AGRICULTURAL HANDLER EXPOSURE TASK FORCE

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Transmittal Letter for the Water Soluble Packet

(WSP) Mixer/Loader Scenario

February 24, 2009

Ms. Kelly Sherman
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Dear Ms. Sherman:

The Agricultural Handler Exposure Task Force, LLC (AHETF) is pleased to provide EPA with this supplemental submission for review by EPA and the Human Studies Review Board (HSRB) at their March 31-April 3, 2009 meeting. The submission involves the mixing and loading of wettable powder formulations of pesticides packaged in water soluble packets (WSP). This submission contains the following Standard Operating Procedures:

<u>SOPs revised following the October 2008 HSRB meeting</u>

AHETF-1.B.4	Personnel Responsibilities
AHETF-8.C.6	Dermal Face/Neck Wipe Samples
AHETF-8.D.4	Collection of Air Samples Using OVS Tubes
AHETF-8.E.5	Fortification of Matrix Samples
AHETF-11.B.4	Recruiting Study Volunteers
AHETF-11.H.2	Emergency Procedures for Human Subjects
AHETF-11.I.1	Language Requirements and Considerations for Study Volunteers
AHETF-11.J.1	Seeking Informed Consent from Study Volunteers

New SOPs written since the October 2008 HSRB meeting

AHETF-1.H.0	Procedure for Recruiting Study Participants
AHETF-11.K.0	Compiling Lists of Potential Growers
AHETF-11.L.0	Compiling Lists of Potential Commercial Applicators
AHETF-11.M.0	Identifying Potentially Eligible Growers and Commercial

The SOPs in this submission incorporate the suggestions made recently by the EPA. The AHETF appreciates the time and efforts of the EPA and HSRB to review and comment on the AHETF SOPs and testing program. We will be pleased to respond to any questions or requests for additional information or clarifications.

Sincerely,

Richard H. Collier by RC

Richard H. Collier, Ph.D.
AHETF Administrative Committee Chair

cc: John Carley

Personnel Responsibilities

Chapter 1: Administration
AHETF-I.B.4.

Effective Date : December 31, 2008

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APPROVAL_____ DATE_____

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APPROVAL_____ DATE_____

Last Revision Date: August 31, 2008 Previous Version Number: 1.B.3

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the roles and responsibilities of personnel participating in studies conducted for the Agricultural Handlers Exposure Task Force (AHETF). This may include contracted personnel who directly oversee the conduct of a study, or phase of a study.

1.2 This SOP was revised to update the ethical training criteria for researchers in Section 7.1 and to update the appropriate training course web links in Section 7.2.

2.0 RESPONSIBILITIES

2.1 The Task Force member companies and contracted companies will provide the appropriate personnel to manage, conduct, and monitor all regulated studies and other projects.

2.2 The AHETF is both the study Sponsor and testing facility. Independent companies that are members of the Task Force are sponsor representatives. They will assure compliance with the following requirements. Please refer to SOP AHETF-1.A.

3.0 TESTING FACILITY (AHETF) MANAGEMENT

3.1 The testing facility management for the AHETF consists of member company representatives serving on various committees and subcommittees, with various levels of responsibility and in various capacities.

3.2 There will be chosen representatives who will be the primary management contacts for the AHETF. These positions will be the Technical Committee Chair, the Technical Committee Vice-Chair, the Task Force Manager, and the Subcommittee Chairs.

3.3 As required by the EPA GLPs, § 160.31, the testing facility management shall:

a. Designate the Study Director.

b. Replace the Study Director promptly, when necessary during the conduct of the study.

c. Assure that there is a QAU.

d. Assure that the test, control, and reference substance(s) or mixture(s) have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

e. Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

f. Assure personnel clearly understand the functions they are to perform via the study protocol, SOPs, and memoranda.

g. Assure that corrective actions are taken, as necessary, for all GLP regulation deviations reported by the QAU, and documented.

4.0 AHETF TASK FORCE MANAGER

4.1 A designated individual will serve as the Task Force Manager for the AHETF. This person may be consulted regarding study conduct by the participants listed above, and may serve as an arbiter to settle issues involving AHETF studies.

4.2 The Task Force Manager, as well as the Study Director, has the authority to terminate an AHETF study that no longer has interest to the AHETF, or has been compromised (scientifically or through regulatory misconduct) by the contractor(s).

4.3 One individual will be assigned by AHETF management as the Task Force Manager, who will authorize study protocols, approve SOPs, oversee the contracting of third-party companies for studies and other projects, and provide overall study coordination until study completion and archiving. The Task Force Manager is a representative of AHETF management.

5.0 STUDY DIRECTOR

5.1 Good Laboratory Practice Standards require that a single person assume responsibility for the conduct of a study. Responsibilities, as defined in the GLPs, §160.33, apply to the scope of the AHETF Study Director's involvement in assigned studies. The Study Director shall assure that:

a. The protocol, including any change, is approved - in writing by the Study Director and sponsor's representative - and followed.

b. All experimental data are recorded and verified.

c. Unforeseen circumstances that may affect the integrity of the study are noted as they occur, and corrective action is taken and documented.

d. Test systems are as specified in the protocol.

e. All applicable good laboratory practice regulations are followed.

f. All raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study.

g. Specific responsibilities are assigned to AHETF personnel, contracted Principal Investigators, or other designees, as necessary.

h. The progress of the field and analytical portions of AHETF studies, including the preparation of each final report, are monitored and the AHETF Management is informed of progress $^{and}/_{or}$ problems.

5.2 The AHETF Study Director will be contracted to oversee the field and analytical phases of each AHETF study. Please refer to SOP AHETF-1.C.

6.0 PRINCIPAL INVESTIGATORS

6.1 For each field and laboratory study, contractor facility management may assign a person to fulfill the role of principal investigator (PFI: Principal Field Investigator; PAI: Principal Analytical Investigator), as necessary. The PFI's and PAI's responsibility involves direct communication with the AHETF Study Director. The PFI/PAI may have direct and immediate responsibility over an AHETF study in the absence of the Study Director or designated AHETF member.

6.2 In situations where several contractors are participating on an AHETF study, each contractor will designate its own PFI/PAI who will coordinate with the Study Director.

7.0 ETHICS TRAINING FOR RESEARCHERS

7.1 Researchers that interact with study participants must undergo ethics training. Training must be completed prior to participation in an AHETF study and researchers must complete recertification training at least every three (3) years.

7.2 The training shall include successful completion of the course from the National Institutes of Health (Protecting Human Research Participants (PHRP)) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). There are links to both of these on-line training courses at www.nih.gov and www.citiprogram.org.

7.3 Copies of the certificates of completion for the ethics courses will be included in the raw data and in the respective personnel files.

Dermal Face/Neck Wipe Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.C.6.
February 15, 2009

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APPROVAL_____ DATE_____

Last Revision Date: August 31, 2008 Previous Version Number: 8.C.5.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes procedures for collecting pesticide residues from workers' face/neck during the Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP was revised to add the steps to follow when the worker is wearing facial Personal Protective Equipment in section 3.3.

2.0 EQUIPMENT REQUIRED

2.1 The following materials are required for collecting dermal face/neck samples:

a. 100% cotton gauze (8 layers, 4" x 4"/10cm x 10cm sponges)

b. Anionic surfactant solution (Aerosol® OT - sodium dioctyl sulfosuccinate).

c. Syringe or pipette

d. Disposable gloves (*i.e.*, latex)

e. Aluminum foil

f. Resealable bags or glass jars with Teflon-lined lids

g. Cooler with dry ice or a freezer

3.0 SAMPLING PROCEDURE

3.1 The field personnel collecting samples will wear clean, disposable gloves while collecting these dermal samples. (Note: some packaging may contain two sponges; check to make sure each sponge is 8 layers)

3.2 Dispense approximately 4 mL of the surfactant solution (0.01% Aerosol® OT) on the gauze sponge with the syringe or pipette (or other appropriate means of moistening the sponge).

3.3 If the worker is wearing additional Personal Protective Equipment (PPE), such as goggles or a respirator, the worker will remove all PPE before having the face/neck wipe collected.

3.4 Thoroughly wipe the worker's face/neck (front & back) with the moistened sponge.

3.5 Repeat steps 3.2 and 3.3 again, for a total of two dermal wipes per sample. Wrap both sponges in aluminum foil (only if using a sealable bag) and place in the prelabelled bag otherwise place both wipes in a prelabelled jar, close the top, and place in frozen storage.

4.0 SAMPLING INTERVALS

4.1 Prior to the monitoring unit start, one dermal face/neck wipe sample will be collected from each worker and the wipes discarded.

4.2 Face/neck wipe samples will be collected before the workers eat anything and any time the workers would normally wash their face.

4.3 After the monitoring unit is completed, one dermal face/neck wipe sample will be collected from each worker after the hand wash sample is collected per SOP 8.B. and before removal of whole body dosimeters. The wipes will be combined with the samples collected prior to eating, if applicable. If more than two samples (4 wipes) are in a sample bag or jar; the laboratory must be notified as to the total number in the container.

5.0 FIELD STORAGE

5.1 Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Collection of Air Samples Using OVS Tubes

Chapter 8: MATRIX SAMPLES
AHETF-8.D.4.

Effective Date : February 15, 2009

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Last Revision Date: October 27, 2008 Previous Version Number: 8.D.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting air samples using OSHA Versatile Sampler (OVS) tubes during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 The OVS tube will be positioned in the breathing zone of the worker. The air will be sampled at a flow rate applicable to the characteristics of the OVS tube. A plastic tube holder will be used to position and protect the OVS tubes on the worker.

1.3 Section 5.1 was revised to add additional hygiene for minimizing cross-contamination of the OVS tubes.

2.0 MATERIALS REQUIRED

2.1 The following materials are required for collecting air samples from each worker:

a. OVS Tubes, 13 mm glass tubes [*e.g.*; mfr. SKC, Inc. with 270 mg & 140 mg absorbent beds separated by polyurethane plug, and glass fiber filter at the inlet], or equivalent

b. Plastic OVS tube holder

c. Tygon® or equivalent tubing and clips for securing tubing to the worker (a minimum of two required)

d. Low volume personal air-sampler pump (battery operated)

e. Air flow meter (*e.g.*, Kurz Mass Flow Meter, rotameter, bubble flowmeter, or equivalent)

f. Sealable bags (*e.g.*, Ziploc® freezer bags)

g. Disposable gloves (*i.e.*, latex)

h. Cooler with dry ice, or freezer

3.0 AIR-SAMPLER PUMP PREPARATION

3.1 Place air-sampler pumps on chargers before each use. If the pump is fully charged proceed to 3.2.

3.2 Adjust air-sampler pump flow rate before use in each monitoring unit. Air sample pump flow rate adjustment will take place on the day prior to or the same day the pumps are to be used.

3.3 Adjust air pumps to the targeted airflow rate with the appropriate OVS tube/ sampling train attached.

3.4 Follow appropriate contractor SOPs for the individual calibration methods for contractor equipment. SOPs used will be documented in the AHETF raw data.

3.5 Adjust the airflow rate to appropriate target rate as defined in the study protocol [*e.g.,* 2 liters per min (L/min)] and document the flow rate and pump number in the raw data.

3.6 Turn off the air-sampler pump and set aside. Repeat steps 3.3 and 3.5 until all needed sampling pumps (including backups) have been adjusted.

4.0 SAMPLING PREPARATION

4.1 Remove the outlet cap from the OVS tube and connect the outlet of the tube (the smaller 6 mm end) to the end of the air tubing that is connected to an adjusted personal air-sampler pump. Be sure the glass fiber filter is attached to the inlet (the larger 13 mm end) and is left open.

4.2 Position a belt snugly around the worker's waist, or use that worker's belt (if appropriate) to support the sampling pump. Attach the pump to the belt using the clip on the pump. Position the pump wherever it feels most comfortable to the worker.

4.3 Place the OVS tube over the shoulder of the worker (to the front of the torso) in the approximate position for sampling (in the breathing zone of worker).

4.4 Use a binder clip to attach the tubing, approximately at its midpoint, to the worker's clothing so that it will not interfere with the normal work operations nor catch on anything. The tubing may be run inside the worker's clothes. If tubing is run inside, ensure that clean, decontaminated tubing is used. **Do not reuse contaminated tubing!**

4.5 Remove the inlet cap and start the pump. Check the flow rate with a calibrated rotameter (Please refer to the AHETF-10.A or appropriate contract testing facility SOP). Adjust the air-sampler pump flow rate if the measured flow rate deviates greater than ±5% from the target flow rate.

4.6 Document the pump number, start time and the flow rate measured with the rotameter in the raw data.

4.7 Place the OVS tube in the plastic holder and clip the holder to the workers' collar (in the breathing zone). If the holder does not have an integral clip, use a binder clip, wire or plastic tie to attach to the worker's collar or lapel. Be sure the tubing is not crushed or restricted when attached. The inlet must face downward, in a vertical orientation.

4.8 Observe the worker for a few minutes upon starting to work to ensure the sampling apparatus is functioning properly, and is not interfering with the worker. Periodically monitor the pump during the monitoring unit to ensure it is functioning properly.

4.9 Pumps will run continuously throughout the duration of the monitoring unit, including lunch and other breaks.

4.10 Should a pump malfunction during the monitoring unit, it will be replaced immediately with a new, prior adjusted pump (section 3) or replace the batteries. Remove the OVS tube from the old pump and attach it to the new, adjusted pump, and repeat steps 4.6 through 4.9. These activities will be documented in the appropriate study file(s) and include (at a

minimum) the time the malfunction was discovered, the time reading on the pump (if available), the time the new pump was started and the new measured flow rate with the original sampling tubing.

4.11 At the end of the monitoring unit, remove the OVS tube from the plastic protective holder, measure the terminal flow rate with the rotameter, turn off the pump, record the stop time and flow rate. The sampling pump, tubing and OVS tube must be removed from the worker before any other samples are collected. See SOP AHETF-10.E.

5.0 SAMPLING PROCEDURE

5.1 Upon completion of the monitoring unit, remove the OVS tube from holder, wipe the outside of the OVS tube with a solvent-moistened wipe to remove potential surface residues, then cap both ends and place into frozen storage (*i.e.*, on dry ice or in a freezer).

5.2 Clean disposable gloves will be worn by sampling personnel to minimize any contamination of the OVS tube. Gloves will be changed after handling each tube.

6.0 SAMPLING INTERVALS

6.1 OVS tubes will be collected at the end of the monitoring unit, unless otherwise instructed by the protocol.

7.0 FIELD STORAGE

7.1 Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into “permanent” frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Fortification of Matrix Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.E.5.

Effective Date : February 15, 2009

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Last Revision Date: April 4, 2008 Previous Version Number: 8.E.4.

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the methods by which agricultural worker exposure monitoring matrices, (*i.e.*, inner dosimeters, hand washes, face/neck wipes, inner socks, outer head patches, inner head patches, and OVS tubes) are to be spiked. This SOP applies to the use of all worker exposure matrices when used for producing field fortification recovery data for the Agricultural Handlers Exposure Task Force (AHETF).

1.2 This SOP was revised to provide additional guidance for Study Directors (SD) to determine when to conduct field fortifications during a cluster (site) location in Section 8.0.

2.0 BACKGROUND

2.1 Field fortification samples are exposure matrix samples that are fortified (or spiked), generally in the field, with known amounts of active ingredient and subsequently analyzed to determine the amount of active ingredient recovered. Field fortification samples are subjected to the same environmental, handling, shipping and storage conditions as worker samples. Because these conditions are similar, and because field fortification samples are analyzed along with worker samples, recovery values calculated from analysis of fortification samples are applicable to worker exposure samples. Field fortification recoveries are therefore used to adjust residue levels found in worker samples for residue losses that might have occurred during collection, handling, shipping and storage.

2.2 It is important that field fortification samples simulate worker samples as much as possible. For example, some worker matrices collect residue throughout the entire monitoring period and are therefore subject to environmental conditions for several hours. To simulate this in field fortification samples, certain matrices are "weathered" in the field concurrently with worker samples. That is, they are fortified (generally before any worker monitoring starts) and exposed to the environment until worker monitoring has been completed on that day. Samples that are weathered include: inner dosimeters, socks, head patches (inner or outer) and OVS tubes. On the other hand, face/neck wipes and hand wash samples are collected at discrete times during the day and are not subject to environmental conditions during sample collection. Therefore, these sample types (both worker samples and field fortified samples) are not weathered, but are instead placed into storage immediately after collection.

2.3 The field fortification process simulates two other conditions that worker samples experience. First, inner cloth dosimeters (whole body dosimeters, WBD), socks, and head patches are covered with a material similar to what covers the worker samples: a layer of cloth to simulate outer clothing covers inner dosimeter and sock samples, and headgear material (e.g., chemical-resistant hat) covers inner head patches. Second, OVS tubes have air drawn through them at the same rate that air is drawn through the worker air tubes.

2.4 AHETF also prepares and collects non-fortified (control) samples to determine if background residues of active ingredient are present. For the same reasons as described above, control samples of inner dosimeter, inner and outer patch, sock and OVS tube are weathered, while control samples of hand wash and face/neck wipe are not weathered.

2.5 In addition, fortified inner dosimeters (and if appropriate, socks and head patches) and OVS tubes are prepared as "travel spikes" and are not weathered. These samples provide a source of determining whether or not degradation occurs in transit. Travel spikes are not analyzed unless there are unexplained low residue recoveries of the corresponding field fortification samples. In this situation, recovery results from travel spikes might provide insight into where in the preparation, collection, transit and storage process, losses may have occurred.

3.0 EQUIPMENT/REAGENTS REQUIRED

3.1 The following examples of equipment and solutions are required for each day that field fortifications are to be conducted:

a. Exposure monitoring matrix samples based upon protocol specified monitoring matrices (inner dosimeter material cut according to SOP AHETF-8.A. [upper and lower sections for two section monitoring or upper/lower arms & legs and front/rear torso for six section monitoring], moistened face/neck wipes, OVS tubes, and hand wash solutions, and if required, 50 cm^2 and 100 cm^2 head patches [made of inner dosimeter material], and socks).

b. Appropriate containers for fortified matrix samples (*e.g.*, bags, bottles, jars, *etc.*)

c. Appropriate pipettes (*e.g*. 1.0 mL, non-graduated Pasteur pipettes, *etc.*)

d. Appropriate syringe (*e.g.*, 100 µL)

e. Distilled or deionized water

f. Anionic detergent solution (0.01% v/v Aerosol® OT 75). Refer to the SOP AHETF-8.B for solution preparation.

g. Paper towels

h. Disposable gloves

i. Aluminum Foil

j. Rinsing solvent (to be the same as the solvent used to make spiking solutions)

4.0 SPIKING MATERIALS

4.1 Spiking materials may be in the following forms:

a. Active ingredient (ai) in an organic solvent

b. Formulated product in water

c. Formulated product pre-weighed into a container in which a specific amount of water is to be added in the field prior to being spiked onto (into) a matrix material.

d. Pre-spiked OVS tubes.

5.0 SPIKING TECHNIQUES

5.1 There are two (2) basic procedures that may be used for the fortification of worker dermal exposure matrices for the AHETF. They are by pipette and by vial.

5.2 When applying a spiking material to the various matrices, it is important to ensure that the solution/suspension gets well mixed prior to spiking and/or distributed as evenly as possible.

5.3 The spiking material needs to be distributed mechanically, typically with a pipette or vial, over the largest amount of matrix area as possible.

5.4 **Spiking ai in solvent**: A volume, typically 1 mL, of spiking solution will be drawn up into the pipette and then applied appropriately to the matrix of choice.

5.5 **Spiking formulated product in water**: A well-mixed aliquot, typically 1 mL, will be taken from a well-shaken bottle of the formulation suspended in water. The shaking may be done by hand, on a stirring plate, or using a mechanical shaker. Once the suspension looks evenly distributed, an aliquot is taken and applied appropriately to the matrix of choice.

5.6 Spiking using entire solution vials: Vials containing a known aliquot of a known concentration of spiking material will be sent to the field along with instructions on how to apply the spike to a matrix. The person doing the spiking will take a given spiking vial, unscrew the cap, and apply the contents to the matrix. The contents may be poured directly from the vial or removed via a Pasteur pipette (or equivalent). Use of a pipette may be desired for smaller matrices where more exact placement of material is necessary. The vial and pipette will sometimes be rinsed several times with the solvent (e.g. deionized or distilled water, acetone, acetonitrile,

etc.) that was used to prepare the solution and applied to the matrix or as directed by the analytical laboratory (see below). The vial shall be retained with the fortified sample. The cap should be discarded and should not be rinsed. Vials should be marked with a label that may be tied to the vial with string or is a self adhesive label, which may be removed easily from the vial and will not interfere with analysis of fortified matrices.

6.0 SPIKING PROCEDURES

6.1 Inner Dosimeters

a. The dosimeters must be placed on a piece of aluminum foil prior to spiking. After spiking and weathering (if applicable), the sample will be wrapped in the same piece of foil it was placed on for spiking and weathering then inserted into the sample container.

b. The spiking material will be added to inner dosimeters; ensure the fortification is added to a dosimeter that has been folded to provide at least 6 layers of cloth. This insures that all the material is absorbed by the cloth.

c. When spiking with solution vials, the person doing the spiking will unscrew the cap and apply the contents to the matrix. The vial will be rinsed several times as directed by the analytical laboratory with the solvent that was used to prepare the solution or suspension. This may be done several times, however; too much solvent will cause the spike to run through the fabric, so judgment is needed. The empty spiking vial will be placed on its aluminum foil with the matrix prior to folding the foil.

d. When pipetting the solution onto the dosimeter, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the dosimeter. At no time can there be a bead of spiking material left on the surface. (The spiking liquid may tend to bead up on the surface. Gently pushing the pipette tip over the bead will help to get the liquid into the matrix.)

e. For dosimeters exposed to ambient conditions, the inner dosimeters will be folded over after fortification and covered with a single layer of shirt material during exposure. Effort should be made to ensure that the spiking solution has been completely absorbed by the material prior to covering.

6.2 Hand Washes

a. When spiking from a solution or suspension in the field, the appropriate amount of spiking solution (typically 1 mL) will be added to the hand wash.

b. When spiking with vials, the cap to the solution vial will be unscrewed from the vial and discarded without rinsing. The contents will be added to a 500 mL Aerosol OT (AOT) sample and the vial then dropped into the sample. The sample will then be swirled or the jar inverted to ensure proper mixing of the spiking material with the sample matrix.

6.3 OVS tubes

a. The tubes will be spiked at the laboratory with the proper amount of analytical standard. The tubes will always be spiked with an ai solution using a syringe. The spike will be applied by inserting the needle through the glass fiber filter and approximately one quarter of the way into the front sorbent bed.

b. Depress the syringe plunger slowly to avoid the ai solution from "bleeding out" of the sorbent and adhering to the glass tube. Each tube will be spiked with a minimum of 5μL up to, but not exceeding, 100 μL of solution. The actual amount of spiking solution to use will be determined by the analytical laboratory and documented in the raw data.

c. Tubes fortified in the laboratory will be sent frozen in plastic bags to the field. The bags will be to be taken out of the freezer and allowed to come to ambient temperature before they are used in the field. Just before they are to be put on the personal air sampling pumps, they should be taken out of the bag and allowed to finish equilibrating with the environment.

They then will be placed onto the pumps and air pulled through them for the approximate length of time the worker replicates are in the field.

6.4 Face/Neck Wipes

a. Pre-wet two face/neck wipes as described for field samples in SOP AHETF-8.C.

b. When spiking with solution vials, the two gauze pads will first be placed into the sample jar or on clean foil. The contents of the vial will then be transferred onto the gauze pads. The vial will be placed with the sample without being rinsed. The cap will be discarded without rinsing. The sample will be wrapped in foil and placed in a plastic bag, or the jar will be capped and sealed after fortification, as appropriate. In the laboratory, the vial will be rinsed as part of the extraction procedure.

c. When pipetting the solution onto the wipe, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the wipe, if necessary.

6.5 Socks

a. The socks must be placed on a piece of aluminum foil prior to spiking. After spiking and weathering, the sample will be wrapped in the same piece of foil it was placed on for spiking and weathering then inserted into the sample container.

b. For spiking and weathering, ensure the sock sample consists of 2 socks (1 pair). The actual spiking material will be placed on the one sock that is closest to the foil. This sock will then be covered by the second sock and both socks will be folded. This procedure simulates a sock covered by a worker's pants and shoes.

c. When spiking with prepared solutions in vials, the person doing the spiking will unscrew the cap and apply the contents to the matrix. The cap will be discarded without rinsing. The vial will be rinsed several times with the solvent that was used to prepare the solution, as directed by the analytical laboratory. Multiple rinses may be done; however, too much solvent will

cause the spike to run through the fabric, so judgment is needed. Place the empty spiking vial in its aluminum foil with the matrix.

d. When pipetting the solution onto the dosimeter, the tip of the pipette may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the dosimeter. At no time can there be a bead of spiking material left on the surface. (The spiking liquid may tend to bead up on the surface. Gently pushing the pipette tip over the bead will help to get the liquid into the matrix.)

6.6 Outer Head Patches

a. For field fortification samples, only, an outer head patch will consist of 6 layers of inner dosimeter material, each layer cut to a 50 cm^2 area wrapped in aluminum foil. The foil should be placed underneath the pile of patches and used to wrap the weathered spiked patch sample once the weathering period is completed.

b. The field fortification suspensions will be applied to the topmost layer of patches. The additional layers will be used to ensure that no spiking material leaches out onto the foil that underlies the pile of patches.

c. Outer head patches **will not be** covered during the weathering period.

6.7 Inner Head Patches

a. For field fortification samples, only, an inner head patch will consist of 4 layers of inner dosimeter material, each layer cut to a 100 cm^2 area, wrapped in aluminum foil. The foil should be placed underneath the pile of patches and used to wrap the weathered spiked inner dosimeter patch sample once the weathering period is completed.

b. The field fortification suspension will be applied to the topmost layer of material. The additional layers will be used to ensure that no spiking material leaches out onto the foil that underlies the pile of patches.

c. Inner head patches will be covered with chemical resistant headgear similar to the type worn by the workers during the application period, or other suitable material to simulate the headgear, as approved by the Study Director.

7.0 FORTIFICATION SAMPLE IDENTIFICATION AND HANDLING

7.1 Refer to SOP AHETF-8.F. for the procedures to uniquely identify fortification samples.

7.2 Fortification samples that are exposed under the open sky should have the necessary materials to protect the samples in the event of rain.

7.3 Fortification samples are packaged, stored and transported in the same manner as the test samples for a particular matrix. The fortification samples should not be placed into the same shipping/storage container with control samples or with field samples.

8.0 FIELD FORTIFICATIONS GUIDELINES DURING A STUDY

8.1 At least one field fortification set for each surrogate a.i. used on an AHETF exposure study should be prepared and collected at each cluster location (site) described in the protocol. Fortifications do not need to be collected at each individual monitoring unit within a cluster.

8.2 If multiple a.i.'s are used in individual MUs on the same day, it is necessary for only one a.i. to have field fortifications prepared on that day. The SD can choose which surrogate to fortify with, but if one surrogate will only be used once at the cluster, it should have precedence for fortifications that day.

8.3 Additional field fortifications may be prepared at the Study Director's discretion if the following conditions are expected:

a. Different meteorological conditions between study days (*e.g.;* hot, dry, and full sun vs. cool, humid, and cloudy).

b. Significant distances between sites that could provide some environmental differences.

c. One set of field fortifications becomes compromised during the weathering period (*e.g.;* heavy rain, contamination, *etc…*)

Procedure for Recruiting Study Participants

Chapter 1: Administration
AHETF-I.H.O.

Effective Date : February 1, 2009

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APPROVAL_____ DATE_____

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the general procedures for identifying growers and/or commercial applicators, and recruiting study participants for exposure studies conducted by the Agricultural Handler Exposure Task Force (AHETF).

2.0 DEFINITIONS

2.1 **Universe List**: A compilation of names from public or private sources of all growers or commercial application companies for a given site where an exposure study will be conducted. This list will generally contain at least 75% of the estimated population based on agricultural census information or expert opinion.

2.2 **Master List**: A random sub-sample of the Universe List that is expected to provide a sufficient number of names to fulfill the scenario sampling design. The Universe List will be sampled such that every member has an equal chance of being placed in the Master List. If the Universe List contains fewer names than desired (generally 300 growers or 200 commercial applicators), it becomes the Master List.

2.3 **Qualified List**: A subset list developed from the Master List that, through telephone interviews (generally by a professional call center), includes only growers or commercial applicators who meet basic qualifications for participation in an exposure study. This information includes things such as handling of pesticides, growing target crops on desired acreage, and using specific mixing/loading and/or application equipment as defined in individual study protocols. Growers or commercial application companies that do not meet the requirements to participate in an AHETF study are eliminated from the list.

2.4 **Potentially Eligible List**: A refined list of potential growers/applicators derived from the Qualified List. This list is developed after direct contact between the AHETF and potential growers or applicator companies to explain the mission of the AHETF and to detail the study to be conducted. This list is presented to the AHETF Study Director for determination of an Efficient Configuration of MUs that may be contacted (for example, by calling or a site visit) to confirm their eligibility for the AHETF study.

2.5 **Eligible List**: The final list of growers or application companies from which study participants are recruited.

2.6 **Study Participant**: An employee of a grower or commercial application company who participates in an AHETF worker exposure study as an applicator, mixer/loader, or mixer/loader/applicator (handler).

2.7 **Monitoring Unit (MU)**: A dataset fully describing a single worker handling a particular pesticide under a particular set of circumstances that represent a single workday. MU is also commonly used to refer to a study participant who dons appropriate dosimetry and is monitored for the prescribed work period as well as the resulting exposure measurements from that worker that end up in the AHETF database.

2.8 **Site**: A geographic area and a range of dates where a cluster of AHETF exposure MUs will be obtained. This could be a single county, several adjacent counties, or even an entire state. Within a site, each MU will be collected from a different farm or commercial applicator. Typically five (5) farms or commercial application companies will be chosen to conduct five separate MUs per cluster.

2.9 **USDA Census of Agriculture**: Multiple sources for agricultural demographic data that are compiled by outside sources and publicly accessible or available for purchase from third party vendors. Useful information includes the number of farms the size of farms in acres for particular crops and counties.

2.10 **Efficient Configuration**: The final selection of eligible workers for inclusion in a study that best fits the total number and type of Monitoring Units to be collected at a given site in a cost-effective manner. This involves identifying farms or commercial applicators that are near each other and can provide the required number of handlers who will handle various amounts of active ingredient in a short period of time.

3.0 GENERAL PROCEDURE

3.1 The typical scheme for contacting growers or application services, which will lead to recruiting individual handlers to participate in an AHETF study, is shown graphically in Attachment 1-H-1.

3.2 Development of the Universe, Master, and Qualified Lists will be completed as described in SOPs AHETF-11.K or AHETF-11.L.

3.3 The Qualified List will be further refined to the Potentially Eligible List as described in SOP AHETF-11.M.

3.4 The Potentially Eligible List will be presented to the designated AHETF Study Director who will further refine the list by contacting and/or visiting interested growers or application services.

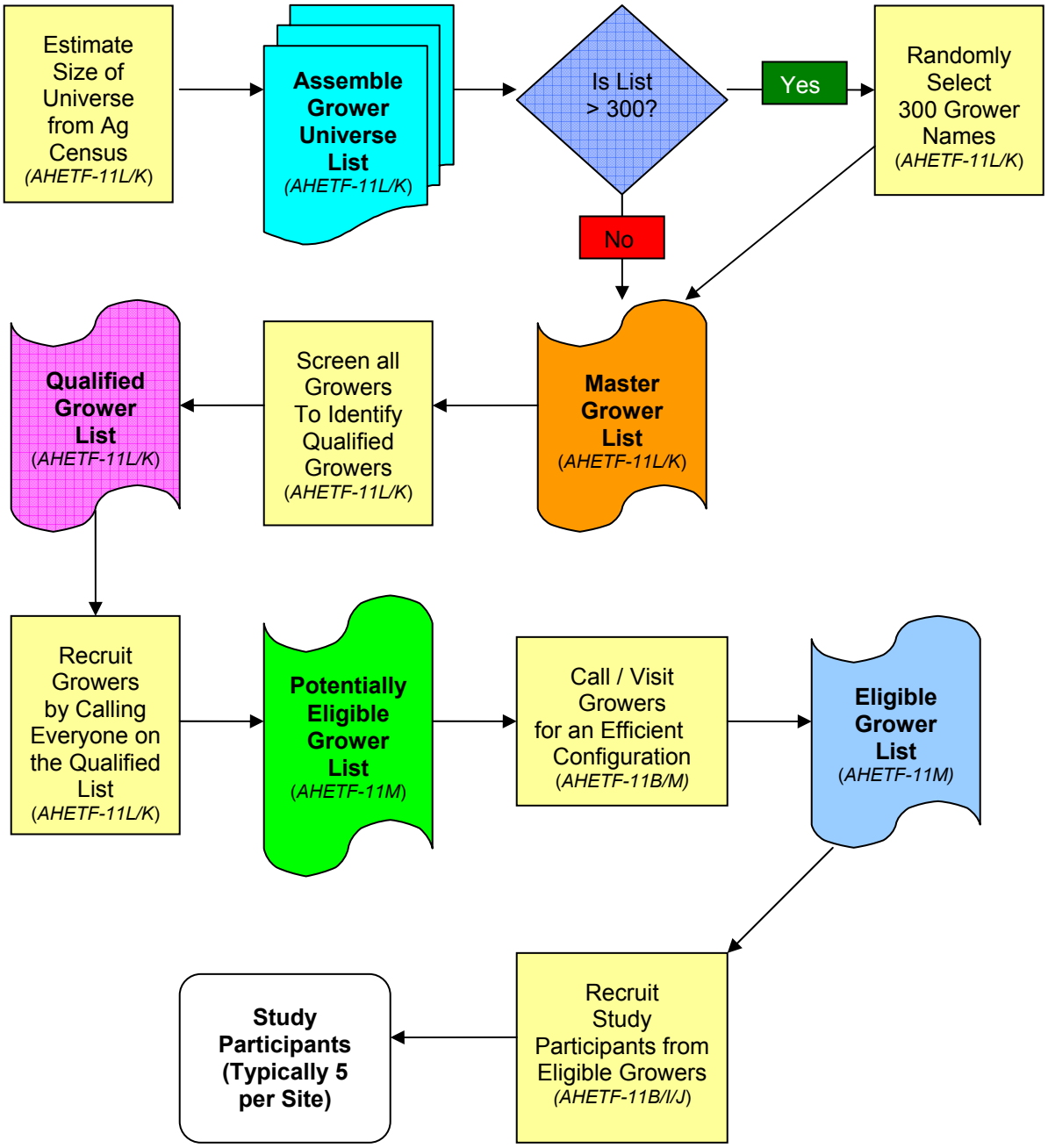
3.5 After contacting growers or application services, the Study Director will have the Eligible List that will be used to select the most appropriate facilities in which to conduct the study according to an Efficient Configuration design.

3.6 Using the Potentially Eligible List, the Study Director will contact (either by calling or performing location visits) to confirm the suitability of the facility/operation for the study. During the onsite visit (or a later date) the Study Director will meet with the workers to present an overview of the research, including the risks and benefits of participation in the AHETF study. Typically, a copy of the informed consent form, sample product risk statement, and other appropriate documents are provided to the workers at this recruitment meeting. If the contacted grower/applicator will participate as a worker, then procedures outlined in SOP AHETF-11.B apply.

3.7 Consent of workers expressing an interest in participating in the research will be sought according to SOPs AHETF-11.B, -11.I, and -11.J. Participant recruitment may take place prior to or on the day of monitoring. When more than one worker at a facility volunteers to participate, the participant will be selected by a random method, such as drawing names from a hat or flipping a coin.

Attachment 1-H-1

Example Process for Recruiting Growers and Study Participants



Recruiting Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.B.4.

Effective Date : February 15, 2009

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APPROVAL_____ DATE_____

Last Revision Date: October 10, 2008 Previous Version Number: 11.B.3

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for recruiting workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). Additional study-specific detail will be included in individual protocols as needed

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify the language in Sections 2.1, 4.0, 4.1, 4.2.c, 4.3.c, e, and g to follow language in the study protocols. Section 5.2 was rewritten to standardize the language for inclusion criteria, and section 5.3 was deleted to remove exclusion criteria.

2.0 REQUIRED TRAINING FOR RESEARCHERS

2.1 The Study Directors (SD), Principal Field Investigators (PFI), Task Force Field Study Monitors, Local Site Coordinators (LSC), worker observers, and other Task Force researchers who interact with study participants, will have completed one or more ethics training courses. Certificates of completion for the course(s) will be available prior to their participation in the field phase of the study on behalf of the AHETF. Details on the courses are defined in SOP AHETF-1.B.

3.0 RESEARCH APPROVAL

3.1 Workers will not be recruited for participation in any field study until after the following items have been completed:

a. IRB approval has been obtained for the study protocol, consent forms and documentation required by 40 CFR 26

b. Approval of the proposed study by the California Department of Pesticide Regulation when a study is to be conducted in California

c. Review of the proposed study by EPA and the Human Studies Review Board (if required), and

d. IRB approval of any changes in the protocol or any supporting document required as a result of the reviews by EPA, the HSRB, and/or CDPR

4.0 PROCEDURE FOR RECRUITMENT OF POTENTIAL WORKERS

Recruitment of workers typically occurs in two steps. A study-specific recruitment plan will be specified in each study protocol.

4.1 The first step typically involves contacting and selecting growers and/or commercial application companies that can provide the necessary crop/site, equipment, workers, and are willing to use an AHETF surrogate. This will be done by calling from a randomized list of growers in a local area (See SOP AHETF-11.M). Growers that meet the criteria listed above will be placed in a pool of eligible growers. At this time, growers (employers) will be asked for permission to recruit their workers for the research study. Written assurance will be obtained from the employer that the workers will not suffer any consequence if they decide either to participate or not to participate in the study and that there will be no coercion of the workers (see Attachment 11-B-1).

4.2 The second step typically involves recruiting workers from a pool of eligible growers and/or commercial applicators identified in the first step. These workers may be the growers themselves, their employees, or employees of commercial applicators. The process is as follows:

a. Growers and/or commercial applicator companies will have been selected who meet all criteria for eligibility, who are willing to cooperate with AHETF in the monitoring study, and who the SD will have determined are acceptable. The grower or other responsible personnel will have given permission for the SD (or designee) to contact their employees to determine employee interest in study participation.

b. The SD (or designee) then initiates contact with the employees, sometimes by distributing an IRB-approved flyer which generally describes what participation in the study entails and provides a toll-free phone number to accommodate both English and Spanish speakers, or by conducting an on-site visit. Appropriate language flyers (English or Spanish) will be distributed at the discretion of the SD (or designee) or at the request of the employer. The SD (or designee) organizes a recruitment meeting with only the interested workers present. This may be done one-on-one or with a group of interested workers. Each interested worker will attend at least one recruitment meeting. Follow-up recruitment meetings will be held at the discretion of the SD (or designee) or at the request of the worker. Note that growers themselves (if they are qualified handlers) may be recruited. If this is indicated as a possibility during the potential growers/applicators eligibility call (see SOP AHETF-11.M), they will be told another study team member will contact them to begin the recruitment process.

c. In cases where the grower or commercial applicator contacted is the owner/operator of the equipment and conducts his/her own applications, the Study Director or designee contacting the grower or commercial applicator may proceed to recruit the owner/operator as an “employee” or worker following sections 4.3(c) - (f). In these cases, the Employer Cooperation Statement signed by the owner is not necessary, as there are no employees.

4.3 The recruitment meeting(s) with interested workers will consist of the following (meetings will be held in the preferred language(s) of the attendees):

a. Growers, commercial application company managers, or other personnel to whom employees might report will not attend.

b. Growers and management personnel who express an interest in participating in a study will be invited to a separate recruitment meeting.

c. The nature of the study and general content of the protocol and Consent Form will be presented. Any recruitment materials used during this recruitment meeting will be approved by the IRB before use.

d. Eligibility criteria will be reviewed with the potential volunteers and all questions will be answered.

e. Informed Consent Forms, an example PRS, and for studies conducted in California the California Experimental Research Subject's Bill of Rights (in their preferred language), will be given to all potential volunteers who attend a recruitment meeting. Workers will be urged to take the copy home for review.

f. Potential volunteers will be given a copy of the written assurance obtained from the employer that they will not suffer any consequence if they decide not to participate in the study and that there will be no coercion of, or undue influence on, the workers. The copy will be available in English and, if needed, in Spanish.

5.0 INCLUSION CRITERIA FOR STUDY PARTICIPATION

5.1 Potential participants may be farm owners, farm operators, farm employees, contract applicator employees, or commercial applicators, *etc*.

5.2 Although additional eligibility criteria may apply in specific cases, all AHETF study participants must meet these inclusion criteria:

a. Have experience within the past year with the work activity being monitored in the study (including the particular equipment to be used during mixing/loading or application).

b. Handle pesticides as part of their job.

c. Be trained in safe pesticide handling procedures in accordance with the Worker Protection Standard (WPS) or equivalent Canadian regulations, or be exempt from such training.

d. Provide proof of being at least 18 years old with a government-issued photo ID.

e. Confirm they do not work for a pesticide company or a contractor of the AHETF

f. Consider their general health status to be good and tell researchers they have no medical conditions that affect their ability to participate in the study. See SOP AHETF-11.C for health status determination.

g. Not be pregnant or nursing. (See SOP AHETF-11.D.)

h. Confirm they do not normally wear personal protective equipment that is not required by the label and that might impact the objectives of the study, such as chemical-resistant clothing. Confirm they will follow label directions.

i. Have a private meeting with a researcher to review and discuss the consent form.

j. Understand English or Spanish (see SOP AHETF-11.I for detailed discussion of this topic).

k. Understand and sign the consent form, Product Risk Statement, and if in California, the California Experimental Research Subject's Bill of Rights.

ATTACHMENT 11-B-1

Employer Cooperation Statement

Employer / Supervisor: _____

Study Director: _____

Date of Discussion: _____

Site of Discussion: _____

Employer / Supervisor Cooperation Statement:

I certify that I'm authorized to make the following statements:

- After discussing the nature of the study with the Study Director, I will allow AHETF to recruit any of my employees with applicable training and experience (as determined by the Study Director) in the tasks involved in the study.
- While I acknowledge that there may be benefits to me:
    - I will neither encourage nor discourage my employees to participate in the study.
    - An employee's decision to participate, not to participate, or to withdraw from participation in the study will have no impact on his/her employment status or pay.
    - Employees who decide not to participate, who withdraw from participation, or who complete participation in less than a typical work shift will be offered alternative work at their usual pay to complete their usual work shift.
    - Employees will receive their normal pay for days they participate in the study.

Signature: _____ Date: _____

Title and Affiliation: _____

Emergency Procedures for Human Subjects

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.H.2.

Effective Date : February 15, 2009

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APPROVAL_____ DATE_____

Last Revision Date: August 31, 2008 Previous Version Number: 11.H.1

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the procedure(s) to be followed in the event that a study participant requires emergency medical attention during his/her participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure monitoring study.

1.2 The user of this SOP should be familiar with the SOP AHETF-11.G, "*Identification and Control of Heat Stress*".

1.3 The Study Director will identify any employer plans to handle on-site emergencies. As an adjunct to existing plans, the Study Director will discuss the AHETF procedures with the on-site employer and workers. The Study Director shall gain agreement to utilize the AHETF procedures during the conduct of the study.

1.4 This SOP was revised to clarify the AHETF policy on medical reimbursement to volunteers participating on an AHETF worker exposure study. Section 2.2 was revised to describe who will determine when a study-related injury occurred. A new section 2.3 was added to clarify a worker may choose to refuse treatment. Section 2.4 was revised to clarify the work period covered by the AHETF. Section 6.1 was revised to specify the costs covered by the AHETF as a result of an injury during a study.

2.0 PROCEDURES

2.1 Prior to initiation of exposure monitoring, the Study Director will determine the medical treatment facility nearest to the study site(s) that may be used in event of a medical emergency during the study.

a. Specific information about the medical treatment facility, including the address, telephone number and directions from the field site will be obtained.

2.2 The Study Director shall make arrangements to provide a medical professional (emergency medical technician [EMT], paramedic, physician's assistant [PA], licensed practical nurse [LPN], or registered nurse [RN]) on-site during the conduct of an AHETF study while participants are being monitored. The medical professional will be provided the product label, its MSDS, and AHETF SOPs related to pesticide safety and heat stress. The medical professional shall become familiar with these documents and conduct periodic observations of participants during monitoring and will alert the Study Director to possible signs of illness (heat-related or pesticide) or injury. The Study Director will consult with the on-site medical professional (when immediately available) when determining if a study related injury/illness has occurred that will require medical attention.

2.3 The study participant (worker) may refuse medical treatment unless the injury or illness is directly due to pesticide exposure or is heat-related, or if the worker is too sick to make a rational decision about getting medical treatment.

2.4 If a study participant is injured or becomes ill (including heat-related illnesses) during the study (from the time the worker is asked to arrive at the test site until the dosimetry samples are collected), the medical professional shall provide appropriate medical care. However, if the injury or condition requires emergency care, a member of the study team will call 911 (or other local emergency number) and allow emergency medical personnel to respond and treat the participant as appropriate.

a. If cell phone service is needed to make the 911 call but service is not available, a study team member will drive to the nearest phone or until cell phone service is available.

2.5 As deemed appropriate by the emergency medical personnel, the participant may be taken by ambulance to the nearest emergency medical facility.

a. The Sponsor will not have a physician on-call at any medical facility, but will rely on local emergency services as described above.

2.6 If a participant is taken to a medical treatment facility for examination or care, a member of the research team will accompany the participant to the facility so the Sponsor can stay informed through discussions with the physician or other medical professional that is involved.

3.0 EMERGENCY SITUATIONS AND COLLECTION OF DOSIMETRY MATRICES

3.1 No exposure samples will be collected from a participant who requires emergency medical treatment during study participation. If the medical professional determines the worker needs non-emergency medical assistance, the SD will consult with the medical professional and determine if exposure samples will be collected.

3.2 Any participant whose monitoring is terminated for medical reasons will still receive the remuneration ($80, or as specified in the study protocol) from AHETF for his/her participation in the study.

4.0 FOLLOW-UP OF MEDICAL TREATMENT EVENT

4.1 If a participant receives medical treatment related to his/her participation in the study, the Study Director will document how the participant was treated and released. This includes whether or not the participant refused treatment.

5.0 MEDICAL RECORDS

5.1 Medical records will not become part of the research records.

6.0 EXPENSES

6.1 AHETF will cover the cost of reasonable and appropriate medical attention for a study-related injury or illness that is not covered by the worker's own insurance or insurance provided through the worker's employer. This includes any deductible or out-of-pocket expenses, including co-payments.

7.0 INCIDENT REPORTING

7.1 Any emergency event will be reported by the Study Director to the Sponsor (AHETF), the EPA, and the Institutional Review Board (SOP AHETF-11.F).

7.2 If the emergency event is a result of exposure to the pesticide product, additional reporting to EPA may be required in accordance with AHETF's SOP AHETF-1.F Potential Referable Findings.

Language Requirements and Considerations for Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.I.I.

Effective Date : February 15, 2009

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APPROVAL_____ DATE_____

Last Revision Date: October 27, 2008 Previous Version Number: 11.I.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for how AHETF will, from a language perspective, accommodate English- or Spanish-speaking volunteers, including readers and non-readers. Additional study-specific detail will be included in individual protocols as needed.

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify that the Product Risk Statement will be presented to the worker in their preferred language in Section 2.1; to allow the worker to choose a witness or have one assigned to them in Section 2.2.c; to clarify the witness's responsibility and remuneration in Section 2.3; how a witness will be recruited in Sections 2.3.a. – d., and to clarify the consenting process in Section 2.5.

2.0 LANGUAGE REQUIREMENTS AND CONSIDERATIONS

2.1 Study participation will be limited to subjects who understand English or Spanish since study information, including benefits and risks of participation, will be verbally described to the subject. Potential subjects will choose whether these discussions are conducted in English or

Spanish. Potential subjects will also receive the Consent Form in the language of their choice for reading during the consent process (if they are readers) and will sign that version of the form. For workers whose preferred reading language is Spanish, AHETF will obtain an IRB-approved translation of the Consent Form any associated Product Risk Statements and, if applicable, the California Experimental Research Subject's Bill of Rights.

2.2 While AHETF does not intentionally recruit workers with limited literacy, pesticide handlers occasionally do fall into this category and will therefore not be excluded from participation. Special precautions are used with such workers. Potential volunteers will be told by the person conducting the recruitment meeting that:

a. Volunteers do not need to be able to read to participate in a study, but that they must understand either English or Spanish.

b. Each potential subject will decide for himself/herself whether or not they are comfortable reading the consent form, and can inform the study member conducting the recruitment meeting privately of their decision.

c. Workers, self-identified as non-readers, may choose a witness, or a third-party witness will be identified by the Study Director or designee and provided to the worker during the private consent meeting. The person conducting the consent meeting will read all appropriate materials and the witness will confirm that they were read completely.

d. Workers who identify themselves as readers will have their reading ability assessed by the person obtaining consent by asking the workers to read a portion of the consent form and explain what was read.

2.3 Witnesses are only needed in cases where a worker is a non-reader. The witness is provided to attest that the person conducting the consent meeting reads the Consent Form in its entirety to the volunteer. The witness must be unassociated with the conduct of the research (*i.e.,* not employed by the Sponsor or any of its contractors.) The witness will also sign the Consent Form. Such witnesses are not considered part of the study team, but will receive compensation of $20.00 for their participation.

a. A worker may choose a witness (such as a trusted co-worker, friend, or family member) who can attend the consent meeting along with the worker.

b. If no one is available to attend the consent meeting, the SD or designee may ask the worker, the grower/applicator, local site coordinator, local extension agent(s), or others, for a list of people that might be interested in acting as a witness (*e.g.*, a local clergy member). The Study Director or designee will make every effort (*e.g*. contacting local growers, agricultural associations, local churches, *etc*.) to find a local resident to act as a witness.

c. A potential witness will be contacted by study personnel, explained what is required, asked if they would be interested in being a witness, and informed they will be brought to and from the field site (if requested) and will be compensated for their time.

d. If the worker chooses a witness, the witness will be contacted and will attend the consent meeting along with the worker. If the witness is a third-party witness, he/she will be identified and arrangements will be made for him/her to attend the consent meeting along with the worker.

2.4 When study volunteers choose to have recruitment and consent discussions conducted in Spanish, a bilingual researcher will conduct the consent meeting. A Spanish-speaking or bilingual witness will be provided for non-readers.

2.5 The following procedures will be followed with each individual wanting to participate in an AHETF study. The person conducting the consent meeting will go through the entire consent process with the worker (see SOP AHETF-11.J). The following paragraphs describe how workers with varying reading and language skills will be guided through the consent process. Attachment 11-I-1 provides a summary of the procedures described below.

a. Workers who read and understand English will be provided a copy of the Consent Form (and any other required documents) in English prior to the consent meeting, and will be asked to read the Consent Form in its entirety. During the consent meeting the SD (or designee) will review the entire Consent

Form and encourage the worker to ask questions pertaining to their participation in the study. The person conducting the consent meeting will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A copy of the signed Consent Form (and any other required documents) will be provided to the worker.

b. Workers who understand English, but cannot read English, will have the Consent Form (and any other required documents) provided to them in English prior to the consent meeting, and will be asked to discuss the document with their family or trusted friend. During the consent meeting the SD (or designee) will read the entire Consent Form to them in English and will encourage them to ask questions pertaining to their participation in the study. A witness will be present to attest that all of the information was properly read to the potential subject. The person conducting the consent meeting will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A copy of the signed Consent Form (and any other required documents) will be provided to the worker.

c. Workers who read and understand Spanish will be provided a copy of the Consent Form (and any other required documents) in Spanish prior to the consent meeting, and will be asked to read the Consent Form in its entirety. During the consent meeting a bilingual researcher will review the entire Consent Form and encourage the worker to ask questions pertaining to their participation in the study. The bilingual researcher conducting the consent meeting will also be available during exposure monitoring to communicate with the Spanish-speaking participants. The person obtaining consent will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions to assess comprehension (see SOP AHETF-11.J). A Spanish version copy of the signed Consent Form (and any other required documents) will be provided to the worker.

d. Workers who understand Spanish, but cannot read Spanish will have the Consent Form (and any other required documents) provided to them in Spanish prior to the consent meeting, and will be asked to discuss the document with their family or trusted friend. During the consent meeting a bilingual researcher will read the entire Consent Form to them in Spanish and will encourage the worker to ask any questions pertaining to their participation in the study. A bilingual researcher conducting the consent meeting will also be available during exposure monitoring to communicate with the Spanish-speaking participants. In addition, a Spanish-speaking or bilingual witness will be present to attest that all of the information was properly read to the potential subject. The bilingual researcher will verify that the worker has apparently understood the materials read to and discussed with them by asking specific questions in Spanish to assess comprehension (see SOP AHETF-11.J). A Spanish version copy of the signed Consent Form (and any other required documents) will be provided to the worker.

ATTACHMENT 11-I-1

Language Procedures

	Worker Prefers English	Worker Prefers Spanish
Worker is a Reader of This Language	Person obtaining consent Discussions in English Consent Form in English read by worker No Witness needed	Bilingual researcher Discussions in Spanish Consent Form in Spanish read by worker No Witness needed
Worker is a Non-reader of This Language	Person obtaining consent Discussions in English Person obtaining consent reads English Consent Form to worker Witness needed (English)	Bilingual researcher Discussions in Spanish Bilingual researcher reads Spanish Consent Form to worker Witness needed (Spanish/bilingual)

Seeking Informed Consent from Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.J.I.

Effective Date : February 15, 2009

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APPROVAL_____ DATE_____

Last Revision Date: October 27, 2008 Previous Version Number: 11.J.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for seeking informed consent from workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). Additional study-specific detail will be included in individual protocols as needed

1.2 The term "designee" used throughout the text refers to any person or persons designated by the Study Director (SD) to perform duties normally done by the SD. This includes, but is not limited to, Principal Field Investigators, bilingual researchers, and sponsor representatives. Any of these researchers may be the person obtaining consent.

1.3 This SOP was revised to clarify the language in Sections 2.1, 3.4, and 3.7 to allow better consistency with language used in the study protocols and consent materials.

2.0 REQUIRED TRAINING FOR RESEARCHERS

2.1 The Study Directors (SD), Principal Field Investigators (PFI), Task Force Field Study Monitors, Local Site Coordinators (LSC), worker observers, and Task Force researchers who interact with study participants (*e.g.* researchers who will contact growers to determine their willingness to participate; see SOP AHETF-11.L) will have completed one or more ethics training courses. Certificates of completion for the course(s) will be available prior to their participation in the field phase of the study on behalf of the AHETF. Details on the courses are defined in SOP AHETF-1.B.

3.0 INFORMED CONSENT PROCESS

3.1 Although Consent Forms are unique to individual studies, each Consent Form will contain the elements required by 40 CFR 26.1116.

3.2 The SD (or designee) will be responsible for obtaining informed consent from all study workers prior to their participation in the study. Any materials used during the consent meeting will be approved by the IRB before use.

3.3 Informed consent will be sought in an individual meeting with each worker. The worker may have a friend, family member, or advisor with them during the meeting. Witnesses may also be present as described in SOP AHETF-11.I.

3.4 The person conducting the consent meeting will inform the worker that he/she will receive $20 (or another amount specified in the protocol) for participating in the meeting, whether or not he/she volunteers to participate in the research.

3.5 During the private consent meeting the person conducting the consent meeting will provide each worker with a full explanation of the study, its requirements, any potential risks, its benefits, alternatives to participation, *etc*. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers or their daily wages. Workers will be told they will receive an additional $80 (or another amount specified in the protocol) if they decide to participate and put on the dosimeters, whether or not they complete the monitoring period.

3.6 The person obtaining consent will provide information about the risk of the surrogate chemical in the study, including signs and symptoms of acute overexposure. This information will be presented as an attachment to the Consent Form (referred to as Product Risk Statement {PRS}). WPS requirements, especially proper use of clothing, personal protective equipment, *etc*., will be discussed. Refer to SOP AHETF-11.E for details.

3.7 Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. Information will also be provided about the availability of medical attention during the study. Details on heat stress and its presentation are outlined in SOP AHETF-11.G, while details on emergency medical procedures are outlined in SOP AHETF-11.H.

3.8 During the discussions between potential participants and the person obtaining consent, ample time will be provided for questions and the person obtaining consent will provide any additional information or clarification that is requested.

3.9 The IRB-approved Consent Form (and all supporting documents) will be presented in the preferred language (English or Spanish) of the worker. All sections of the Consent Form will be explained in detail. When the person obtaining consent is satisfied that the worker understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the Consent Form and the person obtaining consent will provide a copy of the signed form to the worker.

3.10 An additional IRB-approved document, "Product Risk Statement", will be attached to the Consent Form. If the study is conducted in California, the IRB-approved "California Experimental Research Subject's Bill of Rights" will also be attached. These documents (in the appropriate language) will be reviewed, signed and dated by the worker, and copies will be provided.

a. In all situations, the person obtaining consent will not sign the Consent Form unless he/she believes the candidate fully understands the information presented. This will be ascertained by providing repeated opportunities to ask questions and by asking questions of the potential workers that would require a response that indicates understanding of key issues. The form in Attachment 11-J-1 will be used to ascertain general understanding.

3.11 The person obtaining consent will not sign the Consent Form unless he/she believes that the process has been free of any element of coercion or undue influence and the witness (when required) has signed the consent form.

4.0 FOLLOW-UP PROCEDURES

4.1 Each study participant will be provided an opportunity to request a copy of the exposure data resulting from their activities in the study. A summary of their personal study data (including the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs and a comparison to the results for other workers performing the same task) will be sent to the address provided by the participant(s) desiring it (the SD or designee will complete the form in Attachment 11-J-2). This form (and all forms that contain the worker's name and address) will be maintained in a confidential file with the study records as outlined in SOPs AHETF-6.B and -6.D.

4.2 When the monitoring period is completed, or at the time a participant withdraws from the study, the person obtaining consent will remind the worker that he/she has received a copy of the signed Consent Form that has a toll-free phone number for reporting any health changes the worker thinks may be related to his/her participation in the study.

5.0 DATA RETENTION

5.1 The following records will be maintained by the AHETF as described in SOP AHETF-6.D:

a. Signed Consent Forms
b. Signed California Bill of Rights (if applicable)
c. Notes taken by the person obtaining consent
d. Consent Form Understanding – Worker Feedback Form (Attachment 11-J-1) & other forms/questionnaires
e. Request for Personal Study Results Form (Attachment11-J-2)

ATTACHMENT 11-J-1

Consent Form Understanding – Worker Feedback Form

Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
Introduction & Purpose				
What is the purpose of this study? ***To measure how much pesticide I might breathe or get on my skin.***				
If you agree to be in this study, will you be given a signed & dated copy of everything you sign? ***Yes***				
Eligibility				
Do you have to consider yourself to be in good health? ***Yes***				
Do you have to understand and sign this consent form? ***Yes***				
Study Duration				
How long during the day will you participate in the study? ***Four to eight hours***				
Procedures Before the Day of the Study				
What are examples of personal information that you must provide? ***Name; years experience; height; weight; gender; age; preferred language***				
Will you be photographed during dressing or undressing? ***No***				
Procedures on the Day of the Study				
What type of clothing will you wear underneath your normal work clothing? ***Long underwear***				
When will you have your hands washed? ***Before the study starts, before eating, anytime I normally wash my hands (toilet) and at the end of the day***				

Signed by: _____ Date: _____

Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
Products Handled				
Is the product you will be handling approved for use by the EPA? ***Yes***				
Will you know the name of the product before you sign the consent form? ***Yes***				
Risks & Discomforts				
Name two risks that you might have by participating in this study. ***Equipment, heat, product, embarrassment, eye/skin irritation, etc.***				
What are some early signs of heat stress? ***Dizziness, being tired, irritability, lack of concentration***				
Injury to Participant				
Where can you get medical treatment if you are injured or get sick during the study? ***Either on-site or at a nearby health care facility***				
Who will pay for your medical treatment? ***Either my own insurance, my employer's, or AHETF***				
Confidentiality				
Will your name be given in any written report of this study? ***No***				
Will information about your participation in this study be given to your employer? ***No***				
Costs				
Will there be costs to you for participating in this study*?* ***No***				
Benefits				
Will you benefit directly from participating in this study? ***No***				

Signed by: _____ Date: _____

Worker Code: _____ Study ID: _____

QUESTIONS	ANSWERED CORRECTLY?		REVISITED MATERIAL WITH APPARENT UNDERSTANDING?	
	YES	NO	YES	NO
Payment for Participation				
When will you receive $80? ***At the end of monitoring; after I withdraw; after AHETF removes me from the study***				
Will you still receive your normal pay from your employer if you participate in this study? ***Yes***				
Voluntary Participation / Withdrawal				
When can you withdraw from the study? ***Anytime I want***				
Will your normal pay be affected if you drop out? ***No***				
Alternatives				
What will you do on the day of the study if you decide that you do not want to participate in the study? ***Perform my normal work***				
Questions				
Can you call the AHETF toll-free if you have questions about this study or think you have a study-related illness? ***Yes***				
Consent				
If you sign the CF, name two things that you are agreeing to. ***I have read the CF; all my questions have been answered; I freely consent; I authorize release of records to 3rd parties; I have not given up any legal rights***				
Product Risk Statement				
What product will you be using today? ***Response will be site-specific***				
What symptom or symptoms might result from being overexposed to this product? (for example, if there is a spill) ***Response will be product-specific***				

Signed by: _____ Date: _____

ATTACHMENT 11-J-2

REQUEST FOR PERSONAL STUDY RESULTS - AHETF Study (AHExx)

This worker wishes to receive a copy of his/her personal study results.

Name: _____

Address: _____

City: _____

State: _____

Zip Code: _____

Study Worker ID: _____

Description of Data Sent:_____

_____

_____

Sent By: _____

Date Sent: _____

Compiling Lists of Potential Growers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.K.O.

Effective Date : February 15, 2009

THIS IS AN APPROVED ELECTRONIC SIGNATURE COPY OF THIS SOP

APPROVAL_____ DATE_____

ORIGINAL SIGNED COPIES ARE ON FILE WITH THE AHETF QAU

APPROVAL_____ DATE_____

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for developing a Grower Universe List, a Master Grower List, and a Qualified Grower List when planning an Agricultural Handlers Exposure Task Force (AHETF) worker exposure field study.

2.0 SUMMARY

2.1 Refer to SOP AHETF-1.H. for common terminology and the overall process for recruiting growers.

2.2 The word “site” as used in this document refers to a geographic area where a cluster of AHETF exposure MUs will be conducted. This may be a single county, several adjacent counties, or an entire state. .Within a site, each MU will be collected from a different farm. Typically five (5) farms will be chosen to conduct five separate MUs per cluster.

2.3 The Grower Universe List and Master Grower List will be compiled by individuals selected by the AHETF who have experience in conducting surveys of this type. The “qualifying” calls of the Master Grower List will be conducted by a third-party professional surveying service. The Qualified Grower List will be compiled by persons selected by the AHETF who have experience conducting phone surveys of this nature. Persons or companies performing these activities will be identified in an attachment to the individual field report for each site.

2.4 An estimate of the number of growers in the universe will be compiled from the most recent USDA Census of Agriculture for the crop(s) and region.

2.5 Following investigation and selection of a crop(s) and geography for a given cluster of MUs involving growers and their workers, the AHETF will produce a list of growers called the "Grower Universe List." The Grower Universe List is derived from a sampling frame that attempts to include the majority of specific crop growers in the selected site.

2.6 Five major sources will be used to identify specific growers within the universe as defined in section 3.2. Only one source will be used for the Grower Universe List if it maintains a collection that approaches the number of growers in the universe for the targeted region. Otherwise, multiple sources will be used so that their combined lists approach the number of growers in the universe. If multiple sources are used, duplicate names will be removed. The final Grower Universe size will be determined by the particular exposure scenario defined in each study protocol.

2.7 A "Master Grower List" will be selected randomly from the Grower Universe List. When the universe of growers for a site is small, the Master Grower List is identical to the Grower Universe List. When the grower universe for a site is large, one or more random batches of growers from the Grower Universe List are used to form the Master Grower List. Multiple passes from the Grower Universe may be required to fulfill the Master Grower List.

2.8 After the Study Director has signed the protocol, a trained and experienced interviewer will call every entry on the Master Grower List to determine whether they meet the qualification requirements for the exposure study. Any entry not meeting all qualification requirements is deleted from Master Grower List; the net result of this process is the Qualified Grower List, which will be used to contact and further evaluate growers for potential recruitment.

3.0 DEVELOPING THE GROWER UNIVERSE LIST

3.1 An estimate of the total number of growers in the target region (*i.e.*, the "site") meeting the qualifications for participation in the exposure research is obtained from the most recent USDA Census of Agriculture for the crop(s) and region. (The Census of Agriculture is conducted every five years and includes information on the number of farms and acres by crop, state, and county.) Should an initial pass of the census provide inadequate numbers of growers, the geographic region defined in the study protocol may need to be expanded.

3.2 AHETF will strive to develop a Grower Universe List that represents the complete universe of target growers for each selected monitoring site. The Grower Universe List is constructed from separate lists obtained from one or more sources. Five sources are recommended for developing the Grower Universe List for a given crop and site:

a. Farm Market ID
b. Commercial List Providers
c. State and Local Government Entities
d. Grower Associations (crop and/or region specific)
e. Grower Publication Subscription List

3.3 These sources are listed in order of preference based on the number of growers or universe of growers they represent, list reliability, amount of expected bias, difficulty in obtaining lists, and time required for cleaning (*e.g.,* looking up missing phone numbers). The sources which are actually used will depend on their availability for each scenario, crop, and site.

3.4 If a single source lists growers comprising at least 75% of the universe, that list will be the Grower Universe List. If no single source can provide at least 75% of the universe, two (or more) sources must be used, suppressing duplicate entries, until a satisfactory Grower Universe List is compiled.

3.5 If multiple sources are used in Section 3.4, purge any duplicate records in the Grower Universe List before producing the Master Grower List. Compare duplicate records by phone number if available. If phone numbers are missing, compare duplicate records by address.

3.6 If the list provider identifies the size of the farm, remove any growers that farm an inadequate number of crop acres to achieve the smallest amount of active ingredient required by the cluster design or to be considered a commercial farm. Adequate acreage will be defined in each study protocol.

3.7 The Grower Universe List will be considered complete if it (a) contains at least 300 growers or (b) all available resources yield less than 300 growers for a geographic region but that number is still sufficient to generate the minimum number of participants as defined in the study protocol. All documentation (electronic and hard copy) on list development will be archived by the completion of the study.

4.0 DEVELOPING THE MASTER GROWER LIST

4.1 If the universe contains less than 300 growers, the Master Grower List is equal to the Grower Universe List.

4.2 If the estimated size of the grower universe is greater than 300, select a random sample from the Grower Universe List that yields a batch of at least 300 callable names. This random subset of the Grower Universe List will be the Master Grower List. It may be necessary to select more than 300 names if, for example, all names on the Grower Universe List do not contain phone numbers. The subset selected from the Grower Universe List should be large enough to ensure a Master Grower List including at least 300 entries with proper phone numbers.

4.3 Random selections from the Grower Universe List must ensure that every grower has an equal chance of being included in the Master Grower List. In these cases, the Grower Universe List will be randomly ordered using MS-Excel® “RAND()” function. One column will be filled with random numbers using this function, the list will be sorted by the generated random numbers, and the random number sorted list will be renumbered from 1 to *n*. Growers will be selected sequentially from this randomly ordered Grower Universe List for inclusion in the Master Grower List. In certain special cases (*e.g.*, large size of universe), an outside source like Farm Market ID may maintain the Grower Universe List. In such cases, AHETF will request that the source provide a random sample of growers using their internal randomizing techniques to select growers for the Master Grower List. In most cases, and especially when lists are combined, AHETF will maintain the Grower Universe List.

4.4 Attempt to find any missing phone numbers using a minimum of three internet look-up sites. Typically, phone numbers can be found for 60% of growers using this procedure. Internet sites used in past look-ups include:

a. *Switchboard* — www.switchboard.intelius.com

b. *YellowPages.com* — www.yellowpages.com or www.superpages.com

c. *WhitePages.com* — www.whitepages.com

d. *USdirectory.com* — www.usdirectory.com

4.5 After reconciling all possible phone numbers, delete any remaining entries in the Master Grower List which do not have phone numbers, and suppress any entries with duplicate phone numbers.

4.6 If it proves to be impossible to fulfill the sampling design from the initial Master Grower List, repeat steps 4.3 through 4.5, generating a supplemental Master Grower List of a size likely to provide the needed number of qualified growers by the same methods, but including only entries not on the initial Master Grower List. Use phone numbers to suppress duplicates not only within the second or subsequent Master Grower List, but also between the second or subsequent MGL and all previously defined Master Grower Lists.

4.7 The Master Grower List will be considered complete when the above requirements have been met and there are suitable names and phone numbers generated. All documentation (electronic and hard copy) will be archived by the completion of the study.

5.0 DEVELOPING THE QUALIFIED GROWER LIST

5.1 A professional telephone interviewing company with previous experience surveying growers will conduct the survey. The specific company used will be documented in the raw data.

5.2 A reasonable attempt will be made to reach every grower on the Master Grower List. Fifteen to twenty attempts will be made to reach each of the growers before the list is considered “exhausted.”

5.3 The Qualified Grower List consists of all growers who completed the survey in this SOP and met the minimum requirements of the exposure field study (*i.e.*, acreage, pesticide type use, equipment use). This list will be used to contact and evaluate growers for potential recruitment in exposure monitoring events.

5.4 All growers on the Master Grower List will be contacted by phone to confirm that they meet the qualification requirements defined in the protocol and to characterize the grower's equipment and history of use of surrogate chemicals. A sample survey is appended in Attachment 11-K-1. Survey questions typically address::

a. Crop acres grown
b. Location of crop acres
c. Pesticides used on crop
d. Equipment used to mix, load, and/or apply pesticides to crop
e. Use of commercial applicators
f. Number of workers who handle pesticides
g. Number of acres treated per worker per day
h. History of and/or plans for use of identified surrogate chemicals
i. Best days and times to call for follow-up questions

5.5 Dispositions will be used to calculate the incidence rate and response rate.

a. The incidence rate is indicative of the quality of the Master Grower List and is used as a guide for measuring the difficulty in reaching potential interviewees. It is expressed as:

$$\frac{\text{Completes + Initial Refusals + Mid Interview Terminates}}{\text{Completes + Initial Refusals + Mid Interview Terminals + Not Qualifieds}}$$

b. The response rate is a reflection of the non-response rate, which indicates the amount of non-response error in the survey. It is calculated by the following formula:

$$\frac{\text{Completes}}{\text{Number in Sample - (Not Qualified + Not Contacted)}}$$

5.6 If the number of qualified growers is insufficient to fulfill the sampling design, it will be necessary to select a supplemental Master Grower List from the Grower Universe List, repeat the survey procedures in this SOP, and identify additional qualified growers.

5.7 All documentation collected during the development of the Master Growers List as well as during the survey and recruitment of growers will be considered raw data and shall be recorded and maintained per all applicable EPA GLPs and AHETF SOPs.

Attachment 11-K-1: Sample Survey for Qualifying Growers on the Master Grower List

Hello, this is **[interviewer name]** calling from **[interviewing company name]**, may I speak with **[Respondent Name]**. **[If not available, schedule call back.]** We are doing a very brief survey on **[mixing, loading, applying equipment]** used in **[crop(s)]** and are talking to **[crop]** growers like yourself. We only have a couple of questions to ask and all of your answers will be held in complete confidence.

1) How many acres of **[crop]** do you have or manage in your operation? **[If less than [minimum size determined by protocol], terminate; otherwise continue.]**

2) In what county are most of your **[crop]** acres located?

   [Do not prompt:
   1) [target county 1]
   2) [target county 2]
   3) [etc.]
   4) Other _____]

3) Do you use **[pesticides or pesticide type(s), e.g., insecticide, fungicide]** to manage pests in your **[crop]**? **[If No, terminate; otherwise, continue.]**

4) Do you do most of your **[pesticide type]** spraying yourself or do you hire spraying done by a commercial applicator? **[If hire a commercial applicator, go to Q10; otherwise continue.]**

   1) Self
   2) Hire

5) Do you typically use a **[targeted equipment type, e.g., open cab or closed cab tractor for pulling your airblast sprayer]**?

   1) [targeted equipment type 1 or "Yes"]
   2) [targeted equipment type 2 or "No"]

6) How many **[targeted equipment type]** do you use in your operation?

7) What is the tank size [in gallons] of your (1st, 2nd, 3rd, 4th) **[targeted equipment type]**?

   1) [Volume 1]
   2) [Volume 2]
   3) [etc.]
   4) Other_____

8) Are you typically the person that makes the **[sprayer equipment type]** applications on your **[crop]**, or do you employ other workers to do the applications?

   1) Self
   2) Worker
   [If self, skip to Q10, otherwise continue.]

9) How many experienced **[sprayer equipment type]** applicators do you employ in your **[crop]** operation?

10) When applying a **[pesticide type]** on a good day without wind, how many of your **[crop]** acres are routinely treated by one experienced applicator during a typical work day?

11) Do you use **[pesticide type]** products such as **[surrogate chemical 1]** or **[surrogate chemical 2]** for pest control in your **[crop]**?

1) **Yes**
2) **No**
[If No, skip Q12]

12) Which **[pesticide type]** products do you typically use? **[Accept up to three answers.]**

1) _____
2) _____
3) _____

13) If we have any further questions, when would be the best time to reach you?

1) Day of week: _____
2) Hour of day: _____

[Thanks and Terminate]

Compiling Lists of Potential Commercial Applicators

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.L.O.

Effective Date : February 15, 2009

THIS IS AN APPROVED ELECTRONIC SIGNATURE COPY OF THIS SOP

APPROVAL_____ DATE_____

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APPROVAL_____ DATE_____

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for developing an Applicator Universe List, a Master Applicator List, and a Qualified Applicator List when planning an Agricultural Handlers Exposure Task Force (AHETF) worker exposure field study.

2.0 SUMMARY

2.1 Refer to SOP AHETF-1.H.for common terminology and the overall process for recruiting commercial applicators.

2.2 The word “site” as used in this document refers to a geographic area where a cluster of AHETF exposure MUs will be obtained. This may be a single county, several adjacent counties, or an entire state. .Within a site, each MU will be collected from a different commercial applicator. Typically five (5) commercial application companies will be chosen to conduct five separate MUs per cluster. The term “applicator” will refer to any commercial applicator service making commercial pesticide applications.

2.3 The Applicator Universe List and Master Applicator List will be compiled by individuals selected by the AHETF who have experience in conducting surveys of this type. The “qualifying” calls of the Master Applicator List will be conducted by a third-party professional surveying service. The Qualified Applicator List will be compiled by persons selected by the AHETF who have experience conducting phone surveys of this nature. Persons or companies performing these activities will be identified in an attachment to the individual field report for each site.

2.4 An estimate of the number of target applicators in the universe will be compiled by interviewing experts knowledgeable of commercial applicators in the targeted area.

2.5 Four major sources will be used to develop the universe of applicators: Commercial List Providers, State and Local Government Entities, Applicator Associations, and Applicator Publication Subscription Lists. Only one source will be used for the Applicator Universe List if it maintains a collection that approaches the number of applicators in the universe for the targeted region. Otherwise, multiple sources will be used so that their combined lists approach the number of applicators in the universe. If multiple sources are used, duplicate names will be removed.

2.6 A "Master Applicator List" will be selected randomly from the Applicator Universe List. When the universe of Applicators for a site is small, the Master Applicator List is identical with the Applicator Universe List. When the applicator universe for a site is large, one or more random batches of applicators from the Applicator Universe List are used to form the Master Applicator List. Multiple passes from the Applicator Universe may be required to fulfill the Master Applicator List.

2.7 After the Study Director has signed the protocol, a trained and experienced interviewer will call every entry on the Master Applicator List to determine whether they meet the qualification requirements for the exposure study. Any entry not meeting all qualification requirements is deleted from Master Applicator List; the net result of this process is the Qualified Applicator List, which will be used to contact and further evaluate growers for potential recruitment.

3.0 DEVELOPING THE APPLICATOR UNIVERSE LIST

3.1 An estimate of the total number of applicators in the target region (*i.e.*, the "site") meeting the qualifications for participation in the exposure research will be obtained by interviewing experts knowledgeable of commercial applicators in the target areas. Should an initial pass of the census provide inadequate numbers of applicators, the geographic region defined in the study protocol may need to be expanded

3.2 The Applicator Universe List is constructed from separate lists obtained from one or more sources. Four sources are recommended for developing the Applicator Universe List for a given crop and site:

a. Commercial List Providers
b. Applicator Associations (crop and/or region specific)
c. State and Local Government Entities
d. Applicator Publication Subscription List

3.3 These sources are listed in order of preference based on the number of applicators or universe of applicators they represent, list reliability, amount of expected bias, difficulty in obtaining lists, and time required for cleaning (*e.g.,* looking up missing phone numbers). The sources which are actually used will depend on their availability for each scenario, equipment type, and site.

3.4 If a single source exists that represents at least 75% of the estimated size of the universe, this source will define the Applicator Universe List. If no single source exists that represents at least 75% of the universe, use two (or more) sources whose combined list counts approach if not exceed the estimated size of the universe of applicators. Following attempts to remove duplicate names, these combined lists define the Applicator Universe List.

3.5 If multiple sources are used in Section 3.4, purge any duplicate records in the Applicator Universe List before producing the Master Applicator List. Compare duplicate records by phone number if available. If phone numbers are missing, compare duplicate records by address.

4.0 DEVELOPING THE MASTER APPLICATOR LIST

4.1 If the universe contains less than 200 applicators, the Master Applicator List is equal to the Applicator Universe List.

4.2 If the estimated size of the applicator universe is greater than 200, select a random sample from the Applicator Universe List that yields a batch of at least 200 callable names. This random subset of the Applicator Universe List will be Master Applicator List.

4.3 Random selections from the Applicator Universe List must ensure that every grower has an equal chance of being included in the Master Applicator List. In these cases, the Applicator Universe List will be randomly ordered using MS-Excel® "RAND()" function. One column will be filled with random numbers using this function, the list will be sorted by the generated random numbers, and the random number sorted list will be renumbered from 1 to *n*. Applicators will be selected sequentially from this randomly ordered Applicator Universe List for inclusion in the Master Applicator List. In certain special cases (*e.g.*, large size of universe), an outside source may maintain the Applicator Universe List. In such cases, AHETF will request that the source provide a random sample of applicators using their internal randomizing techniques to select applicators for the Master Applicator List. In most cases, and especially when lists are combined, AHETF will maintain the Applicator Universe List.

4.4 Attempt to find any missing phone numbers using a minimum of three internet look-up sites. Typically, phone numbers can be found for most applicators using this procedure. Internet sites used in past look-ups include:

a. *Switchboard* — www.switchboard.intelius.com

b. *YellowPages.com* — www.yellowpages.com or www.superpages.com

c. *WhitePages.com* — www.whitepages.com

d. *USdirectory.com* — www.usdirectory.com

4.5 After reconciling all possible phone numbers, delete any remaining entries in the Master Applicator List which do not have phone numbers, and suppress any entries with duplicate phone numbers.

4.6 If it proves to be impossible to fulfill the sampling design from the initial Master Applicator List, repeat steps 4.3 through 4.5, generating a supplemental Master Applicator List of a size likely to provide the needed number of qualified growers by the same methods, but including only entries not on the initial Master Applicator List. Use phone numbers to suppress duplicates not only within the second or subsequent Master Applicator List, but also between the second or subsequent Master Applicator List and all previously defined Master Grower Lists.

4.7 The Master Applicator List will be considered complete when the above requirements have been met at there are suitable names and phone numbers generated. All documentation (electronic and hard copy) will be archive by the completion of the study.

5.0 DEVELOPING THE QUALIFIED APPLICATOR LIST

5.1 A professional telephone interviewing company with previous experience performing agricultural surveys will conduct the survey. The specific company used will be documented in the raw data.

5.2 A reasonable attempt will be made to reach every applicator on the Master Applicator List. Fifteen to twenty attempts will be made to reach each of the applicators before the list is considered "exhausted."

5.3 The Qualified Grower List consists of all growers who completed the survey in this SOP and met the minimum requirements of the exposure field study (*i.e.*, acreage, pesticide type use, equipment use). This list will be used to contact and evaluate growers for potential recruitment in exposure monitoring events.

5.4 All growers on the Master Applicator List will be contacted by phone to confirm that they meet the qualification requirements defined in the protocol and to characterize the grower's equipment and history of use of surrogate chemicals. A sample survey is appended in Attachment 11-K-1. Survey questions typically address::

a. Acres treated
b. County or Region where applicator makes treatments
c. Use of pesticides or pesticide types required by study protocol
d. Application or mixing/loading equipment used
e. Size of application equipment used
f. Number of workers using application equipment
g. Crop(s) often treated with specified equipment
h. Number of acres sprayed per worker in one work day
i. Use of surrogate chemistry
j. Best days and times to call for any follow up questions

5.5 Dispositions will be used to calculate the incidence rate and response rate.

a. The incidence rate is indicative of the quality of the Master Applicator List and is used as a guide for measuring the difficulty in reaching potential interviewees. It is expressed as:

$$\frac{\text{Completes + Initial Refusals + Mid Interview Terminates}}{\text{Completes + Initial Refusals + Mid Interview Terminals + Not Qualifieds}}$$

b. The response rate is a reflection of the non-response rate, which indicates the amount of non-response error in the survey. It is calculated by the following formula:

$$\frac{\text{Completes}}{\text{Number in Sample - (Not Qualified + Not Contacted)}}$$

5.6 If the number of qualified applicator is insufficient to fulfill the sampling design, it will be necessary to select a supplemental Master Applicator List from the Applicator Universe List, repeat the survey procedures in this SOP, and identify additional qualified applicators.

5.7 All documentation collected during the development of the Master Applicators List as well as during the survey and recruitment of applicators will be considered raw data and shall be recorded and maintained per all applicable EPA GLPs and AHETF SOPs.

Attachment 11-L-1: Sample Survey for Qualifying Applicators on the Master Applicator List

Hello, this is **[interviewer name]** calling from **[interviewing company name]**, may I speak with **[Respondent Name]**. **[If not available, schedule call back.]** We are doing a very brief survey on **[mixing, loading, applying equipment]** used by **[equipment]** applicators like yourself. We only have a couple of questions to ask and all of your answers will be held in complete confidence.

1) How many acres do you typically treat per day in your operation? **[If less than [minimum size determined by protocol], terminate; otherwise continue.]**

2) In what county are most of your **[commercial]** applications located?

   [Do not prompt:
   1) [target county 1]
   2) [target county 2]
   3) [etc.]
   4) Other _____]

3) Do you use **[pesticides or pesticide type, e.g., insecticide, fungicide]** in your operation? **[If No, terminate; otherwise, continue.]**

4) Do you typically use a **[targeted equipment type, e.g., open cab or closed cab tractor for pulling your airblast sprayer]**?

   1) [targeted equipment type 1 or "Yes"]
   2) [targeted equipment type 2 or "No"]

5) How many **[targeted equipment type]** do you use in your operation?

6) What is the typical tank size [in gallons] of your **[targeted equipment type]**? What is the smallest tank size? What is the largest tank size?

   1) Typical _____
   2) Smallest _____
   3) Largest _____

7) Are you typically the person that makes the **[sprayer equipment type]** applications in your business, or do you employ other workers to do the applications?

   1) Self
   2) Worker
   [If self, skip to Q10, otherwise continue.]

8) How many experienced **[sprayer equipment type]** applicators do you employ in your operation?

9) When applying a **[pesticide type]** on a good day without wind, how many acres are routinely treated by one experienced applicator during a typical work day?

10) Do you use **[pesticide type]** products such as **[surrogate chemical 1]** or **[surrogate chemical 2]** for pest control?

1) Yes
2) No
[If No, skip Q12]

11) Which **[pesticide type]** products do you typically use? **[Accept up to three answers.]**

1) _____
2) _____
3) _____

12) If we have any further questions, when would be the best time to reach you?

1) Day of week: _____
2) Hour of day: _____

[Thanks and Terminate]

Identifying Potentially Eligible Growers and Commercial Applicators

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-II.M.O.

Effective Date: February 15, 2009

THIS IS AN APPROVED ELECTRONIC SIGNATURE COPY OF THIS SOP

APPROVAL_____ DATE_____

ORIGINAL SIGNED COPIES ARE ON FILE WITH THE AHETF QAU

APPROVAL_____ DATE_____

Last Revision Date: N/A Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for identifying Potentially Eligible Growers or Potentially Eligible Commercial Applicators by calling Qualified Growers and Qualified Commercial Applicators for participation on an Agricultural Handler Exposure Task Force (AHETF) Study

1.2 This SOP also describes procedures for preparing a discussion guide and answer sheet as well as procedures for calling Qualified Growers/Applicators and documenting their responses when preparing to conduct an Agricultural Handler Exposure Task Force (AHETF) worker exposure field study. Attachments 11-M-1 and 11-M-2 respectively show examples of a discussion guide and answer sheet to be used by the caller.

2.0 Glossary of Terms

2.1 Please refer to SOP AHETF-1.H. which describes an overview of the terminology and the steps in the process of recruiting AHETF study participants.

2.2 The terms “Qualified Grower” and “Qualified Applicator” used in this SOP refer to farmers or growers, commercial application companies, and commercial pesticide applicators that meet basic qualifications to provide support for an AHETF study (as per SOPs AHETF-11.K. and AHETF-11.L.). It will refer to any person at the above named entities authorized to make the decision to cooperate with the AHETF.

2.3 The terms "Potentially Eligible Grower" or "Potentially Eligible Commercial Applicator" refer to qualified growers/applicators who agree to cooperate in the study, and if land owners will allow use of their land for the study, have the appropriate equipment for the study, will use or allow use of a surrogate pesticide while participating/cooperating in the study, and will allow one or more workers to participate in the study without the grower/applicator influencing the worker's decision to cooperate in the study. The list of potentially eligible growers/applicators that results from implementation of this SOP is referred to as the "Potentially Eligible List."

3.0 CALLER REQUIREMENTS

3.1 The AHETF will designated a person to contact with the Qualified Growers or Qualified Commercial Applicators. This researcher will be referred to as the "caller" in this SOP and will directly communicate with the assigned AHETF Study Director regarding all recruitment procedures.

3.2 The caller will perform the contact with Qualified Grower/Applicators using a Qualified Grower or Qualified Commercial Applicator List developed under SOP AHETF-11.K or 11.L, respectively. The person who performs the calling and identifying of Qualified Growers/Applicators shall have previous experience performing telephone interviews with farmers/growers/commercial applicators, have experience working with the AHETF and worker exposure studies, and have taken ethics training as per AHETF SOP AHETF-1.B.

4.0 REQUIREMENTS FOR IDENTIFYING POTENTIALLY ELIGIBLE GROWERS AND COMMERCIAL APPLICATORS

4.1 Growers or Commercial Applicators **may not be called** in any field study **until** the study Director signs the study protocol.

4.2 All contact will be documented, either in writing or through electronic documentation. An Answer Sheet similar to the example in Attachment 11-M-2 will be used to document all initial contact as well as the responses of the Qualified Grower/Applicators. This form may be completed as a hard copy or electronically.

5.0 DEVELOPING THE DISCUSSION GUIDE

5.1 The caller will obtain the Qualified Growers or Qualified Applicators List from the person designated to develop this list. This list will have been developed according to SOP AHETF-11.K or SOP AHETF-11.L. The list will contain the names of qualified growers or qualified commercial applicators who have been qualified for crop acreage or acres treated, use of pesticide type, and use of appropriate equipment. The list will also contain information obtained by a grower survey as described in SOP AHETF-11.K. or commercial applicator survey described in SOP AHETF-11.L.

5.2 The caller will develop a discussion guide similar to the example in Attachment 11-M-1 to use during the eligibility assessment call. This guide will be specifically designed from the protocol and the scenario-specific MU selection plan. Guides may be modified as necessary for each study site.

5.3 The guide will include the following content:

a. Introduction of the caller to the Qualified Grower/Applicator, stating that the call is a follow up of the survey described in SOP AHETF-11.K or SOP AHETF-11.L and a brief introduction of the AHETF as well as the purpose of the call.

b. The benefits of the research to the farming industry and to society.

c. Summary of purpose and design of the study.

d. Confirmation of survey responses from the Grower/Applicator Survey to assure the qualifications of the Qualified Grower/Applicator for participation in the study and to make sure the Qualified Grower/Applicator is informed of the needs of the AHETF (*e.g.*, size of the farm/applicator business, its geographical and physical location, whether or not the Qualified Grower/Applicator uses the designated application equipment, characteristics of the application equipment, and how many experienced applicators the grower or commercial application facility employs or hires).

e. Confirmation that the Qualified Grower/Applicator is willing or not willing to have his/her crop treated with, or allow the application service to use the designated surrogate for the study. At this time the caller will inform the Qualified Grower/Applicator of any compensation for the grower/applicator that is specified by the study protocol.

f. Determination if the Qualified Grower/Applicator would allow at least one of his/her experienced (in the specified operation) employees to chose to be recruited as a volunteer worker for the study.

g. Inform Qualified Grower/Applicator they will have to certify that they will not influence his/her employee(s) to participate in the study.

h. Confirm that the Qualified Grower/Applicator is willing to promise in writing not to influence his/her employees' free choice to participate or decline to participate in the study, and agree in writing that the worker volunteers will receive full pay for the time spent participating in the study.

i. If the Qualified Grower/Applicator agrees to cooperate, inform the Potentially Eligible Grower/Applicator that he/she may be contacted and visited by the Study Director in the near future to finalize the arrangements for the research.

6.0 USING THE ANSWER SHEET

6.1 All calls made by the caller to anyone on Qualified Growers/Applicators List or to anyone else in the process of identifying growers or commercial applicators to participate in the research will be documented on an answer sheet like the example in Attachment 11-M-2 and signed by the caller.

6.2 For GLP purposes, there are signature and date spaces at the bottom of the answer sheet for the caller to sign and date when that answer sheet is completed. Data are to be recorded per GLP requirements and SOP AHETF-9.E.

7.0 CONTACTING QUALIFIED GROWERS/APPLICATORS VIA TELEPHONE

7.1 Using the appropriate Grower/Commercial Applicator Qualified List, the designated caller will begin contacting the listed Qualified Growers/Applicators.

7.2 The entire list of Qualified Growers/Applicators shall be called during the process of identifying Potentially Eligible Growers/Applicators for the study. At least seven attempts will be made to reach each Qualified Grower/Applicator to maximize the response rate, after which the contact will be classified as unreachable. The caller will try to contact the grower/applicator on the preferred contact time obtained in the survey qualifying growers/applicators. If the Qualified Grower/Applicator is not reached after several attempts at this time, other appropriate time periods can be tried.

7.3 The Study Director may contact the designated caller during the identification process to monitor progress, and has the option of limiting the number of calls to Qualified Growers/Applicators if the number of identified Potentially Eligible Growers/Applicators is at any time sufficient to construct an efficient configuration for the study .

7.4 If an answering message/machine is encountered, the caller should leave an introductory message briefly describing the AHETF and purpose of the study. The caller should then provide the Qualified Grower/Applicator with the option of returning the call (provide phone number of the caller). The caller may resume calls to the Qualified Grower/Applicator if they do not return his/her call within 24 hours.

7.5 When a Qualified Grower/Applicator is contacted, the caller will introduce themselves and cover the points outlined in Section 5.3.

7.6 For Qualified Growers/Applicators who are not currently available or do not have the time to talk presently, the caller will ask to schedule a time to call back. Answer sheets designated for call back will be grouped separately and chronologically to insure they are made at the appointed time.

7.7 The interview is then cordially wrapped up and if the Qualified Grower/Applicator agrees to cooperate during the study, he/she is then informed that they might be contacted and visited by the Study Director in the future to finalize the arrangements for the research.

7.8 Record all necessary information on the telephone answer sheet. Sign and date the form on the bottom of the page. A copy of the discussion guide and all answer sheets will be placed in the raw data file for Quality Assurance review, and eventually archived using all appropriate GLP procedures

7.9 All data generated from the Qualified Grower/Applicator contact calls will be collected, recorded, maintained, and archived by the AHETF, as per all applicable EPA GLPs as well as per AHETF SOP AHETF-6.D.

Attachment 11-M-1: Sample Discussion Guide

AHETF Protocol: AHE__ Site ID: _____

1. Introduction of AHETF and reason for calling: AHETF is made up of nearly 25 major agricultural chemical companies that are working cooperatively to perform worker exposure studies while mixing, loading, and applying crop protection products. The studies, which will be submitted to EPA, will be used to insure safe working conditions for workers and to help maintain effective pest control products for protecting growers' crops.

2. Confirm answers given in qualifying survey. [Previous answers are on answer sheet.]

- **a.** You stated you grow / treat [number] acres of [crop]. Is that correct?
- **b.** The [crop] [you grow] / [your company sprays] is located in [county]? What is your zip code?
- **c.** You indicated you hire a commercial applicator to spray your crop. Could I confirm the name of the commercial applicator and their phone number? [Grower's Only]
- **d.** You typically use a [closed cab or open cab] tractor for your [equipment type] rig?
- **e.** You use [number] [equipment type] applicator rigs in your operation?
- **f.** Your [sprayer] type is [number] gallons in size?
- **g.** You indicated you employ [number] experienced applicators in your operation?
- **h.** On a typical work day, you can spray [number] acres?
- **i.** You indicated that you use <product> or <products> for pest control in the [crop] [you / your company] sprays?
- **j.** Which months do you typically use this (or these) product(s)?

3. At this time the caller should explain the technical aspects of the study to the respondent:

- **a.** Explain that the Ag Handler Exposure Task Force is performing an exposure study with [applicators] or [mixer/loaders] in [crop] using [equipment type] for 1 or 2 days in the respondent's area in and around [time frame]. Explain that the task force will reimburse the Grower/Applicator for the cost of the pesticide used for the application on the day of research.
- **b.** Explain how worker exposure data are generic and that since exposure does not depend on the chemical itself that representative or surrogate chemicals are used for the study using their spray equipment.
- **c.** Explain the choice of surrogate chemicals for this study and that the AHETF cannot test every pesticide out there, so the AHETF has chosen specific products since they are easy to analyze and relatively safe pesticides to handle.
- **d.** Briefly describe the AHETF research team and what they might be doing on the farm: research team of 3-5 field scientists stays at least 1 day at research site (grower's farm, applicator's facility).
- **e.** Describe the dosimeters that the workers will wear, how the dosimeters will help provide samples for exposure information, and that the results of the analyses of the dosimeters will provide exposure data for workers spraying with their equipment.

Attachment 11-M-1 (con't)

4. Would you be interested in using one of the potential products suggested for pest control by the Task Force on your [crop] in [date / month] of this year? [See choices in table below.]

5. Would you be interested in providing the Ag Handler Exposure Task Force with an appropriate acreage of [crop] which would allow for one full day of application of [appropriate active ingredient/product] using one of your [equipment] sprayers?

6. Would you be willing to allow one of your experienced [equipment type] applicators be recruited by the Ag Handler Exposure Task Force to participate in this important research?

7. In order to uphold the utmost ethical standards for such research, the worker who volunteers to participate in this research may do so only if there is no outside influence with respect to his or her decision to participate. As such, the Ag Handler Exposure Task Force is obligated to ask you as an employer of this potential volunteer, if you would find it difficult to withhold any influence over your worker to participate in the study?

8. Would you be willing to sign a brief agreement with the Ag Handler Exposure Task Force that would allow the Task Force to use your [crop], use your [equipment type] equipment, and recruit one of your workers for this project? This agreement will also provide that you as an employer will not influence your worker's decision to participate in the study.

[If "No" to Q4 to Q8; thanks and terminate]

[If Yes: [Study Director's name] who is the Study Director for this research and who works for the Ag Handler Exposure Task Force will be in touch with you shortly to follow up on our conversation and to provide you with more specific information about the timing of the research project. I appreciate your willingness to cooperate with the Ag Handler Exposure Task Force and look forward to working with you on this project.]

Surrogate product choices [Filled in with actual products from protocol]:

Pest Type	Active Ingredient	Product

Attachment 11-M-2: Sample Answer Sheet

AHETF Protocol: AHE___ Site ID: _____ Final Status Code: _____

ID#: _____ Name: _____ Ph#: _____

2. Confirming Questions [Answers from qualifying survey will be inserted where brackets [] are. Circle Yes or No. Where No, write-in correct answer on line provided.]

a. [Acres] 1.Yes 2.No _____
b. [County] 1.Yes 2.No _____
Zip _____
c. [Com. App.] 1.Yes 2.No _____
Name _____
Ph# _____
d. [Equip] 1.Yes 2.No _____
e. [Equip#] 1.Yes 2.No _____
f1. [Gal 1] 1.Yes 2.No _____
f2. [Gal 2] 1.Yes 2.No _____
f3. [Gal 3] 1.Yes 2.No _____
g. [App#] 1.Yes 2.No _____
h. [Ac Trtd] 1.Yes 2.No _____
i. [Prods] 1.Yes 2.No _____
[Prods] 1.Yes 2.No _____
j. [Month Trtd] _____

4. 1.Yes 2.No Potential Product(s) _____ _____

5. 1.Yes 2.No Acres/day _____ Number of sprayers available _____

6. 1.Yes 2.No Number of workers: _____ 7. 1.Yes 2.No 8. 1.Yes 2.No

Notes: _____

_____

	Date	Time	Status Code	Initials	Call Back Date	Call Back Time
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Status Codes: B = Busy; NA = No answer; AM = Answering Machine; NH = Not home (not available); CB = Call back
IR = Initial refusal; RP = Refused to Participate (put reason in notes above); WP = Will Participate

Caller: _____ Date:_____