendors and regulatory agencies.
- Must be able to effectively prioritize own work as well as the work of other staff members in order to accomplish the objectives of the office.
- Excellent communication, management, analytical, and technical skills.
- The ability to use independent judgment throughout at any hour, day or night, to respond to requests, and provide assistance by making decisions and assigning the follow-up actions of those decisions.
- The nature of this position requires an understanding of the different components of the NEIDL, the University, and the BMC in order to maintain a high level of service.
- Extensive managerial or supervisory experience, including performing performance evaluations, developing staff training, and monitoring performance of staff.

Authority

The CSO has full authority to:

- Temporarily suspend any operations, construction, or maintenance activities that in his/her professional judgment are deemed to present an imminent health and safety hazard or are in violation of regulatory requirements or NEIDL policies.
- The CSO may remove the privileges of an individual to work with hazardous materials whose activities in his/her professional judgment are deemed to present an imminent health and safety hazard or are in violation of regulatory requirements or NEIDL policies.
- Direct appropriate personnel, whether directly reporting to him/her or not, to take immediate corrective actions to rectify any potentially unsafe conditions.
- The CSO will immediately notify the NEIDL director and the AVPRC of any suspension of an activity or removal of individuals' privileges and convene an emergency meeting of the NEIDL Safety Committee to review the actions taken and their circumstances.

The AVPRC, based on the circumstances of the issue and the input from the NEIDL Safety Committee, will decide on whether the action should be reviewed by:

- An independent review committee;
- The NEIDL Safety Committee; or,
- A BU oversight committee (e.g. IBC).

In addition to the CSO, who has overall responsibility for the safety at the NEIDL, two experienced individuals have been specifically appointed as Maximum Containment (BSL-4) and High Containment (BSL-3) Safety Officers.

Appendix-II-C: Role of Laboratory Safety Coordinator (LSC) at the NEIDL

While the Principal Investigators (PIs) bear the full responsibility for health and safety in their laboratories and the activities performed, the Task Force on Biosafety recommended that each PI designate a knowledgeable individual to act as the LSC for day-to-day operations.

The LSC will serve a critical function in the overall *culture of safety* and for the monitoring of safety practice at the NEIDL laboratories. Therefore, each NEIDL PI must appoint an LSC and identify the specific responsibilities, including those listed below, that he/she is delegating to the laboratory LSC *in writing*.

The following are key requirements for the individuals who are designated as the LSC:

- The LSC has the responsibility and authority to represent the PI in matters related to the implementation of laboratory and worker safety, and to work in concert with the CSO on safety issues in the laboratory.
- To fulfill their role, the LSC must be an individual who is working at the NEIDL and who is knowledgeable in laboratory operations and relevant safety requirements.
- In the NEIDL, any individual who is listed under a training position will not be eligible to act as an LSC.
- Because of the special safety considerations of the NEIDL, the PI for BSL-3 and BSL-4 laboratories must act as the LSC.
- The LSC will serve as the primary laboratory contact with EHS for issues related to safety, including chemical hygiene, biological, and radioactive materials.
- While the day-to-day implementation of applicable policies and directives related to safety will be the responsibility of the LSC, *the ultimate responsibility for this implementation rests solely with the PI*. The LSC is responsible for assuring that all laboratory personnel and operations comply with applicable requirements. These include:
 - Taking action to determine and reduce, to as low as reasonably achievable, the potential for accidents and incidents associated with laboratory operations.
 - Informing all laboratory personnel of the safety hazards associated with their work.
 - Instructing all laboratory personnel in safe work methods.
 - Reporting all accidents, near misses, or safety concerns to the PI and CSO.
 - Keeping all individuals that perform specific tasks apprised of the most recent procedures and ensuring that they are appropriately trained.
 - Ensuring that all work is performed in a safe manner and in accordance with approved SOPs as well as the regulatory and institutional requirements.
 - Working with CSO, or his/her designee, to determine best safe practices and procedures.

- Working with CSO, or his/her designee, to ensure that all members of the laboratory complete all required training(s) in a timely manner.
- Ensuring that all deficiencies identified by EHS or outside regulatory inspectors are addressed and corrected within the time required.
- Ensuring that the Standard Operating Procedures (SOPs) for all laboratory procedures are approved and are current; that SOPs include appropriate safety instructions related to the use of personnel protective equipment (see Appendix-D for template); special precautions for any infectious agents or highly hazardous chemicals are implemented; and instructions to perform procedures with appropriate safety equipment such as a fume hood, biological safety cabinet, or sealed centrifuge are followed.
- Participation in the incident review process.

The PI must inform the laboratory employees that the LSC has the authority to stop operations that are in clear violation of the safety requirements, approved SOPs, or, in the professional judgment of the LSC, may result in injuries or potential exposures.

Appendix-II-D: NEIDL Communication Specialist

The Task Force on Biosafety Report stated that effective communication is a key factor in the success in the development, implementation, and maintenance of a *culture of safety*. The NEIDL Communications Specialist will perform the key functions surrounding the development of a strategic communication plan.

The individual, working with the NEIDL leadership will be responsible for:

- Keeping NEIDL employees up to date with safety news by means of designing, composing, editing, and producing publications such as newsletters, leaflets, and brochures as well as other media, on the NEIDL *culture of safety* and its importance.
- Assisting with and/or writing news releases and articles related to the *culture of safety* at the NEIDL.
- Coordinating NEIDL communication on the *culture of safety* with those of the BU community.
- Assisting in the development of protocols for reporting incidents to the internal audience at the NEIDL, as well as the outside community, including neighborhood associations and the press.

The individual, working with the CSO, NEIDL leadership, and Corporate Communications, will develop and present a communication plan for review and adoption that includes:

- Developing safety communication objectives and communication plans.
- Identifying internal and external constituencies and deciding what to communicate to each group and the best forms of communication for each.
- Publicizing the importance of safety at the NEIDL through various outlets.
- Developing strategies for enhancing the training and informational programs to emphasize:
 - The NEIDL *culture of safety* where elimination of fear of reporting incidents, near misses, and unsafe trends pervades.
 - The need for compliance with all safety policies,
- Creating an environment where all staff members collaborate in sharing best safety practices.

Appendix-II-E: NEIDL Employee Certification Form

If you need additional information, please contact the Chief Safety Officer at (617) 638-8830.

All NEIDL employees are required to complete a NEIDL Employee Certification Form before they start their duties, and annually thereafter.

Certification

By signing this form, I certify that (Please check Box A or B, as appropriate):

A. ___ For Laboratory Workers:

- I have attended all required EHS NEIDL-specific Laboratory Safety Training and refresher trainings;
- I have been provided training specific to the laboratory by the PI and LSC as well as any required agent specific training identified in the protocol;
- I have read and understood the protocol-specific safety requirements and the laboratory SOPs;
- I understand and will follow all laboratory safety and security procedures at all times;
- I understand that at the NEIDL I will be working in a *safety-first environment* and will follow all laboratory safety procedures at all times;
- *I understand that at the NEIDL any violations of health and safety requirements are considered as serious infractions that may result in:*
 - *Suspension and/or termination of the research protocol, or my privileges to access the NEIDL or to work with hazardous materials.*
 - *Disciplinary action, including permanent termination of my privileges or employment.*
- I will report any incidents or safety concerns to my supervisor immediately.

B. ___ For Non-Laboratory Workers:

- I have attended the required EHS NEIDL-specific Safety Training and refresher trainings appropriate for my job;
- I have been provided training specific to my job by my supervisor;
- I understand and will follow all safety and security procedures at all times;
- I understand that at the NEIDL I will be working in a *safety first* environment and will follow all safety procedures at all times.
- *I understand that at the NEIDL any violations of health and safety requirements are considered as serious infractions that may result in:*
 - *Suspension or termination of my privileges to access the NEIDL; or,*
 - *Disciplinary action, including permanent termination of my privileges or employment.*
- I will report any incidents or safety concerns to my supervisor immediately.

First Name, MI	Last Name	Core	Date	Signature

PI Certification: This is to certify that all individuals have completed the training requirements described above.

Signature: _____

Date: _____

Appendix-II-F: Standard Operating Template

Standard Operating Procedures (SOPs) are documents that describe how to perform various routine operations by providing a set of standard systematic procedures for a given activity. At the NEIDL, development of SOPs is a requirement of approval process for any operations. The standard template provided below is used for this purpose.

Unit:	SOP #:
	Revision #:
	Current Version Implementation Date:
Page #: Page X of Y	Last Reviewed/Update Date:
Expiration Date:	Approval Authority:

1. Purpose and Scope
2. References
 - 2.1. Regulations
 - 2.2. Other SOP
 - 2.3. Supplementary Documents
3. Definitions
4. Roles & Responsibilities
5. Special Requirements
 - 5.1. Equipment and Supplies Required
 - 5.2. Safety Requirements
 - 5.3. Training
 - 5.4. Monitoring Requirements

5.5. Personnel Protective Equipment (PPE)

5.6. Medical Surveillance

5.7. Other Prerequisites

6. Applicable Locations

7. Procedures and Instructions

8. Forms

9. Records Management

10. SOP Revision History

Version	Section / Paragraph Changed	Changes Made	Effective Date
V.1	N/A	None, Original Version	