

## SCOPE OF WORK

### SUPPLEMENTAL RISK ANALYSES AND REPORTS ON THE OPERATION OF THE BOSTON UNIVERSITY MEDICAL CENTER NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES

*TASK ORDER NO. 0005*  
*CONTRACT NO. W91278-09-D-0096*

11 December 2009

**1.0 BACKGROUND:** The National Institutes of Health (NIH) is conducting additional risk analyses and site comparisons to supplement impact analyses previously completed for the siting, construction, and operation of the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University Medical Center. The NEIDL Risk Assessment (RA) Report will characterize the relative risks for each of the three (3) potential sites and will analyze the relative risks across those sites. The areas for risk analyses for site comparisons are: (1) Boston University Medical Center, BioSquare Research Park, Boston, Massachusetts; (2) the former Boston University Corporate Education Center, Tyngsborough, Massachusetts; and (3) Boston University Sargent Center for Outdoor Education, Peterborough, New Hampshire.

**2.0 SCOPE OF WORK:** This Scope of Work (SOW) is for the Architect-Engineer (A-E) or Tetra Tech Inc. to provide additional effort, expertise, technical, and administrative support in the preparation of additional risk analyses and site comparisons for the Boston University Medical Center NEIDL in Boston, Massachusetts as specified in **Enclosure 1**. These additional risk analyses will assess potential risks and public health consequences of accidental and malevolent releases of infectious agents and exposure to infectious agents in urban versus less populated locations.

**3.0 OBJECTIVE:** The principal objective of this effort is to provide the NIH with an RA Report that is an objective appraisal of the potential risks and public health consequences of accidental and malevolent releases of infectious agents and exposure to infectious agents in urban versus less populated locations.

The RA Report shall comply fully with NIH requirements, both procedurally and analytically, and is intended to be sufficient to withstand a challenge in Federal court. The NIH is the customer, but the U.S. Army Corps of Engineers (USACE), Mobile District will be designated as the "Government" in this SOW. USACE, Mobile District will assist the NIH to monitor, review, guide, and approve the A-E's work products.

**4.0 DESCRIPTION OF WORK AND SERVICES (Risk Analyses):** **Enclosure 1** describes the work and services specified by this SOW for preparation of additional risk analyses and site comparisons.

## ENCLOSURE 1

### DESCRIPTION OF WORK AND SERVICES

#### 1.0 INTRODUCTION:

(a) Management/Approval. The National Institutes of Health (NIH) has continued to designate the U.S. Army Corps of Engineers (USACE), Mobile District to contract for and assist with the continued oversight of the risk analyses preparation of the Risk Assessment (RA) Report. Tasks associated with this Scope of Work (SOW) supplement those included in another Task Order and Modification. The Architect-Engineer (A-E), also referred in this SOW as Tetra Tech Inc. will take contractual guidance from the USACE, Mobile District. Both the A-E and USACE, Mobile District work for NIH.

(b) Previous Contract, Task Order, and Scope of Work. Contract No. W91278-08-D-0017, Task Order No. 0015, was awarded in August 2008, Modification was awarded in April 2009, and these SOW requirements remain in effect except where specified in this SOW.

(c) Labor, Materials and Equipment. The A-E shall furnish all labor, materials, plant, equipment, and transportation (including mail or facsimile fees) to perform all work and services in accordance with the requirements of this SOW.

(d) Data Management. All data, reports, and materials contained or developed in this project will not be released to the public without written approval from NIH and USACE, Mobile District technical manager(s).

#### 2.0 METHODOLOGY DEVELOPMENT:

Below is the description of the additional services to be conducted for the National Emerging Infectious Diseases Laboratories (NEIDL) RA Report.

Quality Assurance and Quality Control (QA/QC). The A-E will conduct QA/QC for all Section 3.0 SERVICES REQUIRED as stated below in accordance with the provisions outlined in the following:

(a) Contract No. W91278-09-D-0096, this Task Order, dated December 2010 (see SOW, Section 11.0, Paragraph (c));

(b) Final Risk Assessment Work Plan (includes reference to Tetra Tech's QA/QC Plan), dated February 26, 2009, Section 8.2; and

(c) Contract No. W91278-08-D-0017, Task Order 0015, dated August 2008 (see SOW, Section 12.0, Paragraph (c)).

The A-E has complete responsibility for the professional quality, technical accuracy, and coordination of all work or materials produced and furnished by the A-E's in-house or consultant's forces. If determined by NIH and USACE, Mobile District that QA/QC has not been sufficiently completed, the A-E shall correct or revise any errors or deficiencies in the A-E's work, notwithstanding any review, approval, acceptance, or payment by the NIH and/or USACE, Mobile District.

### **3.0 SERVICES REQUIRED:**

**TASK 1. Prepare a Project Schedule.** The A-E shall prepare and submit a Draft Project Schedule **10 working days** after receipt of the Notice to Proceed. NIH and USACE, Mobile District will then have **5 working days** for review and approval or request changes to the draft schedule. The schedule will specify dates for all bi-weekly technical working group progress calls, technical working group meetings, data collection meetings/workshops, and conference calls, deliverables and comment responses (i.e., three (3) bundled deliverables as described in Task 2 below). This schedule will be used by the A-E to manage work on the project and by the Government to monitor the progress of work on a regular basis. The schedule will also include specific dates that demonstrate when milestones will be met. A copy of the schedule, with any revisions or updates, and status of the project milestones will be presented in the monthly progress reports.

*(NOTE: The estimated cost for this task should be captured in the estimated costs for Tasks 2-8.)*

Deliverables for Task 1: An electronic copy of the Draft and Final Project Schedule for the NIH and USACE, Mobile District.

**TASK 2. Risk Assessment (RA) Report Deliverables.** The A-E shall provide 12 Chapters (organized as identified in **Exhibit 1**) and approximately 12-15 Appendices (in the 89% Check Copy Draft Final).

- (a) The A-E will bundle chapter deliverables for review by NIH and USACE, Mobile District.
- (b) In order to maintain continuity NIH will assign and coordinate a joint NIH/Boston University review team for the entire A-E/NIH review process of all deliverables. The NIH Review team may include non-NIH personnel designated by NIH.
- (c) The NIH and USACE, Mobile District shall provide all comments in writing within the specified review/comment period in the provided Comment Response Matrix. Any additional review/comment time may result in schedule slippage.
- (d) The A-E will provide all 12.0 Chapters and their Appendices as the 89% Check Copy Draft Final. There will be one (1) comment period on this deliverable. *(NOTE: A comment period*

will also occur with the deliverable, 90% Check Copy Draft Final.)

(e) The A-E will provide all responses to comments in the Comment Response Matrix within **10 working days** after receipt.

(f) All resolved comments will be incorporated into the document at the 90% Check Copy Draft Final document stage (as defined in Contract No. W91278-08-D-0017, Task Order 0015, dated August 2008).

(g) Any additional comment resolution and/or additional drafts of any given chapter (which meet the Tetra Tech Inc. QA/QC requirement) will be considered out of scope and will require a modification to this Task Order.

*(NOTE: The deliverables of Contract No. W91278-08-D-0017, Task Order 0015, dated August 2008 will continue to be prepared in accordance with the original Task Order once the 89% Check Copy Draft Final RA Report has been delivered and approved by NIH and USACE, Mobile District. These tasks include the following: (1) Prepare 90% Check Copy Draft Final RA Report and 90% Draft Final RA Report, and Attend and Participate in a RA Public Meeting; (2) Prepare 100% Check Copy Final RA Report [including the Executive Summary]; and (3) Prepare 100% Final RA Report [includes Updated "Report on Biosafety BSL-3 and BSL-4 Laboratories" by Karl M. Johnson, MD].)*

Deliverables for Task 2: The A-E will provide deliverables in three (3) bundles. The three (3) bundles will contain the following:

- Bundle 1 will include Chapters 1.0, 2.0, 3.0, and 6.0;
- Bundle 2 will include Chapters 5.0 and 9.0; and
- Bundle 3 will include Chapters 4.0, 7.0, 8.0, 10.0, 11.0, and 12.0.

All bundles will be delivered as identified in the Project Schedule, Task 1. The order in which the bundles are delivered could change based upon data needs, analysis, and coordination of like chapters. NIH and USACE, Mobile District must approve all changes to the contents of the bundles.

The A-E will provide the deliverables in electronic form via email, with two (2) hard copies for the NIH and two (2) hard copies for the USACE, Mobile District. The NIH shall have **ten (10) working days** to review and comment on each bundle. **Ten (10) working days** after receipt of comments the A-E will conduct one (1) telephonic In-progress Review with the NIH Review team and USACE, Mobile District.

### **TASK 3. Data Collection Meetings/Workshops and Progress Calls.**

(a) Data Collection Meetings/Workshops. The A-E will participate in three (3) meetings and/or workshops as described below:

(1) Team Lead Work Session with Boston University subject matter experts in Santa Fe, New Mexico.

(a) The A-E will review plans, policy, procedures, safety information relating to the NEIDL for accuracy, consistency, and currency.

(b) Items previously provided were not current to the state of the facility, Standard Operating Procedures are not developed, etc.

(2) On-site data collection meeting at Boston University Medical Center.

(a) The A-E will conduct a meeting for the development of site characteristics, building overview, and tour of current facility setting.

(3) Team Lead Workshop at Boston University Medical Center.

(a) The A-E will conduct a three-day meeting at Boston University Medical Center. The A-E will provide up to five (5) attendees.

(b) The meeting will be designed to clarify NEIDL policy, procedure, practices, and design.

(c) These workshops are intended to reduce the need for teleconferences for verification and consensus of calculation package and accident/pathogen pairing documents.

(d) In the event that information is not fully clarified, follow-up conference calls will be conducted by the A-E to obtain clarification.

(b) Progress Calls.

The A-E will conduct approximately 11 progress calls with NIH and USACE, Mobile District to determine the path forward for the development and collection of project required data from Boston University i.e. HVAC and ventilation system, uninterrupted power supply, emergency diesel generators (EDG), and spill response, liquid and solid waste, centrifuges, BSCs communication and alarms, Institutional Biosafety Committee (IBC) and source term concentrations, and verification and consensus of calculation package/accident/pathogen pairing documents, etc.

Deliverables for Task 3:

(a) Data Collection Meetings/Workshops. The A-E shall participate in three (3) meetings/workshops at Santa Fe, Boston University Medical Center, and Boston University with NIH and USACE, Mobile District. The A-E is responsible for meeting/workshop preparation, materials, as well as developing draft and final meeting/workshop minutes. The A-E shall

prepare and submit minutes electronically within **5 working days** to the NIH and USACE, Mobile District.

(b) Progress Calls. The A-E shall participate in approximately 11 progress calls with NIH and USACE, Mobile District. The A-E is responsible for call scheduling, notifications, call preparation, materials, as well as developing draft and final conference call minutes. The A-E shall prepare and submit minutes electronically within **5 working days** to the NIH and USACE, Mobile District.

**TASK 4. Technical Working Group Meetings and Bi-weekly Technical Working Group Progress Calls.** The A-E will participate in four (4) Technical Working Group Meetings and approximately 27 Bi-weekly Technical Working Group Progress Calls with NIH and USACE, Mobile District.

(a) Technical Working Group Meetings.

(1) In conjunction with the Bi-weekly Technical Working Group Progress Calls, the A-E will hold four (4) one (1) day face-to-face Technical Working Group Meetings with NIH and USACE, Mobile District. These meetings will be held at the University of Utah or agreed upon alternative site every six (6) weeks. Though at this time it is difficult to determine the exact nature of the upcoming meetings, it is assumed that they will be held in conjunction with the two previous/two upcoming Bi-weekly Technical Working Group Progress Calls.

(2) The A-E will have in attendance, depending on the subject matter, at least four (4) of the technical working group (project manager, RA, Modeling, and Human Health and Ecology [HH&E] team leads or their designees).

(3) Extensions to the schedule may require additional technical working group meetings. Additional meetings will be considered out of scope and will require a modification to this Task Order.

(b) Bi-weekly Technical Working Group Progress Calls.

(1) During preparation of the RA the A-E will conduct approximately 27 Bi-weekly Technical Working Group Progress Calls with NIH and USACE, Mobile District. The exact subject matter of these upcoming calls is unknown at this time; however, the purpose of the calls will be based on the current data gathering effort, analytical needs, development of deliverable documents, review and comment response or as needed items develop which need group discussion or consensus.

(2) The A-E attendees, depending on the subject matter, will include at least four (4) of the technical working group present (project manager, RA, Modeling, and HH&E Team leads or their designees), as well as an administrative assistant.

(3) Additional calls will be considered out of scope and will require a modification to this Task Order.

Deliverables for Task 4:

(a) Technical Working Group Meetings. The A-E shall conduct four (4) meetings/workshops at the University of Utah or other agreed upon location with NIH and USACE, Mobile District. The A-E is responsible for meeting/workshop preparation, materials, as well as developing draft and final meeting/workshop minutes. The A-E shall prepare and submit minutes electronically within **5 working days** to the NIH and USACE, Mobile District.

(b) Bi-weekly Technical Working Group Progress Calls. The A-E shall participate in approximately 27 progress calls with NIH and USACE, Mobile District. The A-E is responsible for call preparation, materials, as well as developing draft and final progress call minutes. The A-E shall prepare and submit minutes electronically within **5 working days** to the NIH and USACE, Mobile District.

**TASK 5. Risk Assessment/Accident Analysis.**

The A-E (risk team in collaboration with the HH&E and Modeling teams) will develop the accident-pathogen pairings for each exposure pathways (i.e., inhalation, ingestion, puncture/bite, and direct contact) for each type of exposed person (i.e., the lab worker, facility worker, or member of the public) in order to provide basis for the bounding analysis.

(a) The A-E will identify and develop candidate accident scenarios for each exposure pathway, exposed group, and pathogen.

(b) The A-E will select the bounding consequence (e.g., probable number of people infected, etc.) scenario for each exposure pathway and exposed group from the list of candidate accidents. An example of the process would be: for inhalation exposure for a lab worker, the selection will include such factors as the airborne release factor for various types of accidents (e.g., centrifuge, dropped container, etc.), as well as the quantity of organisms at risk for various pathogens. It is anticipated that the number of bounding scenarios selected at this point will be less than (4 pathways x 3 groups x “worst” pathogen = 12) since it is anticipated that some of the selected scenarios will cover more than one cell of the pathway-person matrix.

(c) Based on results of the above steps and the matching of the accidents with specific pathogens, the A-E will (1) determine if there are unique attributes of any pathogens that warrant addition of unique accident scenarios and (2) if so, additional scenarios will be added to ensure that the scenarios selected adequately address each pathogen. It is expected that additional scenarios will need to be added based on these results such that the final number of accident-pathogen pairs will be 12 or more.

(d) The A-E will then consider non-human environmental effects and confirm that the scenarios selected from the previous steps adequately consider potential impacts. Additional scenarios will be added as appropriate.

(e) The A-E will document the increased number of assumptions, underlying data, scenarios, containment elements, etc.

(f) The A-E will accomplish this task by also adhering to the supporting information included in **Exhibit 2**, The Effect of Accident-Pathogen Pairing for Additional Pathogens.

Deliverables for Task 5: The A-E will submit this analysis as Chapter 4.0 Accident Sequence Analysis and Appendices G: Details of Accident Identification and Details of Accident Selection and Appendix H: Details of Accident Sequence and Exposure Analyses. See additional information above in Task 2, Deliverables for Task 2.

### **TASK 6. Quantitative Health Effects Analysis I (Estimates of Initial Infections and Death) and II (Mathematical Modeling of Transmission).**

(a) Estimates of Initial Infections and Death. The health effects and transmission modeling (HH&E/University of Utah) teams will generate estimates of initial infections and deaths for each accident, group of persons, and pathogen. These estimates of health consequences will be developed using the estimated frequency and amounts of releases developed by the A-E team and defensible estimates of human ID50 and case-fatality rates. It is anticipated that deriving such estimates will involve a combination of standard approaches to synthesizing literature and summarizing expert opinion, and that reporting will take the form of tables.

(b) Mathematical Modeling of Transmission. The University of Utah Modeling team will take additional steps to ensure that the pathogens initially selected for modeling are sufficient (i.e., that additional pathogens should not be modeled). The core of this effort will be additional critical literature review for the nine (9) pathogens for which transmission modeling was not originally planned (note that the four for which modeling was planned are SARS virus, 1918 influenza virus, *Yersinia pestis*, and Rift Valley fever virus).

(1) The A-E will conduct a literature search for mathematical models associated with other 9 pathogens (Ebola virus, Marburg virus, Andes Hantavirus, Lassa fever virus, Junin HF virus, *Francisella tularensis*, Tick-borne encephalitis (RSSE) virus, Nipah virus, and *Bacillus anthracis*).

(2) The A-E will conduct a literature synthesis and an assessment of parameter uncertainty based on this synthesis.

(3) The A-E will prepare written justification for the level of detail of modeling attempted for each pathogen. This will include specific justification for not attempting detailed modeling for pathogens with inadequate epidemiological data or uncertain parameters. This will include comparisons among those pathogens with detailed models and those without (e.g., the A-E will

attempt a detailed model for ebola and compare that to a similar pathogen such as Marburg, which is not anticipated to be fully modeled, etc.).

(4) Additional mathematical modeling beyond originally planned four (4) pathogens.

(a) The A-E will conduct a full modeling attempt for Ebola virus (i.e., construct model, properly quantify parameters from literature, run simulations, analyze results, write up interpretation and graphical output, interface with quantitative accident / threat analysis, full uncertainty and sensitivity analysis).

(b) The A-E will model for Andes Hantavirus only if the literature search reveals promising approaches that are likely to be fundamentally different from other pathogens already modeled.

(c) The A-E will only conduct limited modeling effort for other pathogens, if deemed appropriate after the literature search.

Deliverables for Task 6: The A-E will submit this analysis as Chapter 7.0: Quantitative Health Effects I – Initial Infections and Fatalities and Appendix J: Quantitative Health Effects Analysis and Chapter 8.0: Quantitative Health Effects II – Transmission Modeling of Secondary Infections and Fatalities and Appendix K: Splitting Out of Appendix I. See additional information above in Task 2, Deliverables for Task 2.

### **TASK 7. Transportation Analysis.**

(a) Route Analysis. The A-E will conduct an evaluation of the viable transportation routes and modes of entry into downtown Boston (e.g. via Boston Logan International Airport, intermodal transit along Interstate 95 etc.), and ultimately into the existing NEIDL facilities, as well as to the other two specified locations. Department of Transportation data on biohazard transport will be used to the greatest extent possible, however, standard transportation accident rates will be used where biohazard data are not available. The fraction of the total distance in urban, suburban, and rural setting will be provided to the A-E. It is anticipated that air transport will be the common means of transport to Boston from the initiating dispensing location and that the package will be transported via ground transport from Boston Logan International Airport to the NEIDL or two other specified locations.

(b) Packaging Evaluation. The packaging that is planned by Boston University to transport pathogens will be evaluated by the A-E to assess the type of accident scenarios that may result in potential public exposures. Since no drop or leak test data is anticipated to be available for the specific containers Boston University has specified, this evaluation will be based on design criteria to the extent possible and will use comparative approaches.

(c) Consequence Determination. The A-E will conduct an assessment of the potential public consequences from transportation accidents resulting in the release of a pathogen. To the extent appropriate, the MACC2 or similar software, dispersion modeling code will be utilized in a

manner similar to the approach utilized for the facility-specific evaluations, however, dispersion modeling is not appropriate for modeling dispersion conditions in the immediate vicinity of a release. Consequences will be determined by the risk team in collaboration with the HH&E and Modeling teams for urban, suburban, and rural conditions.

(d) Air-transport Analysis. In addition to ground transportation, the A-E will also address air transportation accidents with the potential for direct impact in the Boston vicinity. The air transportation analysis is anticipated to be performed at a qualitative level, based upon the available information.

Deliverables for Task 7: The A-E will submit this analysis as Chapter 5.0 Transportation Analysis and Appendix I: Transportation Analysis. See additional information above in Task 2, Deliverables for Task 2.

### **TASK 8. Environmental Justice.**

The A-E will follow the Council on Environmental Quality (CEQ) general principles for considering *Environmental Justice Guidance under the National Environmental Policy Act* as guidance for the consideration of Environmental Justice principles for the NEIDL RA. CEQ has six guidance principles. Principle #1 applies to the NEIDL RA:

(a) CEQ Guidance Principle #1 - Agencies should consider the composition of the affected area, to determine whether minority populations, low income populations, or Indian tribes are present in the area affected by the proposed action, and if so whether there may be disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, or Indian tribes.

(b) The area affected for the proposed and alternative site locations will then be considered to determine if Environmental Justice communities are disproportionately affected. Additionally, the A-E will collect and present the data in sector grids in order to allow the A-E to overlay Environmental Justice communities and impacts.

Deliverables for Task 8: The A-E will submit this analysis as Chapter 10.0: Environmental Justice and Appendix M: Environmental Justice. See additional information above in Task 2, Deliverables for Task 2.

### **4.0 TENTATIVE SCHEDULE:**

**Exhibit 3** includes a tentative schedule which identifies bi-weekly technical working group progress calls, technical working group meetings, data collection meetings/workshops, and progress calls, and submittal of three (3) bundled deliverables for the project. The A-E shall prepare and submit a complete Draft Project Schedule **10 working days** after receipt of the Notice to Proceed. This schedule should not only include the information identified above but

also milestones to complete the project. The Draft Project Schedule will be provided to NIH and USACE, Mobile District for review and acceptance.

**All work on this Task Order will be completed NLT December 31, 2010.**

**5.0 PAYMENT SCHEDULE:** A-E payments will not exceed the following percentages:

The payment schedule below takes into account the percentages identified in Contract No. W91278-08-D-0017, Task Order 0015, dated August 2008 and revises the remaining percentages for completion of the Task Order(s).

Deliverable - Bundle No. 1 (Chapters 1.0, 2.0, 3.0, and 6.0)	60%
Deliverable - Bundle No. 2 (Chapters 5.0 and 9.0)	70%
Deliverable - Bundle No. 3 (Chapters 4.0, 7.0, 8.0, 10.0, 11.0, and 12.0)	80%
Deliverable - 90% Draft Final RA Report and Attend and Participate in a RA Public Meeting	90%
Deliverable - 100% Final RA Report and Updated "Report on Biosafety as BSL-3 and BSL-4 Laboratories"	100%

**NOTE:** The payment estimates above are based on the A-E providing all deliverables, including the Administrative Record that are of sufficient quality to have been accepted and approved by NIH and USACE, Mobile District. If determined by NIH and USACE, Mobile District that QA/QC has not been sufficiently completed, the A-E shall correct or revise any errors or deficiencies in the A-E's work, notwithstanding any review, approval, acceptance, or payment by the NIH and/or USACE, Mobile District.

## **6.0 MATERIALS AND LABOR:**

### **A-E Furnished Materials and Labor:**

(a) A-E shall provide all labor, materials, equipment, transportation, and lodging necessary to complete all tasks specified in this SOW.

(b) Qualifications of A-E: A-E's professional employees shall have demonstrated expertise in their appropriate field of study and adhere to the highest research standards and ethics of the profession. A-E shall provide or obtain professional and qualified personnel capable of performing all services required.

(c) It is assumed that the A-E already has adequate staff work area(s), telephones, computers and related equipment, facsimile machines, copy machines, microscopes and cameras.

## 7.0 MISCELLANEOUS REQUIREMENTS:

(a) Monthly Progress Reports. The A-E will prepare and submit a detailed monthly progress report to the Government. The monthly progress report will address work on the RA Report to include a description of tasks completed, status of ongoing activities, activities planned for next month, and issues and resolution. This report shall be sent (includes electronically) to the USACE, Mobile District technical manager(s), NIH, and other designated individuals. The monthly report shall contain an accurate, up-to-date account of all work accomplishments and outstanding issues for the RA Report. This report shall be no longer than three pages and should contain a statement of progress against the schedule developed by the A-E. The A-E will report progress as “percent complete”. The Contracting Officer’s Representative (COR) will base the periodic Task Order payment decisions on the “percent complete”. This report shall be submitted to the Government no later than the 10th day of the next month following the end of the monthly period covered by each report.

(b) Centralized File. The A-E will keep detailed records in a centralized file of the information used to prepare the RA Report. A record file will be maintained for the NIH. The record file will contain all documents, data, analytical tools, and reference materials utilized by the A-E in preparing the RA Report. The A-E shall not disclose any Task Order deliverables to the public without prior approval from the NIH and USACE, Mobile District to ensure that disclosure, when appropriate, is made in accordance with the provisions of the Freedom of Information Act, if invoked by the requester. All records and files shall be deemed the property of the Government. Record files will be provided to NIH at the completion of work as a portion of the Administrative Record.

(c) Administrative Records. The A-E will prepare and assemble a separate Administrative Record for the RA Report. The Administrative Record shall be inclusive of all information, and analyses either generated or obtained from other sources, used to support documentation and analyses. A complete Administrative Record is the entirety of the information relied upon within the A-E's possession plus all information in other locations listed in the references used in preparing the RA Report. The A-E will organize the information composing the Administrative Record as accessible files, indexed by topic to the extent possible, and submit the record to the NIH. The USACE, Mobile District technical manager(s) will be notified in writing when this last requirement under the Task Order is accomplished. Final payment to the A-E will be made once all documents have been submitted to the Administrative Record and have been approved by the NIH and USACE, Mobile District. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

(d) Memoranda. The A-E shall furnish the Government a summary memorandum of each meeting to include a summary of any agreements reached as well as any action items developed from said meeting. All memoranda shall be provided within **5 workdays** of the meetings. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

(e) Editorial Requirements. The draft and final reports shall be printed front and back on recycled paper unless specified otherwise. The size of pages shall be 8.5 by 11 inches, except for foldout maps, charts, or other illustrative material. Each line of each page of draft reports shall be numbered to facilitate review. Type size and the font used must be approved by the Government prior to printing. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

(f) Computer Software. Document shall be placed on CDs and provided to the Government in the word processing format agreed upon by NIH. The mailing list shall be saved on CD's and provided to the Government. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

(g) Court Testimony. In the event of controversy or court challenge, the A-E will make available, as appropriate, expert witnesses who performed work under this Task Order and shall testify on behalf of the Government in support of the findings. If a controversy or court challenge occurs and testimony of expert witnesses is required, a modification to the Task Order will be made and an adjustment in the Task Order price will be negotiated. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

(h) Release of Data. All data, reports, and materials contained or developed for this project shall not be released or discussed without written approval from NIH and USACE, Mobile District. This task was included in Contract No. W91278-08-D-0017, Task Oder 0015, dated August 2008 and is repeated here only for ready reference.

## **8.0 CONTRACTING OFFICER'S REPRESENTATIVE (COR):**

The COR will be designated by the USACE, Mobile District, Contracting Officer and will represent the Contracting Officer in those phases of the Task Order specified in the COR appointment letter. The COR is not authorized to change any of the terms and conditions of the Task Order for this project. Any modifications to the Task Order will be completed in writing by the Contracting Officer.

## **9.0 POINTS-OF-CONTACT:**

The NIH point-of-contact for this work is Ms. Kelly Fennington, (301) 435-2051, email: [fenningk@od.nih.gov](mailto:fenningk@od.nih.gov). The Tetra Tech Inc. point-of-contact is Mr. Frank Gallegos, (832) 251-5179, email: [frank.gallegos@tetrattech.com](mailto:frank.gallegos@tetrattech.com). The USACE, Mobile District technical manager(s) are: Dr. Neil Robison, (251) 690-3018, Cell (410) 320-9410, email: [neil.d.robison@usace.army.mil](mailto:neil.d.robison@usace.army.mil) and Mr. Brian Peck, (251) 690-2750, Cell (251)377-4269, FAX: (251) 690-2727, email: [brian.e.peck@usace.army.mil](mailto:brian.e.peck@usace.army.mil)

## 10.0 SUBMISSION AND APPROVAL OF WORK:

(a) Within **10 working days** after date of award of the Task Order, in accordance with Section 3.0, TASK 1 Prepare a Project Schedule will be prepared and submitted for approval. The schedule will show that various items included in the Task Order and the order in which A-E proposes to carry out the work, with dates on which the A-E will start the features of the work and the contemplated dates for completing same. This proposed and actual progress will be updated each month. Milestones such as review submittals shall be annotated. Such schedule shall provide for completion of all work within the Task Order time. The A-E shall assign sufficient technical, supervisory, and administrative personnel to ensure the execution of the work in accordance with the approved progress schedule.

(b) The A-E shall correct the progress schedule at the end of each month and shall deliver three copies to the USACE, Mobile District technical manager(s). Inasmuch as monthly partial payments to the A-E are based to a large extent on the progress schedule, the monthly corrections should be realistically made to the best ability of the A-E.

(c) Review Comments. For each Review Submittal, the A-E will be furnished comments. If the A-E disagrees technically with any comment or comments and does not intend to comply with the comment, the A-E shall clearly outline, with ample justification the reasons for noncompliance within seven (7) working days after receipt of these comments in order that the comment can be resolved. The disposition of the remaining comments shall be furnished in writing with the next scheduled submittal. The A-E is cautioned in that if the A-E believes the action required by any comment exceeds the requirements of this Task Order, the A-E should take no action and notify the USACE, Mobile District technical manager(s) in writing within 2 working days.

(d) Needs List. Throughout the life of his Task Order, the A-E shall furnish the NIH and USACE, Mobile District technical manager(s) a monthly "needs" list. This list shall itemize in an orderly fashion data required by the A-E to advance the project in a timely manner. Each list shall include a sequence number, description of action item, and remarks. The list will be maintained on a continuous basis with satisfied action items checked off and new action items added as required. Once a request for information is initiated, that item shall remain on the list until the requested information has been furnished or otherwise resolved. Copies of the list will be mailed to both the NIH and USACE, Mobile District technical manager(s).

(e) Payment. Partial payments, as authorized by the COR. will be made monthly for the amount and value of the work and services performed by the A-E in accordance with the General Provision of the Task Order. An updated progress chart will be submitted with each payment estimate (ENG Form 93). ENG Form 93 may be found on the Internet at: <http://www.usace.army.mil/usace-docs/forms/>. All ENG Form 93's shall be submitted as hard copies, consisting of the original and five (5) copies, to the U.S. Army Corps of Engineers, Mobile District, Attn: SAMEN-DW (Mary Breland), P.O. Box 2288, Mobile, Alabama 36628. This estimate will be verified by the USACE, Mobile District technical manager(s) utilizing the progress report submitted by the A-E and independent analyses of progress. When submitting for final payment include a Release of Claims Statement on ENG 93. The following statement is

acceptable.

*“The work under the above number task order having been completed and finally accepted, I hereby release the United States of America, its officers and agents from all claims whatsoever arising under or by virtue of this task order upon payment of a balance due of \$\_\_\_\_\_”.*

**11.0 CONDUCT OF WORK:** In performance of Task Orders with the USACE, Mobile District, the A-E shall:

(a) Schedules. Make every effort to meet project schedule milestones which were established at negotiations and/or at the beginning of the project. In this connection, the A-E will bring to the attention of the technical manager(s) any conflict in criteria, lack of criteria, or any condition that appears to put the project schedule in jeopardy if not resolved.

(b) A-E Instructions. The A-E will accept instructions only from the USACE, Mobile District; however, requests or desires of the NIH made directly to the A-E shall be forwarded to the District for consideration. Any changes to the Task Order scope must be authorized in writing by the Contracting Officer.

(c) A-E Responsibilities. The A-E has complete responsibility for the professional quality, technical accuracy, and coordination of all work or materials produced and furnished by the A-E's own in-house and consultant's forces. The A-E shall correct or revise any errors or deficiencies in his work, notwithstanding any review, approval, acceptance, or payment by the Government. Thus the responsibility continues after final payment is made to the A-E. Corrections and changes resulting from review of the A-E's completed work will not be made by the Government but will be returned to the A-E for correction. The A-E shall always be liable to the Government for damages to the Government caused by negligent performance by the A-E.

**12.0 PERIOD OF PERFORMANCE:** The period of performance for the completion of this Task Order is December 31, 2010.

# **EXHIBIT 1**

## **Chapters**

This RA contains Chapters 1.0 through 12.0 and appendices, as described below. In addition this document presentation is subject to change and modification.

<b>Deliverable</b>	<b>Chapter</b>	<b>Appendices</b>
1	Chapter 1.0: Introduction	Appendix A: Response to Comments and Recommendations Raised on Previous Analyses
1	Chapter 2.0: Facility and Site Descriptions	Appendix B: Facility Design and Operations
		Appendix C: Site Characteristics
1	Chapter 3.0: Pathogen Characteristics and Qualitative Disease Assessment	Appendix D: Pathogen Inventory and Characteristics
		Appendix E: Operating Experience at High Biocontainment Facilities
		Appendix F: Qualitative Health Effects Analysis
3	Chapter 4.0: Accident Sequence Analysis	Appendix G: Details of Accident Identification and Selection
		Appendix H: Details of Accident Sequence and Exposure Analyses
2	Chapter 5.0: Transportation Analysis	Appendix I: Transportation Analysis
1	Chapter 6.0: Threat Assessment	
3	Chapter 7.0: Quantitative Health Effects I - Initial Infections and Fatalities	Appendix J: Quantitative Health Effects Analysis
3	Chapter 8.0: Quantitative Health Effects II - Transmission modeling of Secondary Infections and Fatalities	Appendix K: Splitting out 'Appendix I'
2	Chapter 9.0: Environmental Effects	Appendix L: Environmental Effects
3	Chapter 10.0: Environmental Justice	Appendix M: Environmental Justice
3	Chapter 11.0 - Risk Characterization	Appendix N: Risk Summary
3	Chapter 12.0 – References	Appendix O: References Not Cited

**EXHIBIT 2**

## The Effect of Accident-Pathogen Pairing for Additional Pathogens

The effect of performing the NEIDL RA with accident-pathogen pairing for each of the 13 pathogens has two impacts on the effort required:

1. Increased work to include the analysis of pathogens for the accidents.
2. Increased work for the additional accidents that are necessary to ensure the bounding accident-pathogen pairs are analyzed for each pathogen.

Consideration of pathogens has a moderate impact on the accident sequence analysis. The primary impact is in performing and documenting the exposure pathogens by accident.

Of significant impact is the additional effort required to ensure that the bounding accident-pathogen pairings are selected to cover each pathogen for each exposed group (i.e., laboratory worker, facility worker, and members of the public). For example, inhalation-oriented accidents may not result in bounding accidents for pathogens whose exposure pathway of greatest concern may be punctures such as needle sticks. Given that there are five exposure pathways (i.e., direct contact, ingestion, inhalation, puncture, and animal exposure) and there are three exposed groups (i.e., laboratory workers, facility workers, and the public), and the multiple potential locations (i.e., BSL-3, BSL-4, and other areas) from which the risk originates, and 13 pathogens, there are potentially over 500 representative accidents. There will certainly be considerable overlap, but the number of accidents will certainly increase by potentially as much as 50% (e.g., from 8 accidents to 12).

The accident selection process relies heavily on the collaborative efforts of the Risk Assessment, Human Health Effects, and Modeling teams. Initially, accidents will be selected that represent the potential for the greatest release and typically the greatest exposure. This selection will be based on experience and scoping calculations. These accidents will be the representative accidents for the exposure pathways by exposed group by BSL matrix. In general, this is expected to provide the bounding accident for all pathogens.

However, unique attributes of pathogens (e.g., their susceptibility to temperature or the fact that a given pathogen less likely to be involved in the activity associated with the accident) may mean that the accidents selected are not necessarily bounding for a given pathogen. Therefore, the teams examine the accident-pathogen pairs selected to determine if unique accidents are warranted. In those cases where a unique accident is warranted to account for the characteristics of a given pathogen, the teams will select additional accidents to ensure adequate coverage.

The end result of this approach is the selection of accidents initially from the perspective of the scenarios and then from the perspective of the pathogen characteristics. The combination of these accident-pathogen pairs provides confidence that the "bounding" accident-pathogen pairs have been selected.

# EXHIBIT 3

## RISK ASSESSMENT SCHEDULE

<b>TASK NAME</b>	<b>DURATION</b>	<b>START</b>	<b>FINISH</b>
<b>Risk Assessment</b>	<b>273 days</b>	<b>Tuesday 12/08/09</b>	<b>Thursday 12/23/10</b>
Technical working Group Meeting in Boston	2 days	Tuesday 12/08/09	Wednesday 12/09/09
Bi-weekly progress call	0 days	Monday 12/21/09	Monday 12/21/09
Bi-weekly progress call	0 days	Friday 1/08/10	Friday 1/08/10
Notice To Proceed	0 days	Monday 1/11/10	Monday 1/11/10
Final Needs list to NIH/BU	0 days	Tuesday 1/12/10	Tuesday 1/12/10
Bi-weekly progress call	0 days	Friday 1/29/10	Friday 1/29/10
Final Needs list items due from NIH	0 days	Tuesday 2/02/10	Tuesday 2/02/10
Deliverable Bundle 1 (D1) to NIH	0 days	Friday 2/19/10	Friday 2/19/10
NIH Review D1	11 days	Friday 2/19/10	Friday 3/05/10
Bi-weekly progress call	0 days	Monday 2/15/10	Monday 2/15/10
NIH Provide D1 Comments	0 days	Friday 3/05/10	Friday 3/05/10
Bi-weekly progress call	0 days	Friday 2/26/10	Friday 2/26/10
Tech Working Group Meeting in Utah	2 days	Thursday 3/04/10	Friday 3/05/10
Bi-weekly progress call	0 days	Friday 3/12/10	Friday 3/12/10
Bi-weekly progress call	0 days	Friday 3/26/10	Friday 3/26/10
Tech Working Group Utah	2 days	Thursday 4/08/10	Friday 4/09/10
Bi-weekly progress call	0 days	Friday 4/16/10	Friday 4/16/10
Deliverable Bundle 2 (D2) to NIH	0 days	Friday 4/16/10	Friday 4/16/10
NIH Review D2	11 days	Friday 4/16/10	Friday 4/30/10
NIH Provide D2 Comments	0 days	Friday 4/30/10	Friday 4/30/10
Tech Working Group Meeting in Utah	2 days	Thursday 5/13/10	Friday 5/14/10
Bi-weekly progress call	0 days	Friday 5/21/10	Friday 5/21/10
Deliverable Bundle 3 (D3) to NIH	0 days	Friday 5/28/10	Friday 5/28/10
NIH Review D3	11 days	Friday 5/28/10	Friday 6/11/10
NIH Provide D3 Comments	0 days	Friday 6/11/10	Friday 6/11/10
NIH Review 89% Draft	12 days	Friday 6/25/10	Monday 7/12/10
Holiday	1 day	Monday 7/05/10	Monday 7/05/10
Provide 90% Draft Final	11 days	Monday 7/12/10	Monday 7/26/10
NIH Review 90% Draft	5 days	Monday 7/26/10	Friday 7/30/10
90% Final	5 days	Monday 8/02/10	Friday 8/06/10
Public Comment	45 days	Friday 8/06/10	Thursday 10/07/10
NIH Resolution to Public Comments	20 days	Thursday 10/07/10	Wednesday 11/03/10
Provide 100% Check Copy Final	15 days	Wednesday 11/03/10	Tuesday 11/23/10
NIH review of 100% Check Copy Final	10 days	Tuesday 11/23/10	Monday 12/06/10
Provide 100% Final	10 days	Monday 12/06/10	Friday 12/17/10
NIH review of 100% Final	5 days	Friday 12/17/10	Thursday 12/23/10
NIH approves 100 % Final	1 day	Thursday 12/23/10	Thursday 12/23/10

**Operational Date**  
11/6/2009

	13-Nov-09	27-Nov-09	6-Dec-09	17-Dec-09	24-Dec-09	24 Dec - 3 Jan-10	4-Jan-10	15-Jan-10	29-Jan-10	5-Feb-10	12-Feb-10	26-Feb-10	26-Feb-10	12-Mar-10	26-Mar-10	9-Apr-10	16-Apr-10	23-Apr-10	30-Apr-10	14-May-10
Bi weekly progress calls	C	C	C				C	C		C	C			C	C		C			
Technical Working Group In Utah							TM					TM			TM					TM
Deliverables to NIH				D <sub>1</sub>					D <sub>2</sub>								D <sub>3</sub>			
Boston University (tentative)			BU																	
NIH Comment Response				D <sub>1</sub>						D <sub>2</sub>								D <sub>3</sub>		
Draft 89%																				D
<p>There are three deliverable bundles.            D1 - Ch 1, 2, 10 and Pathogen Characteristics            D2 - Ch 7,8 and 9            D3 - Ch 3, 4, 5, 6,            Chapter 11 will be submitted with the 89% or as a separate deliverable.</p>																				