

## **Appendix A**

### **Decontamination Line Standard Operating Guideline (SOG) "Long Term Biological Decontamination Line"**

|                                                                                  |                                                                                                 |  |                                         |                         |
|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--|-----------------------------------------|-------------------------|
|  | <b>Decontamination Line SOG</b><br><b>“Long Term</b><br><b>Biological Decontamination Line”</b> |  | ERTG sub-committee<br>on Bio Decon SOGs |                         |
|                                                                                  |                                                                                                 |  | Revision<br>3.0                         | Issue Date<br>6/15/2010 |

## Purpose and Scope

The purpose of this standard operating guideline (SOG) is to provide guidance to EPA and contractors on decontamination (decon) for personnel in long term responses to biological contamination. This SOG was developed specifically for a biological response where Level C Personal Protective Equipment (PPE) with a full-face powered air purifying respirator (PAPR) is used. Level C PPE is appropriate for the majority of BioAgents and is required when the concentration and type of airborne substances is known and the criteria for using air purifying respirators are met (OSHA 1999). Level C equipment includes a protective Saranex™ or equivalent coverall with integral hood and booties, an air purifying respirator (preferably a PAPR), inner and outer nitrile gloves, hard hat (optional) and disposable latex outer boot covers.

## Personnel Decon Procedure

This SOG has been developed for long-term sites; therefore, the decon line should be constructed with materials durable enough to withstand continued use for a dedicated time period. If possible, decon tent or structures should be utilized and placed under negative pressure with HEPA filtration. Tents, berms, and collection vessels should be able to maintain copious amounts of wastewater in a contained and safe manner. Procedures should be in place to treat and replace contaminated materials used during the decon process as well as replace necessary chemicals and decontamination solutions.

All personnel are required to familiarize themselves with the site-specific decon procedures prior to entering the hot zone. This includes an initial walk through of the decon line prior to entry into the hot zone. The decon attendants will verbally direct decon entrants through each step of the process. Step 1 below will be conducted in the Hot Zone (exclusion zone). Steps 2-7 will occur in the Warm Zone (contamination reduction zone) and steps 8 & 9 will occur in the Cold Zone (support zone).

The “Long Term Biological Decon Line” SOG consists of the following steps:

**Step #1 Equipment Drop:** Place equipment taken into the Hot Zone on a plastic covered table or container provided prior to entering the contamination reduction corridor. Equipment will either be reused if more than one entry is planned, or will be decontaminated at a later time.

**Step #2 Sample Drop:** Place samples in provided container for sample decon. Care needs to be taken to ensure that workers maintain custody of samples. It is recommended that samples are decontaminated in a separate decon line.

**Step #3 Outer Boot and Glove Wash:** The purpose of this step is to enable physical removal of gross contamination if contamination is visible. If gross contamination is not visible, this step may be skipped. Wash outer boots and then outer gloves using a designated decontaminating agent such as soap and water, trisodium phosphate substitute, Alconox or amended bleach.

**Step #4 Glove, Boot, and Suit Wash:** Turn PAPR off and covert cartridges to ensure that the filters are not saturated. Wash all outer surfaces in a contained area (such as a kiddie pool) using a pressurized spray with the designated decontamination solution. Start with decontaminating the boots and gloves, then work on the suit from the top down, including the PAPR casing. Decon personnel should conduct this step. Care should be taken to ensure that all areas are decontaminated, including around the zipper, arms, front torso, and any other area that could have come in contact with contamination. The solution used for decontamination should be contained, collected, and disposed of properly from the decontamination line.

**Step #5 Outer Glove, Boot, and Suit Removal:** While sitting on a stool, remove outer boots and outer gloves. Undo the PAPR belt and hold in hand. While touching only the inside of the suit, remove outer suits by carefully rolling the suit in an outward motion from the shoulders down to your feet. Dispose of boots, gloves and suit in a designated container. This step may require decon personnel to assist either by holding PAPR unit or assisting in suit removal.

**Step #6 Mask Removal:** With inner gloves, remove the mask. Remove cartridge filters and place into designated container. Put mask into mask wash. Decon personnel will clean each mask and PAPR assembly prior to return to service.

**Step #7 Inner Glove Removal:** Remove inner gloves by only touching the outside of the first glove and then only the inside of the second glove. Place gloves into designated container.

**Step #8 Personal Shower (Optional):** If available, personnel should shower using copious quantities of soap and water for a minimum of 5 minutes, and change into clean clothes. If a personal shower is not immediately available then, at the minimal, hands and face should be washed thoroughly

**Step #9 Medical Monitoring:** Report to the medical monitoring station for your post entry monitoring and to the appropriate personnel for debriefing.

**Emergency Egress Corridor:** An emergency egress line must be established. This line will be used to quickly decon personnel who have medical emergencies while in the hot zone. Personnel must be decontaminated prior to receiving treatment from emergency medical technicians or transported to a hospital.

**Hand-Wash Station:** A hand-wash station maybe available for personnel to clean up following entry. However, this may not be available initially at the scene or weather conditions may prohibit their use. If a hand-wash station is not available, it is recommended that personnel wash their hands and face as soon as possible.

**Disposal of Decon Waste:** Waste water will be transferred by sump pumps (or similar) to drums or large scale containers (Baker tanks) and treated (shocked) with amended bleach. The NDT is working to determine waste issues. An optional method may be to place adsorbent diapers in the bottom of the pool to soak up the water.

Breaking down the decon line will require consideration of sampling results. All disposable items will be double bagged and secured until sample results are received and evaluated. Liquid and solid waste will be kept separate and treated as if contaminated until sample data demonstrates otherwise.

**Sample Decon Line:** Sample Decon procedures will be based on site criteria or will follow the protocol from the lead forensic team (FBI or NCERT). The sample decontamination and packaging requirements will be site-specific and will be outlined in the sampling and analysis plan following consultation with the analytical laboratory. The laboratory will provide information on appropriate decon solutions as well as packaging requirements for receiving the samples. During sample decon, the chain of custody must be maintained.

Upon collection, samples will be place into sample container and then placed into a plastic bag. The following steps maybe used to decontaminate samples:

**Step #1** Wipe the outside of the plastic bag with a laboratory approved solution.  
Under most circumstances this will be the same wipes used for personal decon.

**Step #2** Place each individual sample into another plastic bag.

### **Step #3**

Place all samples into a clean over-pack, such as a larger plastic bag or a sealable cooler, with appropriate paperwork and custody seals for transport to laboratory.

**Equipment Decon:** All equipment staged at the equipment drop must be appropriately decontaminated prior to being put back into service.

### **References**

CDC (2008). Guidance on Emergency Responder Personal Protective Equipment (PPE) for Response to CBRN Terrorism Incidents. DHHS, NIOSH..

NIOSH (1985). Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities, NIOSH, OSHA, USCG, EPA.

NIOSH (2009). "Recommendations for the Selection and Use of Respirators and Protective Clothing for Protection Against Biological Agents" NIOSH Publication Number. 2009-132

29 CFR, Part 1910, Section 134, Respiratory Protection.

## **Appendix B**

### **EPA Project Level C Decontamination and Doffing Script**

EPA Project Level C Decontamination and Doffing Script.

| Step |             | Task to be Completed                                                                                                                                                                                                                        | ✓ | Note |
|------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|------|
| 1.   | Attendant 1 | Close Decon Chamber Door and escort Test Subject to Station 1.                                                                                                                                                                              |   |      |
| 2.   | Attendant 1 | Direct Test Subject to take directions from Attendants in Decon Chamber and not from Test Director on PA system.                                                                                                                            |   |      |
| 3.   | Attendant 1 | Direct Test Subject to wash and rinse the sample package.                                                                                                                                                                                   |   |      |
| 4.   | Attendant 2 | Prepare a Ziploc bag to double bag the sample.                                                                                                                                                                                              |   |      |
| 5.   | Attendant 1 | Direct the Test Subject to place the into the Ziploc bag Attendant 2 is holding open. Care should be taken not to touch the Ziploc bag.                                                                                                     |   |      |
| 6.   | Attendant 2 | Close the Ziploc bag and place in the bucket. Take bucket to the clean line and place floor.                                                                                                                                                |   |      |
| 7.   | Attendant 1 | Direct Test Subject to wash hand and dry hands. Dispose of paper towels in waste basket. Station 1.                                                                                                                                         |   |      |
| 8.   | Attendant 1 | Direct Test Subject to wash boot covers with long handled brush.                                                                                                                                                                            |   |      |
| 9.   | Attendant 1 | Direct Test Subject to prepare to move to next station after directions are given.                                                                                                                                                          |   |      |
| 10.  | Attendant 1 | Using low pressure sprayer, rinse bottom of boots as test subject exits one foot at a time from station one. Test subject will step on absorbent pad and stop.                                                                              |   |      |
| 11.  | Attendant 1 | Direct Test Subject to enter station two.                                                                                                                                                                                                   |   |      |
| 12.  | Attendant 1 | Direct Test Subject to loosen paper belt.                                                                                                                                                                                                   |   |      |
| 13.  | Attendant 1 | Direct Test subject to remove PAPR system belt and hand PAPR to Attendant 2.                                                                                                                                                                |   |      |
| 14.  | Attendant 2 | Ensure PAPR is held at a level that will keep the hose from coming in contact with the test subject but will not break the seal of the face piece.                                                                                          |   |      |
| 15.  | Attendant 1 | Using low pressure sprayer, apply decon solution using ¼ turns of test subject.                                                                                                                                                             |   |      |
| 16.  | Attendant 1 | Using sponges and wash basin remove decon solution and simulated contaminant from hood, facepiece, suit, and gloves. All liquid should be removed from exterior of suit and face piece. Rise and ring out the sponge as often as necessary. |   |      |
| 17.  | Attendant 1 | Wash and dry hands in wash basin. Dispose of paper towels in waste basket.                                                                                                                                                                  |   |      |
| 18.  | Attendant 1 | Direct Test subject to wash and dry gloved hands. Dispose of paper towel in waste basket.                                                                                                                                                   |   |      |
| 19.  | Attendant 1 | Exchange your gloves.                                                                                                                                                                                                                       |   |      |
| 20.  | Attendant 1 | Direct Test Subject and Attendant 2 to move to station three, ensuring the                                                                                                                                                                  |   |      |

EPA Project Level C Decontamination and Doffing Script.

|     |             |                                                                                                                                                                                                                                                                        |  |  |
|-----|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
|     |             | hose and PAPR doesn't come in contact with the test subject and not breaking the seal of the face piece.                                                                                                                                                               |  |  |
| 21. | Attendant 1 | Remove tape from exterior of suit. If any visible liquid is observed wipe it off with a paper towel.                                                                                                                                                                   |  |  |
| 22. | Attendant 1 | Wash and dry hands in wash basin. Dispose of paper towels in waste basket.                                                                                                                                                                                             |  |  |
| 23. | Attendant 1 | Position Test Subject in front of stool                                                                                                                                                                                                                                |  |  |
| 24. | Attendant 1 | Un-do flap of suit in preparation to un zip the zipper. If visible liquid is observed wipe it dry with a paper towel.                                                                                                                                                  |  |  |
| 25. | Attendant 1 | Un-zip the suit. Be careful not to touch the inside of the suit at any time.                                                                                                                                                                                           |  |  |
| 26. | Attendant 1 | Wash and dry hands in wash basin. Dispose of paper towels in waste basket.                                                                                                                                                                                             |  |  |
| 27. | Attendant 1 | Starting at hood start rolling suit inside out, careful to not touch the test subject.                                                                                                                                                                                 |  |  |
| 28. | Attendant 1 | When suit is rolled past Test Subject shoulders, have test subject pull arm out of suit. If possible leave out gloves on suit sleeve during this process.                                                                                                              |  |  |
| 29. | Attendant 1 | Continue rolling suit to knees.                                                                                                                                                                                                                                        |  |  |
| 30. | Attendant 2 | In the next task ensure PAPR is maintained at proper level to not break seal of the face piece and not coming in contact with the test subject.                                                                                                                        |  |  |
| 31. | Attendant 1 | Direct Test subject to sit down on stool.                                                                                                                                                                                                                              |  |  |
| 32. | Attendant 1 | Direct test subject that the next step will require he remove one foot at a time from the suit. Once a foot is clear of the suit it will be place on the clean side of the tape located on the floor next to the stool. This step will be repeated with the next foot. |  |  |
| 33. | Attendant 1 | Confirm test subject is clear on the next step.                                                                                                                                                                                                                        |  |  |
| 34. | Attendant 1 | While in a seated position, direct test subject to remove right foot from suit and place across the tape. Attendant 1 will hold suit in place while foot is cleared of suit.                                                                                           |  |  |
| 35. | Attendant 1 | Direct test subject to repeat pervious step with left foot                                                                                                                                                                                                             |  |  |
| 36. | Attendant 2 | Once both feet are clear of the suit and placed on the clean side of tape, direct test subject to stand up.                                                                                                                                                            |  |  |
| 37. | Attendant 2 | Direct test subject with inner gloves still being worn to remove the face piece and place it on the table.                                                                                                                                                             |  |  |
| 38. | Attendant 2 | Place PAPR on table.                                                                                                                                                                                                                                                   |  |  |
| 39. | Attendant 2 | Direct test subject to move to door of dark room and remove inner gloves discarding them the waste basket.                                                                                                                                                             |  |  |

EPA Project Level C Decontamination and Doffing Script.

|     |             |                                                                                                                 |  |  |
|-----|-------------|-----------------------------------------------------------------------------------------------------------------|--|--|
| 40. | Attendant 2 | Instruct Test Subject to keep hands away from white undergarment and wait for IH to provide further directions. |  |  |
|-----|-------------|-----------------------------------------------------------------------------------------------------------------|--|--|

DRAFT



## **Appendix C**

### **ARCADIS Test Participant Briefing on Human Subject Protection Issues**

## ARCADIS TEST PARTICIPANT BRIEFING ON HUMAN SUBJECT PROTECTION ISSUES

**TITLE:** Decontamination Line Protocol Evaluation for Biological Contamination Events

**INVESTIGATOR:** Abderrahmane Touati, PhD, Project Manager,  
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### 1. General Introduction

This project supports the Decontamination and Consequence Management Division (DCMD) within the U.S. Environmental Protection Agency's (EPA) National Homeland Security Research Center, (NHSRC) under the On-site Research Laboratory Support contract No. EP-C-09-027. This briefing will entail details the nature of the human protection issues as applied to human test subjects including test subject privacy and confidentiality, safety, and incident reporting.

Personal information collected from you during this study becomes part of the study records. This can include personal identifiers as well as audio-visual images and photographs. These may be reviewed or copied by the sponsor, government agencies, or others associated with the study.

ARCADIS will investigate Long Term Biological Decontamination Line Protocols during decontamination and doffing (D&D) procedures; the purpose is to develop and validate decontamination line protocols for long- term biological decontamination projects. For testing purposes, PE refers to the overall combination of protective garment, respirator, headgear, footwear, and ancillary equipment, which might be used in a potentially contaminated (chemical, biological, nuclear, or radiological) environment by responders.

### 2. PRIVACY

- a. Personal information collected from the test subjects during this study becomes part of the study records. This can include personal identifiers as well as audio-visual images and photographs. These may be reviewed or copied by the sponsor, government agencies, or others associated with the study.
- b. No pictures or recordings of clearly identifiable full-face view of the test subjects

### 3. Safety

- a. Arrangements will be made immediately for emergency medical care if the test subject sustains an injury or illness in the course of this study.
- b. The test subjects' vital signs will be taken and recorded before the start of the testing sequence. Further, the test subjects will be evaluated of potential concern with respect to their safety:
  - i. Illness – cold, flu, etc., anything that can impact their health during test
  - ii. Respirator fit – imperative that multiple “negative pressure” checks be performed as they are dressed and immediately before entering the dusting chamber
- c. Subjects will be constantly attended from start of donning until released from dark room to the end of D&D process
- d. Checklists – the test subjects will be asked about anything that isn't clear or doesn't seem to make sense, and corrective actions will be implemented for their own safety
- e. Discomfort – The test sequence can last up to 2 hours from the beginning of dress-out until release from dark room after completing doffing.
- f. Hydration – Drinks will be offered once the test subjects are in the dark room to avoid potential dehydration

### 4. OBSERVING AND REPORTING ADVERSE INCIDENTS

The test subjects will be asked to report any activities that could cause or could be potential safety hazards so that ARCADIS can implement corrective actions

### 5. TEST PROTOCOL HAZARD ANALYSIS AND CONTROL PLAN

The ARCADIS Test Protocol Hazard Analysis and Control Plan content will be distributed prior to the test sequence and its content along with the consent form will be discussed in relation to the nature of human protection as applied to human subject testing.



## **Appendix D**

### **Research Subject Information and Consent Form**

## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** Decontamination Line Protocol Evaluation for Biological Contamination Events

**INVESTIGATOR:** Abderrahmane Touati, PhD, Project Manager,  
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### SUMMARY

This document contains information about the study that you are being invited to participate in. Please ask the study staff to explain any information that you do not clearly understand. You may have a copy to review at your leisure before completing the form or participating in the study.

You are invited to serve as a test subject in a study to determine the overall effectiveness of decontamination garments, equipment, and procedures with a non-toxic surrogate contaminant. Your decision to be in this study is entirely voluntary; you have the right to change your mind and leave the study at any time for any reason. Each test will require up to 8 hours in order to complete all planned activities.

Personal information collected from you during this study becomes part of the study records. This can include personal identifiers as well as audio-visual images and photographs. These may be reviewed or copied by the sponsor, government agencies, or others associated with the study.

Arrangements will be made immediately for emergency medical care if you sustain an injury or illness in the course of this study. More detailed information about this study is in this consent form. Please read it carefully.

### PURPOSE

This study is being performed in response to Work Assignment (WA) No. 5-77. This project supports the Decontamination and Consequence Management Division (DCMD) within the U.S. Environmental Protection Agency's (EPA) National Homeland Security Research Center, (NHSRC) under the On-site Research Laboratory Support contract No. EP-C-09-027. ARCADIS will investigate Long Term Biological Decontamination Line Protocols during decontamination and doffing (D&D) procedures; the purpose is to develop and validate decontamination line protocols for long- term biological decontamination projects. For testing purposes, PPE refers to the overall combination of protective garment, respirator, headgear, footwear, and ancillary equipment, which might be used in a potentially contaminated (chemical, biological, nuclear, or radiological) environment by responders. This study does not involve clinical trials of medicines or medical devices, or medical treatments.

Your only alternative to serving as a study participant is to decline to serve as a participant.

## PARTICIPANT SELECTION

You are invited to participate if you are already in a respiratory protection program and are cleared for respirator use.

## TESTING PROCEDURE

Your part in this study is to perform the following activities:

1. Participate in this consent process, which includes health and safety information. If you agree to take part in this study, you will first sign this Research Subject Information and Consent Form before any study-related procedures are performed.
2. Allow a quantitative fit-test to be performed, if necessary, with the selected respirator. The fit-test will ensure that the respirator will provide protection against airborne contaminants.
3. Don a test undergarment over personal issue clothing (such as shorts and a t-shirt). The undergarment will simulate skin or garment surfaces beneath the protective ensemble.
4. Dress in the protective ensemble, including respirator. You will be assisted in this process to ensure proper fit between the subject, garment(s), respirator, and associated equipment. A final check will assure all equipment is functioning as expected.
5. Allow photographs to be taken of you while fully dressed in the protective ensemble.

Perform a qualitative fit-check of the respirator (you will be assisted in this task by members of the testing staff).

6. Wear the protective ensemble in an enclosure while a non-toxic surrogate contaminant is applied to the outer surfaces of the ensemble; material safety data sheets (MSDS) are reviewed as part of this informed consent process.
7. Doff the protective ensemble under the supervision of a test director and assistants.
8. Allow inspection of your extremities (head, neck, hands) for evidence of the surrogate material on your skin or on the test undergarment.
9. Allow the test undergarment to be removed by cutting or doffing under direct supervision.
10. Complete a questionnaire about the procedure.

On completion of the required testing activities, you are free to clean up. Each test run can take up to 4 hours to complete. You may be given the opportunity to participate in multiple test runs.

## RISKS AND DISCOMFORTS

A number of potential risks or discomforts may accompany this testing:

1. Modesty – investigative staff will remove (or assist in removing) the protective ensemble down to the test undergarment. The test undergarment will then be removed to reveal your personal issue clothing (typically shorts and t-shirt). Please tell the testing staff if you have a concern for modesty, and we will do our best to accommodate your wishes.
2. Photographs – you will be photographed while dressed in the protective ensemble, and your personal identity may be revealed. The full protective ensemble usually obscures personal identity to an extent that further protections are not necessary.
3. Brief exposure to materials – application of the surrogate contaminant requires that you be present while a small quantity of the surrogate contaminant brushed onto your outer garment (additional information is contained in the MSDSs that accompany this form). We will help you check for proper respirator fit to prevent the possibility that you might inhale some of the contaminant. The respirator will be the very last item to be removed in the test process at the end of the doffing and decontamination line.
4. Potential skin exposure to surrogate materials – it is possible that traces of the surrogate contaminant will be found on your extremities (head, neck, hands) following the completion of testing. Visible contamination can be removed using soap and water.
5. Claustrophobia and/or restricted vision – the respirator and protective headgear may restrict your field of vision, and the restrictive nature of the ensemble could cause claustrophobia. Allow your escort to help you as much as needed
6. Ultraviolet exposure – You will be briefly exposed to an ultraviolet source used to illuminate traces of surrogate contamination that may have been transferred to your skin or undergarment(s) during the D&D process.
7. Heat or cold discomfort – You may experience increased warmth due to the insulating properties of the protective ensemble; you may become cold if wetted in the D&D process. Let your escorts know if you are uncomfortable, and appropriate actions will be taken.
8. Other – you may have a slight additional risk of injury due to tripping, slipping, or falling during the test. You could also experience some discomfort from the ensemble equipment (e.g., soreness or headache from respirator face piece) as a result of the nature of the protective ensemble and conditions on the D&D line. You will be escorted at all times, and should advise if you are having discomfort of any sort for any reason.

## NEW FINDINGS

We will contact you if the results of this study reveal significant new findings that are applicable to you regarding the doffing and decontamination of protective ensembles. You may contact the investigators at any time after your participation ends to find out if any new information about this study has become available.

## POSSIBLE BENEFITS

This is not a medical treatment study and it is not expected that you will receive any medical benefits from your participation.



1. The results of this study will be used to improve the effectiveness of the protocols of decontamination lines for EPA projects.
2. The persons that benefit most directly from this test are those who rely on the protective capabilities of the PE during response and recovery operations.

## **COSTS**

There are no costs to subjects for participating in this study other than your time and transportation to our facility.

## **PRIVACY AND CONFIDENTIALITY**

Information from this study may be given to the sponsor or any persons or companies contracted by the sponsor to have access to the research information during and after the study. Study records, which identify you, and the consent form you signed may be reviewed or copied for research or regulatory purposes by:

- ARCADIS
- Representatives of the Environment Protection Agency;
- Members of the NNMC Institutional Review Board; .
- Employees of governmental agencies having a legitimate need to review the records (e.g., for auditing or review purposes).

Although we will provide certain security measures for the data we collect, absolute confidentiality cannot be guaranteed because of the possibility of giving information to these parties. Also, the results of this research study may be presented at meetings or in publications, but your identity will not be deliberately disclosed in those activities.

## **RESEARCH-RELATED INJURY**

Medical treatment will be arranged immediately if you are injured or become ill as a result of participation in this study.

## **INCENTIVES**

A \$20/hour will be given to you for your time to take part in this research. The overall stipends for this work will not exceed \$600 for the entire test program.

## **LEGAL RIGHTS**

The above section does not restrict your right to seek legal assistance. You do not give up any legal rights by signing this consent form.

As a participant in this study, you have the following rights:

1. To have enough time to decide whether or not to be in the research study and to make that decision without any pressure from the people who are conducting the research.
2. To refuse to be in the study at all, and to stop participating at any time after you begin the study.
3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
4. To be told about the reasonably foreseeable risks of being in the study.
5. To be told about the possible benefits of being in the study.
6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
7. 7. To be told who will have access to information collected about you, and how your confidentiality will be protected.
8. To be told whom to contact with questions about the research, about research-related injury

## **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

These tests are investigative, and you may withdraw from participation at any time for any reason. You may also be removed from participation at any time by the investigative staff if they believe that there is a safety or health concern or a procedural difficulty related to you. If it is necessary to terminate participation during a test run, either you or the investigators may wish to discuss the possibility of re-scheduling; either you or we may also elect to simply discontinue your participation as a subject for this study.

## **STUDY FUNDING SOURCE DISCLOSURE**

The investigators are being paid by ARCADIS US, Inc., to conduct this research on behalf of the U.S. Environmental Protection Agency under the On-site Research Laboratory Support contract No. EP-C-09-027.

## **CONTACT FOR QUESTIONS**

If you have any questions about this study or your participation in this study or if at any time you feel you have experienced a research-related injury, contact the principal investigator, Dr. Abderramane Touati – 919 541 3662. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

## SUBJECT'S STATEMENT OF CONSENT

### Long Term Biological Decontamination Line Protocols (EPA) Investigation

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered so far, and ARCADIS, Inc. will inform me of any significant new findings that might cause me to re-consider continued participation in this study. In the event that new information is provided to me, I will complete the informed consent process before commencing with further testing or study participation. I have been provided an opportunity to review the surrogate contaminant material safety data sheets. I have been told that digital images or video recordings may make it possible for my personal identity to be revealed. I freely consent to participate in this study. By signing this consent form, I have not given up any of my legal rights.

Subject Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

ARCADIS Project manager \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

## **Appendix E**

### **Overall Team Support and Responsibilities**

## Overall Team Support and Responsibilities

This Work Plan is intended for ARCADIS team members and EPA Volunteers (Test Subjects) that support and/or document each step of each evolution of the decontamination line. Each member will be assigned with an Identification number (ARC 1 through ARC 8), and this member is responsible for all duties assigned to them as listed in this Test Plan. There are also up to 3 Attendants in each test script with assigned duties. However, the Attendants are also considered Test Subjects as they are not dosed with the fluorescent dye, but are evaluated for cross-contamination at the conclusion of each test. Each ARC/Attendant will perform their duties within their designated zone.

### **ARC 1 Roles, responsibilities, and scripts**

ARC 1 is the Task lead for this project and will be stationed in the cold zone or pre-contamination stage area. His role and responsibilities are listed below:

- A. Organize the plan ahead of time
- B. Check that all supplies are present.
  - a. SDSs for fluorescent dye
  - b. Test Subject consent forms
  - c. Cash for Test Subjects
  - d. Three colors of nitrile gloves – blue, green, and purple
  - e. Inner suit (Tyvek coveralls with hoods and booties)
  - f. Outer suit (Tychem coveralls with hoods and booties)
  - g. Full-face Respirators
  - h. Haz Proof Heavy Duty Boots
  - i. Duct Tape
  - j. Clean garb (disposable lab coats)
  - k. Safety glasses
  - l. 3 Digital Cameras, with synchronized timers.
  - m. 3 Notebooks and pens
  - n. Pre-weighed fluorescent dye brush application kits
  - o. UV glasses
  - p. UV lamps – charged
  - q. Pre-weighed “sample” kits
  - r. Decon supplies (Dawn soap)
  - s. Two Video cameras
  - t. UV markers
  - u. Trash cans
  - v. Trash bags
  - w. Containers for used boots and masks
  - x. Alcohol wipes for book and mask decon/recycling
  - y. Snacks and drinks

- C. Lead Test Subjects to staging area
- D. Brief Test Subjects on protocol
- E. Stay in your Zone!
- F. Describe methods of putting on undergarments. Shoes off, don inner suit, tape blue gloves to inner suit leaving a tab for easy removal. Test Subjects to help each other.
- G. Collect consent forms from each Test Subject
- H. Record unique ID numbers for new Test Subject in a Logbook. Write this number on the front torso and back of the Test Subject's inner suit.
- I. In the Background Tent, photograph the Test Subjects wearing their inner suit and gloves under UV light. Pictures will be taken sequentially to allow comparison with the post-decon pictures of the Test Subjects:
  - a. Front head
  - b. Front upper left body
  - c. Right hand
  - d. Left Hand
  - e. Front Lower body (including feet)
  - f. Back
  - g. Right under arm pit
  - h. Left under arm pit
- J. Direct the Attendants to don their inner suits and tape their gloves to the suits, tabbing the tape for ease of removal. Direct the Test Subjects to go next. This is expected to occur in a staggered manner, with 1 person completing every 5 minutes or so.
- K. Photograph each Attendant and Test Subject in their inner suit/gloves under UV light. Reject any participants who fluoresce (and find source of contamination). Record ID of personnel and state of inner suit (correct and taped) in log sheet entitled "Stage 1: Pre-Contamination Stage". Pictures will be taken sequentially to be able to compare with the post-decon pictures of the Test Subjects:
  - a. Front head
  - b. Front upper left body
  - c. Right hand
  - d. Left Hand
  - e. Front Lower body (including feet)
  - f. Back
  - g. Right under arm pit
  - h. Left under arm pit
- L. Attendants, and then Test Subjects, to don outer garments – outer suit, green gloves first, then purple, boots, and respirator. They will help each other tape the following seams, leaving a tab at the end of each seam's tape for easy removal: both the green and purple gloves, boots, mask, and zipper.
- M. Write their unique ID number on the front torso and back of the Test Subject's outer suit. Document state of outer PPE (correct and taped) in laboratory in the log sheet.

## **ARC 2 Roles, responsibilities, and scripts**

ARC 2 is the person in charge of applying the fluorescent powder to the Test Subjects, and will be stationed in the dosing room of the contamination stage area. Their role and responsibilities are listed below

- A. Stay in your Zone!
- B. To don inner Tyvek suit, gloves and mask
- C. To record the ID of the brush kit and the Test Subject ID and time.
- D. To apply Fluorescent powder in 5 discreet locations on the test subjects. Locations include the outside of the face mask, palm of right hand glove, left shoulder, right hip, inner side of left boot. Return the brush to the kit bag and place in "used" bin. Surrogates will not be applied directly to attendants. One Test Subject should not have surrogate applied. This Test Subject should not be the first man through the decon line.
- E. To doff gloves.
- F. Repeat to Step C as necessary.
- G. Collect post-test weights of brush kits at EPA facility.

## **1. ARC 3 Roles, responsibilities, and scripts**

ARC3 will be stationed in the contamination stage area along with ARC2. His role and responsibilities are listed below

- A. To don inner Tyvek suit, gloves and mask
- B. Stay in your Zone!
- C. To photograph subject under UV light in the hot zone photography area.
- D. To direct Test Subjects to pick up samples from hot bin.
- E. To record to notes of any anomalies, vulnerabilities, etc.

## **ARC 4 Roles, responsibilities, and scripts**

ARC 4 will be stationed outside the decontamination stage area. His role and responsibilities are listed below:

- A. Don lab coat and gloves
- B. Stay in your Zone!
- C. To record time and ID code of each Test Subject entering decon line.
- D. To record the time and activities during the decon line process.
- E. To give the go-ahead to ARC2 for the next Test Subject to be dosed.
- F. To set up video camera to record decon line activities on the hot zone side.

## **ARC 5 Roles, responsibilities, and scripts**

ARC 5 will be stationed outside the Post-decontamination stage area. His role and responsibilities are listed below:

- A. Don lab coat and gloves.
- B. Stay in your Zone!
- C. To set up video of warm zone activities.
- D. To record the activities in the decontamination zone, and will record notes of any anomalies, vulnerabilities, etc.

## **ARC 6 Roles, responsibilities, and scripts**

ARC 6 will be stationed outside the Post-decontamination stage area (Cold Zone). His role and responsibilities are listed below:

- B. Stay in your Zone!
- C. Don new lab coat and gloves between Test Subjects.
- D. The test subject will be evaluated in a dark room by ARC6 using one or more 6 watt UV lamps (UVP600, Sirchie, Youngsville, NC) to determine if cross-contamination subsisted/occurred during the decontamination/doffing procedures.
- E. To dictates notes to ARC7 (outside tent). Areas of contamination were identified and an estimate of the size of the contaminated spot was made.
- F. Mark each area with a Sharpie.
- G. To photograph inner garment post-test under UV light. Pictures will be taken as follow sequentially to be able to compared with the pre-pictures of the Test Subjects:
  - a. Front head
  - b. Front upper left body
  - c. Right hand
  - d. Left Hand
  - e. Front Lower body (including feet)
  - f. Back
  - g. Right under arm pit
  - h. Left under arm pit
- H. Exit tent.
- I. Test subjects will doff their inner gloves and inner suit and hand them to ARC7.
- J. The test subject will be re-evaluated in a dark room wearing their regular clothing to determine if cross-contamination subsisted/occurred during the decontamination/doffing procedures. Notes will be dictated to ARC7 (outside tent). Pictures will be taken sequentially to allow comparison with the post decon pictures of the Test Subjects:
  - a. Front head
  - b. Front upper left body
  - c. Right hand
  - d. Left Hand
  - e. Front Lower body (including feet)



- f. Back
  - g. Right under arm pit
  - h. Left under arm pit
- K. Test subjects will be asked by ARC 6 to wash off any fluorescent material present on their skin. A washing station was available in the Cold Zone for this purpose.

#### **ARC 7 Roles, responsibilities, and scripts**

ARC 7 will be stationed outside the Post-decontamination stage area (Cold Zone), and he will work in tandem with ARC 6. His role and responsibilities are listed below:

- A. Don new lab coat and gloves between Test Subjects.
- B. Stay in your Zone!
- C. To records notes dictated to ARC7 (outside tent). Record date, time, Test Subject ID, location, and type of transfer.
- D. ARC 7 to change gloves.
- E. Test subjects will doff inner gloves and hand them to ARC7.
- F. Test subjects will doff the inner overalls and hand them to ARC7.
- G. To package the garments in a large zip-lock bag and record the Test Subject ID , the date and time, and the test run. These garments may be subjected to a second round of UV photography of the undergarments. Areas of fluorescence will be outlined on the undergarment, and the area measured using simple area estimates. The brightness of the fluorescence may be quantified.
- H. Direct Test Subject to complete the survey.

#### **ARC 8 Roles, responsibilities, and scripts**

ARC 8 will be stationed in a buffer zone located between the decontamination line tent and the post-decon zone for cleaning and decontaminating mask and boots for re-use. In this zone, a cart will be set to transport the boots and the masks for re-use to the intermediary zone between the cold zone and the hot zone. His role and responsibilities are listed below:

- A. Don lab coat and gloves
- B. Stay in your Zone!
- C. To clean and decontaminate masks and boots for re-use

## **Appendix F**

### **SOG Test Scripts**

1. **Script 1: SOG using 2 attendants with a 2-step outer garment spray-brush decontamination sequence (Test 1A, and 1B):** In this script the Test Subject followed the EPA scripted SOG using 2 Attendants. The first Attendant's sole function was to wash down the Test Subject, while the second Attendant helped the Test Subject to doff their PPE.

**a. Hand Wash and Boot Rinse Station:**

The following instructions were provided by the support team to the test subjects:

- i. "Drop off the sample."
- ii. "Wash your hands."
- iii. "Brush each boot down and away from yourself."
- iv. "Brush the bottom of one boot, and step into the wash bin under the tent; then brush the bottom of the second boot and step in the wash bin."

Prior to the decon process, Attendant 1 was instructed by the support team to:

- v. Wash all outer surfaces (of Test Subjects) starting with the suit from the top down, including the face mask casing. This was performed in a contained area using a pressurized spray using a soap solution (Dawn Soap). Following the suit wash, Attendant 1 was instructed to scrub the outer suit from the top down (away from the test subjects), including the face mask casing, and the boots.
- vi. Help with the Boot-Removal process:
  - a. "Remove tape."
  - b. "Unlace the boots."
  - c. "Remove boot 1."
  - d. "Step out of the bootless leg first; then remove boot 2."
  - e. "Step out."

**b. Outer Garment Doffing Station:**

Attendant 2 assisted the Test Subjects in doffing the Outer PPE (outer coverall, face mask (PAPR), and outer gloves). The following instructions were provided to Attendant 2 by the support team:

- i. Untape the Test Subject's mask, ankles and outer gloves. Remove outer most gloves and dispose of them.
- ii. Untape the garment zipper, remove the outer suit by rolling it down and dispose of it. (Test Subjects were instructed not touch any part of the inner suit).
- iii. Remove the Test Subject's mask, and set it aside in a bin for cleaning.
- iv. Direct the Test Subject to remove his middle glove, and wash his inner most gloves (mimicking Test Subject's skin) first and then his face with soap solution followed by water.
- v. Repeat Step i-iv of this section for the next Test Subject.

After all Test Subjects undergo the decon procedures, Attendants will follow the decon procedures in the following sequence: Attendant 1 first followed by Attendant 2.

- vi. Attendant 1 self-washed his outer PPE starting with the suit from the top down, including the face mask casing. This was performed in a contained area (same as with Test Subjects) using a pressurized spray using a soap solution (Dawn Soap).

- vii. Attendant 1 was instructed to scrub his outer suit from the top down (away from self), including the face mask casing, and the boots. Following this, Attendant 1 was instructed to remove tape around his boots, unlace the boots and remove his boots (remove boot 1 and step out with the bootless leg first; then remove boot 2, and step out).
- viii. Attendant 2 assisted Attendant 1 in doffing the Outer PPE as specified in Section b (Outer Garment Doffing Station, steps i to iv).
- ix. Attendant 2 was instructed to self-doff his outer PPE as specified in Section b (Outer Garment Doffing Station, steps i to iv).

2. **Script 2: SOG using 2 attendants with a 3-step outer garment spray-brush-rinse decontamination Sequence (Test 1C):**

This script followed the procedure of Script 1 with the first Attendant being asked to add a rinse step following the Test Subjects outer surface swash/scrub procedure. The rinse step was added to determine if it has a positive outcome in reducing the cross-contamination during the doffing step.

3. **Script 3: SOG using 3 attendants with a scripted 3-step outer garment spray-brush-rinse decontamination sequence attendants (Tests 2A and 2B):**

This script followed the procedure of Script 2, with an addition of a third Attendant to the decon line. The Attendants were briefed prior to testing about the role of each of them to simulate real life scenarios without directions from outside support personnel. Attendant 1 was the person in charge to direct the volunteers through the decon station, and Attendant 3 was in charge of doffing the Test Subject outer garment. The scripted duties of each personnel were put on poster in each section of the decon line to help the attendants proceed as listed below:

a. **Hand Wash and Boot Rinse Station:** Attendant 1 will proceed with the following instructions to the Test Subject:

- i. "Drop off the sample."
- ii. "Wash your hands, including between fingers."
- iii. "Brush each boot down and away from yourself."
- iv. "Brush the bottom of one boot, and step into the wash bin under the tent; then brush the bottom of the second boot and step in the wash bin."

b. **Outer Garment Decon and Rinse Station:** Attendants 1 and 2 performed the following 3-steps outer garment spray-brush-rinse-boot removal sequence:

- i. Step 1: Outer Garment Spraying (Attendant 1)
  - f. Instruct the test subject to raise his hands up for the whole 3-step decon sequence
  - g. Spray top to down the front face of outer garment including the boot.
  - h. Instruct the Test Subject to make a quarter turn towards Attendant 2.
- ii. Step 2: Outer Garment Brushing (Attendant 2)
  - a. Brush down and away concentrating on areas such as armpits, back of knees and between fingers
- iii. Repeat steps (i, and ii) for each side of the Test subject
- iv. Step 3: Outer Garment Rinse (Attendant 1)
  - a. Rinse each side of the Test Subjects by asking the Test Subjects to make a quarter turn after each face of the outer garment has been rinsed.
- v. Step 4: Boot Removal (Attendant 2)

- a. Remove tape
- b. Unlace the boots
- c. Remove boot 1 and ask the Test Subject to step out of the bootless leg first; then remove boot 2, and ask the Test Subject to step out.

c. **Outer Garment Doffing Station:** Attendant 3 was in charge of directing and helping the Test Subject in doffing the Outer PPE (Outer suit, face mask, and outer gloves). Steps involved in the doffing sequence are listed below:

- i. Attendant 3 will be donning 3 extra pairs of outer gloves in addition to the 3 pairs of gloves as worn by the other Test Subjects. The 3 extra pairs will not be taped.
- ii. Attendant 3 will help the Test Subject perform the doffing of PPE in the following sequence:
  - a. Untape the mask (Test Subject to stay still and not touch any part of the outer suit).
  - b. Untape the outer gloves and remove/dispose.
  - c. Attendant to check his outer gloves for contamination, and then remove and dispose the outer most gloves.
  - d. Untape the garment zipper, remove the outer suit by rolling it down and dispose of it. (Test Subject: do not touch any part of the inner suit).
  - e. Attendant to check his outer gloves for contamination, and then remove and dispose the outer most gloves.
  - f. Attendant will remove the mask, and set it aside in a bin for cleaning.
  - g. Attendant will direct the Test Subject to remove his middle glove, and wash his inner most gloves first and then his face.
  - h. Attendant to check his outer gloves for contamination, and remove the outer most gloves.
  - i. Repeat Step i of this section for the next Test Subject.
  - j. After all Test Subjects undergo the decon procedures, Attendants will follow the decon procedures in the following sequence: Attendant 1 first, followed by Attendant 2, and Attendant 3.

**Script 4: SOG using 2 attendants with a scripted 1-step outer garment water mist spray decontamination sequence (Tests 3A and 3B):** This script was designed to be in line with script 2 but using only one-step light water spray top to down the front face of outer garment including the boot by Attendant 1. The attendants were briefed prior to testing about the role of each of them to simulate real life scenarios without directions from outside support personnel. Attendant 1 was the person in charge to direct the volunteers through the decon station, and Attendant 2 was charge of assisting the Test Subject doffing their outer garment. The scripted duties of each personnel were put on poster in each section of the decon line to help the attendants proceed as listed below:

d. **Hand Wash and Boot Rinse Station:** Attendant 1 will proceed with the following instructions to the Test Subject:

- i. "Drop off the sample."
- ii. "Wash your hands, including between fingers."
- iii. "Brush each boot down and away from yourself."
- iv. "Brush the bottom of one boot, and step into the wash bin under the tent; then brush the bottom of the second boot and step in the wash bin."
- v. Attendant 1 will spray lightly top to down the front face of outer garment including the boot.

- d. Instruct the Test Subject to make a quarter turn
- vi. Repeat steps (v) for each side of the Test subject
- vii. Step 4: Boot Removal (Attendant 1)
  - a. Remove tape.
  - b. Unlace the boots.
  - c. Remove boot 1 and ask the Test Subject to step out the bootless leg first; then remove boot 2, and ask the Test Subject to step out.

e. **Outer Garment Doffing Station:** Attendant 2 will be in charge of helping the Test Subject in doffing the Outer PPE (Outer suit, face mask, and outer gloves). Step involved in the doffing sequence are listed below:

- i. Attendant 2 will be donning 3 extra pairs of outer gloves in addition to the 3 pairs of gloves as worn by the other Test Subjects. The 3 extra pairs will not be taped.
- ii. Attendant 2 will help the Test Subject perform the doffing of PPE in the following sequence:
  - a. Untape the mask (Test Subject to stay still and not touch any part of the outer suit).
  - b. Untape the outer gloves and remove/dispose.
  - c. Attendant to check his outer gloves for contamination, and then remove and dispose the outer most gloves.
  - d. Untape the garment zipper, remove the outer suit by rolling it down and dispose of it. (Test Subject: do not touch any part of the inner suit).
  - e. Attendant to check his outer gloves for contamination, and then remove and dispose the outer most gloves.
  - f. Attendant will remove the mask, and set it aside in a bin for cleaning.
  - g. Attendant will direct the Test Subject to remove his middle glove, and wash his inner most gloves first and then his face.
  - h. Attendant to check his outer gloves for contamination, and remove the outer most gloves.
  - i. Repeat Step i of this section for the next Test Subject.
  - j. After all Test Subjects undergo the decon procedures, Attendants will follow the decon procedures in the following sequence: Attendant 1 first, followed by Attendant 2, and Attendant 3.

- 4. **Script 5: SOG using 2 attendants with a scripted 1-step outer garment Spam Cooking Oil spray decontamination sequence (Tests 4A and 4B):** This script was designed to be in line with script 4 using Spam cooking oil to spray top to down the front face of outer garment including the boot by Attendant 1.
- 5. **Script 6: SOG using 2 attendants with a scripted 1-step outer garment water mist spray decontamination sequence with Test Subjects donning an extra inner Tyvek suit (Tests 5A and 5B):** This script was designed to be in line with script 4 with the Test Subjects wearing 3 suits (2 inner Tyvek suits, and 1 outer Tychem suit). This test was designed to determine if an added layer of protection would reduce Test Subject exposure to contamination.
- 6. **Script 7: SOG using 2 attendants with a scripted 1-step outer garment water mist spray decontamination sequence with Test Subjects donning 3 Tyvek suits (Tests 6A and 6B):** This script was designed to be in line with script 6 with the Test Subjects wearing 3 suits (all Tyvek suits; no Tychem suit). This test was designed to determine if replacing expensive and water-proof suit

(Tychem) with cheaper and more breathable Tyvek suit does not affect the protectiveness from inner suit contamination.

## **Appendix G**

### **Research Subject Post Test Questionnaire Form**



## RESEARCH SUBJECT POST TEST QUESTIONNAIRE FORM

**TITLE:** Decontamination Line Protocol Evaluation for Biological Contamination Events

**INVESTIGATOR:** Abderrahmane Touati, PhD, Project Manager,  
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### PURPOSE

To collect observations, concerns, and issues with the protective ensemble testing process encountered by the test subjects, or/and assistants.

### SURVEY

Info Participant number

Q1: any safety concerns that you noticed in any aspect of the testing process?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q2: Were there any aspects of the process that were difficult for any reason?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q3: Did you have any difficulties with the instructions used?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q4: Did you have any difficulty performing any of the steps or tasks?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q5: Did you notice any specific actions of interest to the study that might have been blocked from the video-cameras?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q6: Did you experience any difficulty with specific equipment or ensemble interfaces, connections, etc.?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q7: Are there any issues or concerns with the procedures being used in the test?

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Q5: Other items not addressed above (Specify: \_\_\_\_\_ )

- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐
- 5 ☐

Interviewer \_\_\_\_\_

Date \_\_\_\_\_

ARCADIS Project manager \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

Subject's Initials \_\_\_\_\_