Agricultural Handlers Exposure Task Force (AHETF)

VOLUME VI

Standard Operating Procedures (SOPs)

Referenced in Other Volumes

April 7, 2008

Volume VI, Part A:

List of All AHETF SOPs

Agricultural Handlers Exposure Task Force

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Total Available SOPs: 69

SOPs listed in **BOLDFACE** are draft or being revised.
SOP Chapters 1-6 are designated “AHETF Administrative SOPs” for internal use only. They are not distributed to outside parties and may not be included in contractor SOP manuals.

Volume VI, Parts B through AM:

Standard Operating Procedures (SOPs)

Referenced in Other Volumes

Personnel Responsibilities

Chapter 1: Administration
AHETF-1.B.2.

Effective Date : April 4, 2008

APPROVAL David Johnson DATE 04-02-08

APPROVAL [signature] DATE 02 APR 2008

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

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 modify section 6.0 to define Principal Field Investigator and Principal Analytical Investigator, and to add section 7.0 to describe the required ethics training for AHETF personnel.

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 participate in the study and interact with study participants must undergo ethics training. The only exception to this rule is that an interpreter, if used, does not need to have ethics training as long as they are accompanied by a researcher who does have ethics training.

7.2 The training shall include successful completion of the course from the National Institutes of Health (NIH; Human Participant Protections Education for Research Teams) 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.wirb.com (start with link at bottom of home page called Training Requirements).

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.

Potential Referable Findings

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

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines the policy for reporting to EPA potential adverse findings related to an AHETF study as required by FIFRA Section 6(a)(2).

2.0 DEFINITIONS

2.1 Study Director – The consultant who is appointed by the AHETF as the Study Director of a field exposure study as defined in the GLP regulations. The Study Director is responsible for the conduct of the study, reviewing the data as they become available and writing the final report.

2.2 Field Monitor – The AHETF member representative who is assigned to assist the Study Director and provide oversight to a specific field exposure study.

2.3 Adverse Effects Screening Subcommittee – The Subcommittee that will be the first point of contact when a potential adverse effect is identified. This Subcommittee will decide if the potential adverse effect should be referred to the Potential Referable Findings Review Subcommittee.

2.4 Potential Referable Findings Review Subcommittee – The Subcommittee that will decide if a potential adverse effect should be reported to EPA and, if so, will direct the preparation of the submission. The Subcommittee consists of:

a. Members of the Adverse Effects Screening Subcommittee
b. Administrative Committee chair
c. Technical Committee chair
d. Field Studies Subcommittee chair
e. Registrant representative of the relevant test material (in the case of multiple registrants of a test material or a product-specific task force, a representative from each)
f. Task Force counsel

2.5 New findings – This is any potentially adverse data that are generated by AHETF and are not presently covered in PHED or in previously submitted studies.

3.0 BACKGROUND INFORMATION

3.1 EPA rules under FIFRA Section 6(a)(2) concerning the reporting of potential adverse findings was revised on September 19, 1997 as referenced in 62 FR 49370; 63 Fed. Reg. 33580 (June 19, 1998). These rules describe EPA's interpretation of the requirements for pesticide registrants to submit information to EPA concerning adverse effects to the environment, wildlife and human health from their products. The rule applies to registrants, including any employee, agent or other person acting for the registrant.

3.2 There is no requirement for AHETF to submit a 6(a)(2) report since the Task Force is not a registrant. However, the AHETF may make a 6(a)(2) submission on behalf of all Task Force members when the finding involves AHETF studies and results.

3.3 If AHETF discovers a potential adverse finding during the course of field testing or data analysis that falls within the definition of FIFRA 6(a)(2), or an analogous State law, AHETF will report the finding in accordance with EPA and State requirements, as applicable. For exposure monitoring studies, if the results show a higher level of risk or exposure than would be expected from prior reports, data, etc., then a potential adverse finding may exist.

3.4 There are three reporting times (15 days, 30 days, and 3 months). The more common is 30 days after an incident occurs in the field, 30 days after the final report is signed, or 30 days after the results are known which applies when there is a potential serious finding.

3.5 It may be necessary, depending on circumstances, either for the registrant of the test material or a representative from multiple registrants to report a potential referable finding directly, rather than AHETF reporting on their behalf.

3.6 Any AHETF member has the right to submit their own 6(a)(2) letter if they wish, without regard to whether it agrees with the determination of AHETF.

3.7 Regarding the use of surrogate compounds, the AHETF, on the advice of the Potential Referable Finding Review Committee is at liberty, without liability, to report findings under FIFRA 6(a)(2). Prior to reporting, the AHETF shall raise issues and discuss them with registrant(s) of the surrogate compound.

4.0 PROCEDURES FOR IDENTIFYING AND REPORTING POTENTIAL REFERABLE FINDINGS

4.1 Purchase of Existing Data

a. If data have been previously submitted to EPA (and state agencies where applicable), they are not considered “new” and are not Referable Findings.

b. If a Potential Referable Finding issue is identified during data review, the technical subcommittee should bring it to the attention of the registrant(s) of the study test material for resolution.

c. It will be the responsibility of the registrant(s) to report Potential Referable Findings.

4.2 Incidents that Occur During the Conduct of a Study (active ingredient-specific findings)

a. It will be the responsibility of the Study Director, Field Monitor, field contractor, and any other individuals involved with the field exposure study to identify and promptly report any potential adverse effects during the conduct of the study to the Adverse Effects Screening Subcommittee and the registrant(s) of the surrogate active ingredient.

4.3 Data Generated Under Sponsorship of the AHETF that Affects the Surrogate Compound (active ingredient-specific findings)

a. It is the responsibility of the Study Director, or any other Task Force personnel who are reviewing the study data, to keep the registrant(s) of the surrogate compound informed of the results.

b. If there is a potential adverse effect that might affect the registration of the surrogate compound only, it will be the responsibility of the registrant(s) to file a Potential Referable Finding report with the EPA and applicable states.

4.4 Data Generated Under Sponsorship of the AHETF that Could Potentially Affect All Member Products (non-active ingredient-specific finding)

a. Data that could potentially affect all member products would include circumstances where the exposure data exceed what would be derived from a specific scenario in the Pesticide Handlers Exposure Database (PHED), other previously submitted data, or that are defined as “new findings”.

b. It is the responsibility of the Study Director, or any other Task Force personnel who are reviewing the study data, to identify and report any potential adverse effects to the Adverse Effects Screening Subcommittee.

c. The Adverse Effects Screening Subcommittee will be the first point of contact to evaluate whether a potential adverse effect may be referable. If so, then the matter will be referred to the Potential Referable Finding Review Subcommittee.

d. The Potential Referable Finding Review Subcommittee will determine whether a potential adverse effect will be reported to the EPA and any applicable states and, if so, will direct the preparation of the Potential Referable Findings submission.

e. The AHETF Administrative and Technical Committee representatives will be informed in writing of the Potential Referable Finding and the recommendation of the Potential Referable Finding Review Subcommittee. The Task Force representatives will have an opportunity to ask questions and express their opinions during a subsequent conference call or meeting.

Protocol Design and Preparation

Chapter 2: PROTOCOLS
AHETF-2.C.2.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: January 1, 2006 Previous Version Number: 2.C.1.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the content requirements, standard format, responsible personnel, review, and distribution of Agricultural Handlers Exposure Task Force (AHETF) study protocols, which are the written instructions to perform specific experiments investigating exposure to pesticides.

1.2 This SOP is for internal administrative use by the AHETF. It is not to be distributed to contractors, unless specific authorization is provided by the AHETF management.

1.3 This SOP was revised to incorporate additional protocol elements regarding the use of human subjects in exposure research.

2.0 DEFINITIONS

2.1 The EPA GLPs define a study as "any experiment at one or more sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media." (40 CFR Part 160, August 17, 1989, § 160.3).

2.2 A protocol is a written study plan that indicates the objectives and all methods for the conduct of a study.

3.0 PROTOCOL REQUIREMENTS

3.1 AHETF protocols must contain (but not be limited to) the following information for GLP compliance and ethics requirements for human testing. Certain GLP and ethics requirements that are not applicable to most studies conducted by/for the AHETF have been taken into account and either modified or omitted, based upon the importance and impact of those requirements.

a. Descriptive title and objective of the study.

b. Identification of the test substance and control or reference substances by name, chemical abstract service (CAS) number or code number.

c. Name and address of sponsor (AHETF).

d. Name and address of contracted testing laboratories (including field contractors).

e. Proposed experimental start and termination dates.

f. Justification for selection of test system.

g. Procedure for test system identification.

h. Description of the experimental design including the methods for the control of bias.

I. Each level of the test, control, or reference substance to be administered, expressed in appropriate units.

j. The method and frequency of administration of the test, control or reference substance, (*e.g.,* backpack/ knapsack sprayer, granular application, *etc.)*, and the reason for its choice.

k. The type and frequency of tests, analyses, and measurements to be made.

l. The records to be maintained.

m. Dated signatures of the Study Director and AHETF Sponsor Representative (Task Force Manager, and/or Technical Committee Chair).

o. Proposed statistical methods.

p. Ethics requirements for human testing as required by 40 CFR, part 26, including but not limited to: recruitment procedures, health and safety issues, remuneration, and inclusion/exclusion criteria.

3.2 The Study Director or designee is responsible for preparing protocols for studies under his/her direction according to a standard format to be provided by the AHETF.

3.3 All AHETF study protocols will be signed and dated by the Study Director, and Technical Committee Chair or Task Force Manager to initiate the study and indicate Sponsor approval of the protocol. Approval signatures must be obtained from the Study Director before any data collection for that study. The protocol should be acknowledged, either electronically or in writing, by the AHETF Field Monitor and AHETF Analytical Monitor, as appropriate. Monitors do not need to sign the protocol, amendments, or deviations.

4.0 REVIEW PROCESS

4.1 Draft protocols will be forwarded to the appropriate AHETF representatives (as noted in section 6.0 and at the Study Director's discretion) and to the AHETF contracted Quality Assurance Unit for review before finalization.

4.2 The Study Director will be notified of errors found or requested changes noted during the review process. Appropriate corrections or changes will be returned to the Study Director. The revised copy will be approved (*i.e.*, signed and dated) and distributed to the designated personnel.

4.3 The Study Director will submit the final draft protocol, as well as any amendments issued, to a pre-selected Institutional Review Board (IRB) for review prior to finalization and distribution.

5.0 PROTOCOL FORMAT

5.1 Details of the protocol must address all of the applicable items in section 3.1. of this SOP. Requests for copies of AHETF protocols may be directed to the Study Director or the AHETF Task Force Manager. Changes to the protocols will be issued according to section 8.0.

5.2 A standard design, developed by the Task Force, will be followed when preparing study protocols.

5.3 All protocol files must be written in specified word processing program, to be provided to the Task Force upon request. The software that has been selected is the Microsoft® Word® for Windows® (version XP or previous) document processing program. Macintosh® formatted data are not acceptable.

5.4 All signed pages will be optically scanned separately and stored in PDF® format. These signed pages need to be inserted into the final phase report file.

5.5 Electronic submissions to the EPA must be in Adobe® Acrobat® PDF format version 5.0. Later versions of Acrobat® may be used; however, the output must be in the 5.0 format.

6.0 DISTRIBUTION OF STUDY PROTOCOLS

6.1 The original AHETF study protocol, and any amendments, will be submitted to the sponsor-contracted QAU for review. Before study completion, the original protocol, amendments and deviations, if applicable, will be forwarded to the AHETF Archives. The following is the distribution list for protocols and amendments, as appropriate:

a. Study Director (maintain original)

b. AHETF Study Monitor, (field or analytical, as appropriate)

c. AHETF Task Force Manager

d. AHETF Technical Committee Chair

e. AHETF contracted Quality Assurance Unit (copy during study)

f. AHETF Subcommittee Chairs (as applicable)

g. Principal Investigator(s)

h. AHETF Study Archive File (original to archives upon completion)

i. Other appropriate government or regulatory agencies as required.

7.0 Protocol Amendments

7.1 A change of Study Director or any planned change or revision to an AHETF protocol is issued as a protocol amendment. The reason for the change(s) or revision(s) and the effective date(s) of each revision is documented in the amendment.

7.2 The contract principal investigator or facility management will notify the AHETF Study Director of any procedures or items in an AHETF protocol that may need to be revised, added, or deleted. The Study Director will prepare and distribute the amendment(s).

7.3 The Study Director will prepare the amendment(s), and will allow the AHETF Study Monitor(s), Task Force Manager and sponsor-contracted QAU to review it before finalization, if possible. Amendments will be sent to the reviewing IRB as well (see section 4.3.)

7.4 All protocol amendments will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge the amendment as described in section 3.3. Distributions of the original amendment and copies will be followed as outlined in section 6.1 of this SOP.

7.5 Protocol amendments are sequentially numbered according to the date of issue. The first amendment issued for a study is AHETF Protocol Amendment No. 1. The second protocol amendment issued is AHETF Protocol Amendment No. 2, and so on.

8.0 PROTOCOL DEVIATIONS

8.1 Whenever a deviation from the protocol occurs, the Study Director must be notified of the deviation. The AHETF Study Director is responsible for the documentation of any protocol deviation noted for their study.

8.2 The Study Director is required to document the nature of the deviation, date(s) of occurrence, reason for the deviation, effect on the study, and any corrective actions (if any) on an appropriate form or in the raw data. The deviation must be written in a timely manner and acknowledged with the dated signature of the Study Director.

8.3 The Study Director shall notify the appropriate AHETF Study Monitor and QAU of all deviations as soon as practicable.

8.4 All protocol deviations will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge any deviation as described in 3.3. Distributions of the original deviations and copies will be followed as outlined in section 6.1 of this SOP.

Study Report Preparation

Chapter 4: Study Reports
AHETF-4.A.3.

Effective Date : June 30, 2007

APPROVAL _____ DATE 27 MAR 08

APPROVAL David Johnson DATE 03-28-08

Last Revision Date: January 15 2005 Previous Version Number: 4.A.2.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes what information is to be contained in an Agricultural Handlers Exposure Task Force (AHETF) study report, and when and how these reports are to be issued by the AHETF or contract test facility.

1.2 Submission package organization, according to EPA notice PR 86-5, is discussed.

1.3 Formatting requirements (font type and size, margins, *etc. . .*) are presented for all reports prepared for the AHETF, which include electronic formats.

1.4 This Information contained in this SOP was revised to include the ethics requirements as set forth in 40 CFR, Part 26 for human subject testing.

2.0 REQUIRED INFORMATION

2.1 A final study report is a complete, comprehensive presentation of experimental methods, analysis and interpretation of results, and conclusions. Interim or phase study reports are limited reports issued during the conduct of a study or at the end of a specific phase of a study (*e.g.*, field phase report) that present only certain portions of the study results. Specifically, per GLP and Ethics

Testing requirements, all reports must include, but are not limited to the following (note - all sections listed may not apply to interim/phase reports):

a. Name and address of the facility(s) performing the AHETF study and the dates on which the study was initiated and completed, terminated or discontinued.

b. Objectives and procedures stated in the approved AHETF protocol, including any changes in the original protocol.

c. Statistical methods employed in analyzing the data.

d. The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition or other appropriate characteristics.

e. Stability and when relevant to the conduct of the experiment, the solubility of the test, control and reference substances under the conditions of administration.

f. A description of the methods used.

g. A description of the test system used.

h. A description of the informed consent process.

i. A description of the route of administration, application rate and duration.

j. A description of all circumstances that may have affected the quality or integrity of the data.

k. A description of any circumstances that may have affected the health of the worker volunteers.

l. The name of the AHETF Study Director, the names of other scientists or professionals closely involved in the study, and the names of all supervisory (contract test facility) personnel involved in the study.

m. A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

n. The signed and dated reports of each contract testing facility involved in the study. [when applicable]

o. The locations where all specimens, raw data, and the final report are to be stored.

p. The dated signatures of the AHETF Study Director and sponsor's representative.

q. The statement prepared and signed by the AHETF-contracted Quality Assurance Unit indicating the location within the final report of contractor QA reports or statements, phases inspected by the AHETF-contracted QAU, dates of the inspection, and dates reported to the Study Director/ Management.

2.2 A **DRAFT** report will be prepared before the final report. This copy will serve to evaluate the content and accuracy of the report. The draft final report will not be signed by any study personnel. The appropriate contract facility quality assurance unit should review the report before its completion. The draft final report may be audited by the AHETF-contracted Quality Assurance Unit (please refer to SOP AHETF-5.K.). In addition to undergoing a compliance and accuracy review by the QAU, each draft final report will be subjected to a technical review by members of the AHETF.

2.3 Final reports are to be issued by the AHETF after the completion of an AHETF study. Final reports will be issued to the EPA by the AHETF and not by any contractors. The specific schedule for the completion of a final report will depend on the length of the study, amount of data generated, and the time necessary to produce and review the report.

3.0 REPORT ORGANIZATION

3.1 The final report will meet the requirements of the EPA PR Notice 86-5 and follow the general format of the EPA Data Reporting Guidelines. A general outline of a final report format is as follows:

a. Study Title page (this is always page no. 1)

b. Statement of (**No**) Data Confidentiality Claims

c. Good Laboratory Practice Compliance Statement

d. QA Statement(s)

e. Certification of Authenticity

f. Key Study Personnel, including Study Director and management approval signatures

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i. Tables

j. Figures

k. Attachments/Appendices (submitter's option) [NOTE: *by definition, an attachment is a general term for all materials added to the report; an appendix is an addition providing additional statistical or explanatory information.*]

l. Raw Data (submitter's option)

4.0 REPORT FORMATTING

4.1 Due to the possibility that these reports will be scanned onto optical data storage medium, certain precautions are to be taken to ensure clarity and accuracy of transferred data.

4.2 Times New Roman, or equivalent font, shall be used for all text, tables, and figures. The standard size will be 12 pt. with no text smaller than 8 pt. Italicized fonts should be avoided and script fonts may not be used. This is the default font requested by the USEPA for electronic submissions.

4.3 Boldface should be used for highlighting section titles and key words and phrases in the text. Underlining should be avoided. Shading in tables may be used if no greater than 40% or reversed text (white text on a black background) may be used. Single lines are preferred to double lines.

4.4 Line spacing should be 1.0 and not greater than 1.5. Line height should be set to automatic. All documents should be set to automatic kerning.

4.5 Margins should be at least 1.25" on the left and no less than 0.75" on the right. Top and bottom margins should be set between 0.75" and 1.00". For field and analytical reports to be appended to the final summary report, the top and bottom margins may be adjusted to accommodate additional pagination.

4.6 Each page, except the cover page, must have a header or footer with the AHETF study number and pagination. The header or footer may contain a single line at its bottom edge to set it off from the text. The header or footer text shall be in 10 pt.

4.7 Text alignment should be set to either left or full (preferred), and must be consistent throughout the report. Subsections and paragraphs should be indented on the left, with no hanging indentation (even left alignment at each outline level). Tab stops should be no less than 0.25" per level and no greater than 0.50" per level.

4.8 Titles and section headings should be larger than the body text. These items should be set to no more than 14 pt. and should be set in boldface. Individual sections shall be identified by a whole number, with subsections being identified by that number and a sequential decimal, then by a lowercase letter.

4.9 Tables and figures should be identified by numbers, such as "Table 1." or "Figure 7." Appendices shall be identified by Arabic Letters, such as "Appendix A." All tables, figures and appendices must have a descriptive title.

4.10 Photocopies of data may be included in an appendix, as necessary. Copies should be copied at their original size (1:1 if 8.5" x 11.0" or smaller). If oversized pages are to be copied, they should not be reduced greater than 80%. **All information must be legible.** Contrast must be adjusted so that no areas are too dark or light. Any unreadable copies will be rejected, and must be re-photocopied or removed and excluded from the report.

5.0 ELECTRONIC FORMATS

5.1 All report and manipulated data must be presented to the AHETF in an electronic format. To maintain consistency from all contractors, each report document must be in Microsoft® Word® for Windows® 98 or compatible format. All spreadsheet data must be in Microsoft® Excel® for Windows® 98 or compatible format. Macintosh® formatted data are not acceptable. Refer to SOP AHETF-9.I.

5.2 It is strongly recommended that preparation of report tables and figures use the ability to link spreadsheet information with report tables and figures. This automatic linking between documents will reduce repetitive errors due to many versions or multiple entries of the data in the report.

5.3 File size must be considered as well. Text, tables and figures should be separate files. Any computer-generated appendix should be a separate file, also. All spreadsheets will be maintained separately. All related files must be presented together on CD-ROM discs.

6.0 FINAL REPORT MODIFICATIONS

6.1 Once the final report of a study is issued and submitted to the EPA, any modification must be issued as an "Amended Final Report" (OPPTS requirement, except those involving format changes only). A page (or pages) is (are) inserted into the reissued final report (placed in front of the QA Statement) that clearly identifies that part of the final report being modified, states the changes that are being made, and gives the justification for the change(s).

6.2 The amended report receives a new title page stating "Amended Final Report," revised table of contents [to include the page(s) with the amended changes], and a revised QA Statement that includes the date(s) the amended changes were reviewed.

6.3 Each page of the report that was amended should state "amended page" in a page footer.

6.4 The amended report is signed and dated by the AHETF Study Director and all key study personnel involved in the generation or analysis of data modified in the amended report.

Access to Archived Data

Chapter 6: ARCHIVES
AHETF-6.B.I.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: February 1, 2003 Previous Version Number: 6.B.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the Agricultural Handlers Exposure Task Force (AHETF) policy for member companies to obtain access to AHETF study data and final reports for review after being placed in the designated permanent archive facility.

1.2 This SOP was revised to add section 5.0 Confidential Worker Information.

2.0 ACCESS RESTRICTIONS

2.1 Only personnel authorized by AHETF management may have access to review the data. Any person(s) requesting access to AHETF study data must contact the proper AHETF management personnel or Task Force Manager for authorization. All requests must be made in writing.

2.2 Only the Archivist, or alternate, should have direct physical access to the data. A written record of access should be maintained by the designated archive facility for all AHETF studies.

2.3 A list of personnel with clearance to access archived materials should be maintained by the designated archivist, if available.

2.4 No original data may be removed and distributed from the AHETF archives without the written approval of the AHETF. Only verified copies shall be provided for off-site data review, unless otherwise stated.

2.5 As all AHETF data are strictly confidential, no additional or unauthorized copies of any AHETF data may be made, except as authorized in writing by the AHETF.

2.6 Photocopies of the raw data may be retained by the AHETF Quality Assurance Unit, as needed, and will be destroyed at the direction of the AHETF.

3.0 DATA ACCESS PROCEDURES

3.1 The applicable standard operating procedures of the archiving facility shall apply to all access, maintenance, and record keeping of the archived materials.

4.0 POST-ARCHIVING DATA TRANSFER

4.1 Should it become necessary, AHETF study data, or portions thereof, may be transferred to another designated facility or location for retention at the discretion of the AHETF management. The AHETF will notify the archive facility personnel which data will be transferred.

4.2 Data transfer procedures, as described in SOP AHETF-9.G, will apply to all transfers.

5.0 CONFIDENTIAL WORKER INFORMATION

5.1 Certain worker information will be collected during the course of any AHETF that will contain confidential worker information. This information will be kept separate from the raw data generated during the AHETF study. Refer to SOP AHETF-6D for specific handling and access requirements to confidential worker information.

Access to Confidential Worker Information

Chapter 6: ARCHIVES
AHETF-6.D.O.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: None Previous Version Number: None

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the Agricultural Handlers Exposure Task Force (AHETF) policy to obtain access to AHETF confidential worker information for review after being placed in the designated permanent archive facility.

2.0 CONFIDENTIAL WORKER INFORMATION

2.1 Certain worker information will be collected during the course of any AHETF worker exposure study. Forms and paperwork that contain personal information (such as worker's name and address) must be kept confidential.

2.2 The Study Director will place any forms containing such information in a sealed envelope, marked as "CONFIDENTIAL WORKER INFORMATION – DO NOT RELEASE – CONTACT AHETF ADMINISTRATIVE CHAIR" along with the AHETF Study No. and will be placed in the study file with the remaining raw data.

2.3 The confidential information shall be permanently archived with the study raw data as required by Good Laboratory Practices (GLP) regulations (40 CFR Part 160)

3.0 ACCESS RESTRICTIONS

3.1 Only personnel authorized by the AHETF Administrative Committee Chair may have access to the data. Any person(s) requesting access to confidential worker information must submit the request and the reasons for the request in writing to the AHETF Administrative Committee Chair for authorization.

3.2 The designated AHETF Archivist, or alternate, is instructed to remove the Confidential Worker Information envelope from the archived data file when presenting the raw data for review to any AHETF member, company representative, or regulatory agency; unless otherwise directed by the AHETF Administrative Committee chair.

3.3 Access can only be authorized when specifically requested by EPA or when required for legal reasons.

3.4 Only the Archivist, or alternate, should have direct physical access to the data. A written record of access shall be maintained by the designated archive facility for all AHETF studies.

3.5 No confidential worker information may be removed and distributed from the AHETF archives without the written approval of the AHETF Administrative Committee Chair. Only verified copies shall be provided for off-site data review, unless otherwise stated.

3.6 Other than restrictions provided in this SOP, these data are subject to the same storage and handling requirements as set forth in SOPs AHETF-6.A and AHETF-6.B.

Whole Body Sampling – Inner Dosimeters

Chapter 8: **MATRIX SAMPLES**
AHETF-8.A.3.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.A.2.

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from whole body dosimeters worn by workers during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2. The inner dosimeter will be used as a collection medium and will be analyzed. The inner dosimeter will be worn over the worker's own undergarments and directly underneath the specified work clothing and personal protective equipment (PPE), if appropriate.

1.3. This SOP was revised to clarify the privacy allowed the volunteer workers in Sections 3.1 and 4.3. The terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

2.0 MATERIALS REQUIRED

2.1. The following materials are required for using and collecting whole body dosimeter samples from each worker/monitoring unit:

a. 100% cotton, white, long underwear (inner) — with long sleeves, round neckline and no elastic (pre-washed - see SOP AHETF-8.J.).

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

c. Scissors

d. Cleaning solutions (*i.e.,* methanol, isopropanol, alcohol/water mixture, acetone, *etc.*)

e. Sealable bags or other suitable bags

f. Aluminum foil wrap

g. Disposable paper or plastic mat

h. Hangers, if appropriate

i. Cooler with dry ice, or freezer

3.0 USE OF WHOLE BODY DOSIMETER

3.1. The worker(s) will be given a new inner dosimeter prior to initiation of each monitoring unit. The workers will be allowed to change in a clean "privacy area". Once the worker is inside the privacy area, a researcher of the same sex as the worker will remain with the worker to instruct and assist the worker on how to put on the dosimeter. Disposable gloves should be worn by the worker and the research personnel to minimize contamination.

3.2. Care should be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the work clothing cuffs (wrists and ankles).

3.3. Cut the large excess off the pant legs and pull up the inner dosimeter arms so that the inner dosimeter will not come out from underneath the outer dosimeter during the performance of the activity.

4.0 COLLECTION PROCEDURE

4.1. Upon completion of the sock sample collection, as described in SOP 8.I (if sock sample collection is required by the study), the inner dosimeters will be collected. The inner dosimeters must be collected after all other samples have been collected from the worker.

4.2. Disposable paper, plastic mat, or aluminum foil will be placed on the

chairs and floor of the changing area to reduce cross-contamination. The materials will be changed after the processing of each worker.

4.3. After completion of the monitoring unit and collection of other samples, the worker will return to the privacy area. Once the worker is inside the privacy area a researcher, of the same sex as the worker, will accompany the worker in the privacy area to assist with removing the dosimeter, to minimize cross contamination between the worker's clothing and the inner dosimeter, and to minimize loss of residues.

4.4. The research personnel collecting samples will always wear disposable gloves when handling any work clothing, dosimeters, and PPE. Gloves will be changed between handling PPE, work clothing, and inner dosimeter collection. Remove garments in a manner to avoid cross-contamination.

4.5. Ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each worker's dosimeter.

4.6. Remove and discard any buttons from clothing.

4.7. As described in the study protocol, the inner dosimeters will be sampled in one of two methods. If the upper/lower method is used, follow Section 4.8; if the six section method is used, then follow Section 4.9.

4.8. Cut the dosimeter into two (2) sections:

a. Lower Body (all sections below waist*)
b. Upper Body (all sections above waist*)

* Cut just below the second button from the bottom to separate the torso from the lower section.

Proceed to section 4.10 of this SOP.

4.9. Cut the inner dosimeter into six (6) sections:

a. Right & left upper arms (shoulder to elbow)
b. Right & left lower arms (elbow to cuff)
c. Front torso (above the waist*)
d. Rear torso (above the waist*)
e. Right & left upper legs (waist to knee)
f. Right and left lower legs (knee to cuff)

* Cut just below the second button from the bottom to separate the torso from the lower section. Cut along the seams to separate the front torso from the rear torso. Refer to Attachment A.

4.10. Inner dosimeters may be hung on hangers during the sampling as long as the dosimeters do not contact the floor or other dosimeters.

4.11. Place each sample section on a piece of aluminum foil (sufficient size to completely wrap the dosimeter). Do not allow samples to contact any surface before placement onto the foil. Ensure that the edges of the foil wrap are folded together to prevent loss of test material. Place a label on the aluminum foil that identifies the sample and place the sample into a labeled, sealable bag. Seal all bags.

4.12. There shall be either two (2) or six (6) inner dosimeter samples per worker, depending upon the protocol specified sampling method.

5.0 SAMPLING INTERVALS

5.1. Inner whole body dosimeters will be collected at the end of each monitoring unit, unless otherwise instructed by the protocol.

6.0 FIELD STORAGE

6.1. 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.

Attachment A

Diagram of Inner Dosimeter

Hand Wash Samples

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

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: January 1, 2006	Previous Version Number: 8.B.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from worker's bare hands during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 This SOP was revised to clarify that the workers will have their hands washed prior to participating in an AHETF study, as stated in sections 4.1 and 5.1. Also the terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

2.0 EQUIPMENT REQUIRED

2.1 The following materials are required for collecting dermal hand wash samples:

a. Metal or glass bowl **(Do not use plastic bowls for performing handwashes)**

b. Aerosol® OT Solution, 10% w/w. This is a concentrated solution of the anionic surfactant dioctyl sodium sulfosuccinate (also known as AOT) which will be diluted in water and used to wash hands (500 mL for each handwash).

c. Distilled or deionized water (in 1 gallon jugs, or other appropriate container)

d. Graduated cylinder or appropriate measuring device

e. Glass jars with Teflon® lined lids, or equivalent

f. Reclosable plastic bags (1 gallon size; optional for storage)

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

h. Pipette(s) (*e.g.,* 2, 5, 10 mL, *etc.*)

i. Cleaning solutions (*i.e.,* alcohol (methanol, isopropanol), alcohol/water mixture, acetone, *etc.*)

j. Paper towels

k. Cooler with dry ice or freezer

3.0 HAND WASH SOLUTION PREPARATION

3.1 The desired solution concentration is 0.01% v/v Aerosol® OT (AOT) in water (500 mL for each handwash). Sufficient quantities should be made for the projected number of handwashes to be collected on a daily basis or within the allowable shelf life time period.

3.2 Pipette an appropriate amount of 10% w/w AOT solution into the water and dilute 1,000-fold to make a bulk 0.01% v/v AOT solution. For example, 3.8 mL of 10% AOT in one gallon of water or 4 mL of 10% OT in 4.0 liters of water. Document the brand of water (if store bought) and where it was purchased. If the water is **not** store bought, document the source. The AOT solution may be made up in plastic water jugs prior to use, for handwashes or field fortifications. Add the appropriate amount of AOT concentrate directly to the water in the jug or bottle, or other suitable container(s).

3.3 Store the bulk AOT solution in glass jars, plastic bags, water jugs, or suitable container(s). The shelf life of the 0.01% Aerosol® OT solution at room temperature is 48 hours. Reclosable plastic bags may also be used for short-term storage of AOT solution aliquots to facilitate collecting handwash samples in the field.

4.0 WASHING PROCEDURE

4.1 Prior to participating in an AHETF exposure monitoring study, each worker will have their hands washed by a researcher according to the procedure outlined in this SOP. This will serve to clean the hands as well as provide some practice for the hand wash procedure that will be used in the study. The researcher will describe and assist with at least one washing procedure. The rinsate will be discarded.

4.2 At the end of the monitoring unit, upon removal of the worker's personal protective equipment (PPE) and shoes/socks, the worker will be taken to a designated clean "privacy area" for removal of exposed outer clothing. For interim handwashes during the monitoring period, follow steps 4.5 through 4.9.

4.3 Disposable paper, plastic mat, or aluminum foil will be placed on the chairs and floor of the changing area to reduce cross-contamination. The materials will be changed after the processing of each worker.

4.4 Handwash samples must be collected **after** the outer clothing and PPE have been removed, or after sock dosimeters have been collected, as described in SOP 8.I, if applicable. Hand washes must be completed **before** the face/neck samples are collected.

4.5 Don clean disposable gloves, and carefully push up the whole body (inner) dosimeter cuffs from the worker's wrists. Have the worker place both hands over a bowl, and pour approximately 400 mL of 0.01% Aerosol® OT solution over the worker's hands for approximately 30 seconds. The worker will scrub their hands while the wash solution is slowly poured over the worker's hands.

4.6 The worker shall then immerse their hands in the 400mL of the wash solution in the collection bowl and lightly scrub their hands in the solution for a minimum of 30 seconds.

4.7 The worker should lift their hands out of the wash solution, and while holding their hands over the bowl, the remaining approximate 100 mL of Aerosol® OT is poured over the worker's hands to rinse. Allow the hands to drain for approximately five seconds.

4.8 Carefully pour the entire 500 mL of rinsate into a pre-labeled jar seal and place in cool storage. (A total of 500 mL must be collected for each handwash sample.)

4.9 Clean the bowl with solvent between workers. Rinse once with clean water, followed by two rinses with solvent, followed by a final rinse with water. Allow the bowl to air dry or wipe dry with a paper towel before reusing.

5.0 SAMPLING INTERVALS

5.1 Workers' hands will be washed with the diluted AOT solution with the assistance of a researcher, and prior to the monitoring unit. This hand wash sample will be discarded.

5.2 Handwash samples should be collected whenever the workers would normally wash their hands; (*i.e.*, before eating, before using the bathroom, *etc.*) unless specified differently in the study protocol. For interim handwashes, carefully unbutton the cuffs of the worker's outer shirt and push up the sleeves before washing hands.

5.3 After the monitoring unit is completed, one final wash will be collected from each worker.

6.0 FIELD STORAGE

6.1 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 or portable freezer is not available, the Study Director must be notified before sample collection and other suitable storage conditions must be noted in the raw data.

Dermal Face/Neck Wipe Samples

Chapter 8: **MATRIX SAMPLES**
AHETF-8.C..4.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.C.3.

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 change the term "replicate" to monitoring unit or worker.

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 detergent 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 detergent solution (0.01% Aerosol® OT) on the gauze sponge with the syringe or pipette (or other appropriate means of moistening the sponge).

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

3.4 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 One dermal face/neck wipe sample will be collected prior to eating.

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.2.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: March 10, 2003 Previous Version Number: 8.D.1.

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 This SOP was revised to change the terms "replicate" and "monitoring period" were replaced with either "worker" or "monitoring unit."

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). 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.

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, and remove the pump, tubing and OVS tube from the worker.

5.0 SAMPLING PROCEDURE

5.1 Upon completion of the monitoring unit, remove the OVS tube from holder, 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.4

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2006 Previous Version Number: 8.E.3

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 explanation about the purpose of weathering and how fortification samples are handled to simulate exposure conditions. This information is contained in the new Section 2.0.

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.

Sample Identification

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

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: April 30, 2008 Previous Version Number: 8.F.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the procedures to uniquely identify field samples collected during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP was revised to change the term "replicate" to Monitoring Unit (MU) [refers to the monitoring period or worker.]

2.0 NUMBERING PROCEDURE

2.1 All samples (exposure and fortification) will be identified by the protocol (AHETF study) number and a unique identification number that describes the type of sample. Individual MU numbers or codes may not be reused should a specific worker's monitoring period be started and then cancelled, even if no samples were collected for analysis. Additional MU number(s) will be assigned, as necessary.

2.2 The sample identification number will be formatted as an alphanumeric string, separated by hyphens (-) between each code:

SN-XX-NN-YY-ZZ

2.3 The identities of the codes are listed on the following page.

2.4 The following is a list of the coded pairs to be used in the sample identification format SN-XX-NN-YY-ZZ:

SN: The last two digits of the AHETF five character study number.

XX: A code for the type of sample:

WS - Worker Sample
FF - Field Fortification Sample

NN: For exposure samples - The two-digit MU identification number. This can be a sequential number for each MU or an alpha-numeric code to distinguish between applicator and mixer/loader workers, as follows:

Ax - Worker Sample – Applicator only with sequential sample no.
Mx - Worker Sample – Mixer/loader only with sequential sample no.

For exposure field fortification samples - A two digit number to denote the study day of fortification (*e.g.* day 01, 02, 03) based on the actual day of the study the samples are fortified on.

YY: A code for the type of the samples

ID - Inner Dosimeter
AR - Air Sampling Media
HW - Hand Washes
FW - Face/Neck Wipe

ZZ: Unique 2 Character Codes For All Samples

Fortifications (FF samples only)	
Tx*	travel spike
Lx*	low spike
Mx*	mid spike
Hx*	high spike
Cx*	control sample

Dosimeters (WS ID samples only)	
LB	lower body
UB	upper body
LA	lower arms
UA	upper arms
FT	front torso
RT	rear torso
UL	upper legs
LL	lower legs
SX	socks
OH	head patch, outer
IH	head patch, inner

A sequential number will be noted for each control and fortified sample to note worker samples.

	Air – Handwash - Face/Neck Wipe Samples (WS samples only)
	Sequential number to denote multiple samples (if more than one sample is collected) from the same MU during a monitoring period, -01 is the first sample collected, -02 is the second, *etc.* If only one air sample, hand wash, or face/neck wipe sample is collected, then –01 will be the only sample number used. If more than one must be collected during the monitoring period, use a sequential number for each, with the highest number used for the final sample collected that day.

2.5 The following is a list of example sample ID numbers:

01-WS-02-ID-LL:	Study AHE01 – worker sample - MU 2 - inner dosimeter - lower legs
41-WS-A5-ID-BL:	Study AHE41 – worker sample - applicator MU 5 - inner dosimeter - lower body
05-WS-M5-HW-01:	Study AHE05 – worker sample – mixer/loader MU 5 - first (or only) hand wash collected.
55-WS-05-HW-02:	Study AHE55 – worker sample - MU 5 – second hand wash collected
55-WS-03-AR-01:	Study AHE55 – worker sample - MU 3 - air sample (first or only sample)
55-WS-03-AR-01:	Study AHE55 – worker sample - MU 3 - air sample (first or only sample)
55-WS-09-FW-01:	Study AHE55 – worker sample - MU 9 - face/neck wipe (first or only sample)
77-FF-01-IH-L1:	Study AHE77 – Field Fort. - first study day - inner head patch - first low level
11-FF-01-ID-L2:	Study AHE11 - Field fort. – first study day - inner dosimeter - second low level
22-FF-03-FW-H1	Study AHE22 - Field fort. – third study day - face/neck wipe - first high level [this may be the *second* day of fortifications for AHE22]

Worker Clothing Acceptability Criteria

Chapter 8: **MATRIX SAMPLES**
AHETF-8.G.2.

Effective Date : September 1, 2003

APPROVAL David Johnson DATE 08-29-03

APPROVAL Molly Stoudt DATE 8-11-03

Last Revision Date: May 25, 2003 Previous Version Number: 8.G.1.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the criteria to follow when evaluating individual workers' outer work clothing prior to participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

1.2 These criteria were selected based upon the criteria presented in the Worker Protection Standards (WPS) 40 CFR 170, and in the spirit of product stewardship.

1.3 This SOP was revised to allow the workers the choice to wash their own clothing prior to participation on an AHETF study or have their work clothes laundered by AHETF designated personnel as in section 2.1.5. and to add this section as an explanation.

2.0 ACCEPTANCE/REJECTION CRITERIA

2.1 The Study Director will evaluate each worker's outer (work) clothing prior to his or her participation in an AHETF worker exposure study using the following criteria as guidance:

2.1.1 **Condition:** Work clothing should be in relatively good condition. Clothing that does not comply with the spirit of the WPS (*e.g.* clothing with large tears, holes, rips, several missing buttons, or other defects that present a significant exposure to the worker's skin or inner dosimeter) will not be accepted for use during the study. In such cases, if the Study Director feels appropriate, the AHETF will provide the worker with new outer work clothing.

2.1.2 **Coverage:** Only long sleeves and long pants are acceptable. Sleeves and pant legs may not be rolled-up during the exposure phase of the study. Rolled-up sleeves, T-shirts, and shorts will not be accepted for use during the study.

2.1.3 **Fit:** The outer clothing must completely cover the inner dosimeter. Clothing that is too short, whether during movement or at rest will not be accepted for use during the study.

2.1.4 **Size:** Work clothing must be loose enough to allow for wearing an inner dosimeter under the work clothing, and still completely cover the inner dosimeter. Clothing that is too tight to allow the use of the inner dosimeter garment or does not sufficiently cover the inner dosimeter will not be accepted for use during the study.

2.1.5 **Cleanliness:** Workers' clothing should be reasonably clean prior to participation. Clothing should be free from fresh soiling or chemical exposure. Stains and discolorations might be acceptable, if from a previous event. Any clothing that is freshly or grossly soiled, or has any distinct pesticide odors or stains will not be accepted for use during the study.

2.2 All articles of a worker's outer clothing must be laundered prior to participation in an AHETF exposure study. Workers will be notified in advance of this criterion and should make arrangements to have their work clothes laundered. If necessary, clothing will be collected by the AHETF prior to the start of the study, laundered with detergent by the AHETF, and returned to the worker at the start of their exposure period.

2.3 Should the Study Director deem any article of a worker's clothing unacceptable, that specific article shall be replaced with a clean, new garment provided by the AHETF.

2.4 The Study Director will document each article of clothing replaced and the reasons for the rejection of the original workers' clothing in the raw data.

2.5 For exposure scenarios where low exposure is expected (*e.g.*, closed-system mixing and loading), only AHETF-provided outer garments will be worn.

Head Patch Samples

Chapter 8: MATRIX SAMPLES
AHETF-8.H.2.

Effective Date : June 30, 2007

APPROVAL _____ DATE 27 MAR 08

APPROVAL _____ DATE 03-28-08

Last Revision Date: April 1, 2003 Previous Version Number: 8.H.1.

1.0 PURPOSE AND SCOPE

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

1.2 This SOP was revised to clarify section 2.1.a, that head patch material will be pre-washed.

2.0 EQUIPMENT REQUIRED

2.1 The following materials are required for collecting head patch samples:

a. 100% cotton inner dosimeter (1 layer, 100 cm^2 for inner & 50 cm^2 for outer, cut from a whole body inner dosimeter, excluding and seams, collars, cuffs, or buttons; pre-washed – see SOP AHETF-8.J.)

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

c. Aluminum foil

d. Resealable bags or glass jars

e. Cooler with dry ice or a freezer

f. Suitable mechanism for attaching patch to worker's head and outside of hat or chemical-resistant (CR) headgear

3.0 PATCH PLACEMENT

3.1 The inner head patch will be placed at the crown of head, and the edges must not extend beyond the coverage provided by the hat or CR headgear. The inner patch will be secured to the worker's head via nonabsorbent cord(s), which will be cut off during collection.

3.2 The outer head patch will be placed on the top of the hat or CR headgear in a manner that will not compromise the integrity of the hat and will remain securely attached even if wet. Portions of the patch where it attaches to the headgear/hat will be cut off during collection.

4.0 SAMPLING PROCEDURE

4.1 The research personnel collecting samples will wear clean, disposable gloves while collecting these patch samples.

4.2 The head patches will be collected after the research personnel have checked the air pump flow rate and collected the OVS tube sample.

4.3 Outer head patch(s) attached to the worker's hat or CR headgear will be removed by the research personnel after the worker removes their headgear. Using clean scissors cut the outer head patch along the prescribed lines prior to placing in the sample container. Wrap the patch in aluminum foil and place it in the appropriately labeled container, close the container, and then place in frozen storage. Research personnel must change gloves after handling the outer head patch.

4.4 After the worker has removed their hat or CR headgear, the inner head patch from the worker's head will be removed by the research personnel. Research personnel must wear clean gloves to collect the inner head patch. Cut the cord(s) used to secure the patch to the worker's head and discard before placing the inner head patch in a sample container. Wrap the patch in aluminum foil and place it in the appropriately labeled container, close the container, and then place in frozen storage.

5.0 SAMPLING INTERVALS

5.1 One inner and outer head patch sample will be collected from each worker at the end of the monitoring period.

5.2 Should it become necessary to replace an inner or outer head patch sample during a replicate, the worker will be taken to a clean area, the existing patch will be properly collected as described in Section 3.0, and a replacement patch placed on the worker. All additional patches will be documented in the raw data, and multiple head patches will be combined in one container. The total number of patches in a sample should be noted for the analytical laboratory.

6.0 FIELD STORAGE

6.1 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.

Foot Sampling – Socks

Chapter 8: MATRIX SAMPLES
AHETF-8.I.3.

Effective Date : June 30, 2007

APPROVAL	DATE 27 MAR 08
APPROVAL	DATE 03-28-08
Last Revision Date: January 1, 2006	Previous Version Number: 8.I.2.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from workers' feet by use of cotton socks worn by workers during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 The cotton sock dosimeter will be used as a collection medium and will be analyzed. The socks will be worn under the worker's own socks and shoes.

1.3 This SOP was revised to clarify section 2.1.a that socks will be pre-washed.

2.0 MATERIALS REQUIRED

2.1 The following materials are required for using and collecting sock dosimeter samples from each worker:

a. 100% cotton, lightweight socks, ankle high (pre-washed – see SOP AHETF-8.J.)

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

c. Scissors

d. Cleaning solutions (*i.e.,* methanol, isopropanol, alcohol/water mixture, acetone, *etc.*)

e. Sealable bags or other suitable containers

f. Aluminum foil wrap

g. Disposable paper or plastic mat

h. Cooler with dry ice, or freezer

3.0 USE OF SOCK DOSIMETER

3.1 If specified in the study protocol that sock/foot dosimetry will be worn and collected, the worker will be given a new pair of socks prior to initiation of each monitoring period. These socks will be worn on bare feet under the worker's normal work socks and shoes/boots. The worker and the research personnel, to minimize contamination, should wear disposable gloves whenever handling the dosimeters.

4.0 COLLECTION PROCEDURE

4.1 The worker will be taken to a designated clean "privacy area" for removal of exposed clothing.

4.2 Disposable paper, plastic mat, or aluminum foil will be placed on the chairs and floor of the changing area to reduce cross-contamination. The materials will be changed after the processing of each worker.

4.3 The research personnel collecting samples will always wear disposable gloves when handling any work clothing, dosimeters, and PPE. Gloves will be changed between handling PPE, work clothing, and dosimeter collection. Remove garments in a manner to avoid cross-contamination.

4.4 The worker will remove their work shoes/boots before entering the "privacy" area. The worker's socks will remain on the worker, over the sock dosimeters, until he/she removes them.

4.5 After removal of the worker's outer clothing (first shirt, then pants, then work socks), and before the hand wash and face/neck wipe samples have been collected, the research personnel will collect the sock dosimeters.

4.6 Both left and right socks will be placed on a piece of aluminum foil (sufficient size to completely wrap the socks). Do not allow samples to contact any surface before placement onto the foil. Ensure that the edges of the foil wrap are folded together to prevent loss of test material. Place a label either on the aluminum foil or sample container that identifies the sample and place the sample into a labeled, sealable container. Seal all containers.

5.0 SAMPLING INTERVALS

5.1 Sock dosimeters will be collected at the end of each monitoring period, unless otherwise instructed by the protocol.

6.0 FIELD STORAGE

6.1 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.

Laundering of Dosimeter Materials

Chapter 8: MATRIX SAMPLES

AHETF-8.J.1.

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APPROVAL _____ DATE 27 MAR 08

APPROVAL _____ DATE 03-28-08

Last Revision Date: April 30, 2006 Previous Version Number: 8.J.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for laundering whole body inner dosimeter garments, head patch material, and sock dosimeters to be worn by workers or used for field fortifications during the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 Inner dosimeter garments, head patch material, and sock dosimeters must be washed prior to use in an AHETF worker exposure study.

1.3 This SOP was re-titled and revised to include sock and head patch dosimetry.

2.0 MATERIALS REQUIRED

2.1 The following materials are required for laundering dosimeter materials:

a. 100% cotton, white, long underwear (inner) — See SOP AHETF-8.A for description of material)

b. 100%, cotton inner dosimeter material for head patch (1 layer, 100 cm^2 for inner & 50 cm^2 for outer) — See SOP AHETF-8.H for description of material

c. 100% cotton, lightweight socks, ankle high — See SOP AHETF-8.I for description of material

d. Low-suds laundry detergent

e. Washing machine

f. Automatic clothes dryer or clothesline

g. Scissors (cutting off buttons and sectioning dosimeters)

h. Zip-Loc®-style plastic bags (gallon and quart size)

3.0 LAUNDERING OF WHOLE BODY DOSIMETER

3.1 For field and laboratory fortification samples only, remove all buttons from the inner dosimeter garments, prior to washing. Dosimeters that will be worn by workers **must not** have the buttons removed.

3.2 Place an appropriate number of dosimeters in a washing machine. Follow washing machine operating instructions for proper loading.

3.3 Wash the dosimeters, in warm water, **three** separate times (complete washing cycle) using a low suds detergent (*e.g.* All) with the amount specified by the product and washer size each time. For each wash event, allow the washing machine to go through a complete wash, rinse, and spin cycle.

3.4 In addition to the three washings, subject the dosimeters to **two additional** rinse-only cycles (*i.e.*, one full cycle of the washing machine without detergent) to remove all of the detergent.

3.5 Dry the dosimeters, using natural air drying or using an automatic clothes dryer.

3.6 The dosimeters are now ready for use.

3.7 Fold and place each clean dosimeter in Zip-Loc®-style plastic bags for storage and transport to field site or laboratory. Fold and place a single, whole inner dosimeter (up to size XL) in a gallon size bag. For larger sizes, use a suitable plastic bag or container. Socks and head patches should be bagged separately according to size also.

3.8 Use a permanent marker to label each bag or container with dosimeter size. ("S" for small, "M" for medium, "L" for large, "XL" for extra large, *etc.*)

3.9 For fortification pieces, fold and place two-section dosimetry (*i.e.*, upper and lower halves) in gallon size bags; for six-section dosimetry (*i.e.*, upper/lower arms & legs, front & back torso, *etc...*) fold and place individual pieces in quart size bags. One cut section per bag.

3.10 Use a permanent marker to label each bag/container with the garment size as described in Section 3.9 above and the body part as follows:

FT = front torso
RT = rear torso
LA = lower arm
UA = upper arm
LL = lower leg
UL = upper leg
UB = upper body
LB = lower body
SX = Sock Dosimeter
IH =Head patch – inner
OH = Head patch - outer

4.0 DOCUMENTATION OF WASHING PROCEDURE

4.1 A note to the study file shall be prepared for each batch of dosimeters that have been laundered per this SOP. The date of the washing event, person responsible, type of detergent used, and location of washing shall be noted.

5.0 DOSIMETER STORAGE

5.1 Store the washed dosimeters in a clean, dry environment until shipped to the field or analytical laboratory.

Sample Quality

Chapter 8: MATRIX SAMPLES
AHETF-8.K.O.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

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

1.0 PURPOSE AND SCOPE

1.1 Unexpected situations can occur during exposure monitoring studies that can have an effect on sample quality. These situations may occur at various stages of the study (*i.e.*, sample collection, packaging, shipping, storage and analysis). This Standard Operating Procedure (SOP) provides examples of unexpected situations in which samples should be invalidated. This list is not meant to be all-inclusive; however it does provide some examples, especially during the field phase of the study, for when samples may be deemed to be compromised.

1.2 Whenever sample matrices are not collected, analyzed, and/or reported, a full explanation will be provided in the raw data as well as in the appropriate phase report (*i.e.*, Field or Analytical), and/or the Summary Report.

2.0 SITUATIONS DURING EXPOSURE MONITORING IN WHICH SAMPLES ARE INVALIDATED

2.1 In some cases, determining whether a sample has been compromised, and is therefore invalid, is clear. It is the decision of the Study Director to determine that a sample has clearly been compromised and should not be collected for processing (*i.e.*, labeled and stored for possible subsequent analysis). However, if the situation is not so unequivocal, then the samples should be collected and the decision will be made at a

later time whether to analyze them. This decision will be made by AHETF management in conjunction with the Study Director and other appropriate field personnel.

2.2 Examples of circumstances in which samples should be invalidated are listed below:

a) If the worker's activities are not in compliance with the label requirements and/or WPS

b) If the worker is drenched by rain during monitoring

c) If a sample is known to have been contaminated by an event that was not part of the worker's activities (example: face/neck wipe is dropped on the ground in the staging area)

d) If a complete set of dermal dosimeter samples (*i.e.*, whole body dosimeter, face/neck wipes, and hand washes) is not collected (*e.g.*, a worker must leave due to an emergency or a worker forgets and washes his/her hands prior to collection of the last hand wash sample)

e) If a sample cannot be positively identified due to mislabeling

f) If a sample is improperly stored under conditions not consistent with quality assurance samples

2.3 If the portable air sampling pump stops working and the investigator is unable to determine how long the pump was stopped, the inhalation sample will be considered invalid. However, the loss of an inhalation monitoring sample does not preclude acceptability of the dermal monitoring samples.

3.0 SITUATIONS AFTER THE FIELD PHASE IN WHICH SAMPLES ARE INVALIDATED

3.1 It is possible that during transit, storage, or analysis that samples may become compromised. The most likely situation is that individual samples could be compromised during analysis. Decisions regarding sample integrity after the field phase of the study will be made by AHETF management in conjunction with the Study Director and other appropriate analytical personnel.

3.2 Examples of circumstances in which samples should be invalidated are listed below:

a) If a sample is known to have been contaminated (*e.g.*, a matrix sample is inadvertently spiked with standard solutions)

b) If a complete set of dermal dosimeter samples (*i.e.*, whole body dosimeter, face/neck wipes, and hand washes) is not available

c) If a sample cannot be positively identified due to mislabeling

d) If a sample is improperly stored under conditions not consistent with quality assurance samples

Definition of LOD and LOQ

Chapter 9: DOCUMENTATION
AHETF-9.A.0

Effective Date : June 30, 2006

APPROVAL _____ DATE 17 AUG 2006

APPROVAL _____ DATE Aug 22, 2006

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how analytical Limits of Detection (LOD) and Limits of Quantification (LOQ) will be defined for analyses conducted on Agricultural Handlers Exposure Task Force (AHETF) studies.

2.0 DEFINITIONS OF LOD AND LOQ

2.1 The Limit of Quantification (LOQ) for all AHETF studies is defined as the lowest level fortified for a matrix in a study. The LOQ for each matrix is defined in the appropriate analytical method. These are for reporting laboratory results to the AHETF.

2.2 The Limit of Detection (LOD) for all AHETF studies is 0.3 times the defined LOQ in section 2.1. *For example, if the lowest matrix fortification is 1.0* ***pg*** *for the LOQ, then the LOD will be 1.0 x 0.3 = 0.300* ***pg.***

2.3 If a sample result is greater than the LOD, but less than the LOQ, the number shall be reported in the analytical data as the value obtained from the instrument, or if the result is less than the LOD, it shall be reported as less than the numerical value of the LOD, such as: "<0.300 µg". Report values to two (2) digits beyond the LOQ value unless otherwise specified by the AHETF.

Formatting for Tabular Presentation

Chapter 9: DOCUMENTATION
AHETF-9.B.0

Effective Date : June 30, 2006

APPROVAL Vicky Standart	DATE 06/22/06
APPROVAL	DATE 12/01/06
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how numerical data generated on an Agricultural Handlers Exposure Task Force (AHETF) study shall be formatted for presentation in the Summary Report tables.

2.0 AHETF SUMMARY REPORTS

2.1 All calculations will be made using the reported values from the analytical and field reports.

2.2 Dermal dosimeters, Face/Neck Wipes, Hand Washes:

a. In the study summary report, round and report all raw or adjusted whole-body dosimeter residues, dermal patch residues, body area exposures extrapolated from patch residues, face/neck wipe residues, and hand-wash residues as follows:

- Values ≥ 100, round and report as a whole number
- Values < 100, but ≥ 1, round and report to one decimal place; and
- Values < 1, round and report no more than two digits past the LOQ as defined in SOP AHETF-9.A.

b. In specific situations when the data do not conform to these conditions, the Study Director will decide the proper format.

2.3 Air Sampling Media:

a. In the study summary report, round and report raw or adjusted air sampling media residues as follows:

- Values ≥ 1, round and report as one or two decimals, depending on the order of magnitude, at the Study Director's discretion.
- Values < 1, round and report no more than two digits past the LOQ as defined in SOP AHETF-9.A.

b. In specific situations when the data do not conform to these conditions, the Study Director will decide the proper format.

c. Total airflow is calculated as the average flow rate (expressed as L/min) multiplied by the duration in minutes. Air concentration is calculated as the residue value divided by the total airflow value. Either rounded or un-rounded values may be used for these calculations.

2.4 Adjusting Field Sample Results with FF Recoveries:

a. Analytical field sample data (as reported in the analytical report) will be adjusted for representative field fortification mean recoveries; *i.e.,* percent recovery for that matrix and residue level (rounded to one decimal place, following standard rounding rules).

b. Data that are less than the Limit of Quantitation (LOQ) will be given a value equal to ½ LOQ, by default, and no further adjustment will be made for percent recovery.

c. The value (½ LOQ value) will be expressed to the same number of decimal places as specified in sections 2.2.a, 2.3.a, and 2.4.a. All non-detects or "½ LOQ" values will be referenced with a footnote in tabular presentations.

2.5 Means and Standard Deviations:

a. Means and standard deviations will be calculated from **unrounded** values and expressed to the same number of decimal places as specified in sections 2.2.a, 2.3.a, and 2.4.a.

Numerical Formatting and Handling

Chapter 9: DOCUMENTATION
AHETF-9.C.4

Effective Date : June 30, 2006

APPROVAL Thomas Schreier DATE 27 JULY 2006

APPROVAL Wesley Standard DATE Aug 10, 2006

Last Revision Date: April 30, 2006 Previous Version Number: 9.C.3.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how numerical data generated on an Agricultural Handlers Exposure Task Force (AHETF) study shall be handled during calculation and in contractor reports.

1.2 The SOP will set forth specific requirements for rounding and fixed decimal places.

1.3 The requirements set forth in this SOP are designed to maintain consistency for reporting purposes, recognizing that numbers with greater precision are sometimes used in the calculations.

1.4 Information concerning the definitions of the Limit of Detection (LOD) and Limit of Quantification (LOQ), and the reporting requirements for the AHETF Summary Report were removed. Both were placed in new AHETF Standard Operating Procedures. The information pertinent to contractor reports were renumbered in this SOP.

2.0 ANALYTICAL DATA AND CONTRACTOR REPORTS

2.1 All analytical laboratory calculations will be performed using only **un-rounded** numbers (*i.e.*, as generated by the instrumentation), but reported to no more than four decimal places. These include, but are not limited to: means, standard deviations, *etc.* All results must be reported to the AHETF. Calculated values should be presented in the analytical report tables and appendices as described in SOP AHETF-9.B.

2.2 All sample and QC results reported in the summary tables and appendices found in the Analytical Report will be reported to the same accuracy and precision as the final results found in the raw data spreadsheets for these samples. Data should be reported to no more than four decimal places, unless otherwise specified by the AHETF (Study Director or Analytical Monitor).

2.3 If a sample result is greater than the LOD, but less than the LOQ, the number shall be reported in the analytical data as the value obtained from the instrument, or if the result is less than the LOD, it shall be reported as less than the numerical value of the LOD, such as: "<0.300 µg". Report values to two (2) digits beyond the LOQ value unless otherwise specified by the AHETF.

3.0 FIELD DATA AND CONTRACTOR REPORTS

3.1 Raw data will generally be collected to the precision of the equipment or measuring devices. All field calculations with field sample data will be performed using the values provided by the laboratory (*i.e.*, as generated by the instrumentation), and these values will be reported to no more than four decimal places when presented to the AHETF in raw data tables or spreadsheets, unless otherwise specified by the AHETF Study Director. Do not perform calculations on numbers that have been rounded further than those reported by the laboratory. All results must be reported to the AHETF.

3.2 Any calculated values should be presented in the field report tables as described in SOP AHETF-9.B.

Analytical Method Number Assignment

Chapter 9: DOCUMENTATION
AHETF-9.D.O.

Effective Date : February 1, 2003

APPROVAL David Johnson DATE 01-22-03

APPROVAL William Jett DATE 1-28-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how an Agricultural Handlers Exposure Task Force (AHETF) analytical method number is assigned. The Task Force Manager is responsible for tracking and assigning AHETF method numbers.

2.0 RESPONSIBILITY

2.1 The assignment of AHETF analytical method numbers will be the function of the AHETF Task Force Manager. This will ensure continuity and prevent duplication of method numbers, and enable the AHETF to keep accurate records of the individual methods prepared.

3.0 PROCEDURE

3.1 A unique AHETF analytical method number for each method will be assigned. It will consist of the form of AHETF-AM-nn, where nn is a two digit, sequential number beginning with 01. Example method numbers are:

AHETF-AM-01
AHETF-AM-02
AHETF-AM-03

3.5 The analytical method numbers will be assigned as follows:

a. The appropriate personnel shall contact the AHETF Task Force Manager for assignment of the next number in the analytical method series.

b. The AHETF Task Force Manager shall document the method number assigned and provide the number to the requesting personnel, the Study Director or other appropriate personnel.

3.6 Analytical method numbers will be tracked on a form maintained by the AHETF Task Force Manager and will contain the following:

a. Analytical method number

b. Method title

c. Method author (laboratory facility)

3.7 Revisions to AHETF analytical methods will be denoted by a version number, *e.g.* Version 1, Version 2, *etc...* The revision date, laboratory, and principal chemist who made any changes should also be noted on the revised method(s).

Raw Data Collection

Chapter 9: DOCUMENTATION
AHETF-9.E.O.

Effective Date : February 1, 2003

APPROVAL David Johnson DATE 01-22-03

APPROVAL William D. Ware DATE 1-28-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the preferred methods for documenting raw data, identifying automated data, and identifying who is responsible for reviewing the raw data generated for/by the Agricultural Handlers Exposure Task Force (AHETF).

2.0 PREFERRED METHODS FOR MANUALLY RECORDED DATA

2.1 All persons involved in an AHETF study should record all raw data on standard data forms (designed for recording raw data pertaining to the particular type of study being conducted) or in a (preferably bound) notebook.

2.2 All raw data should be collected with the utmost care, accuracy, neatness and legibility. Personnel involved in collection of raw data shall:

a. Initial and date all entries in data notebooks/files and entries made on data collection forms. Initials and date must be made on the day of entry and by the person making the entry.

b. Record all data in indelible ink, preferably black. Do **NOT** use pencil, water soluble ink or erasable ink to record raw data.

c. Record units of measure when appropriate.

d. Record the AHETF study number and contractor number (if applicable) on notebook covers, 3-ring binders and all loose pages or standard data forms.

e. No data prompts on a form should be left unanswered or blank. If the required information is not applicable, state "N/A" or draw a line through the unused portion. It is not necessary to address blank comment sections or sections to provide additional information.

3.0 PREFERRED METHOD FOR AUTOMATED SYSTEMS DATA

3.1 All data generated by automated laboratory instruments and computer systems, including spreadsheets, should indicate (or have added to the print-out) the following information:

a. Date

b. Sample numbers/Identity

c. Cross-reference to the study notebook or data collection form that describes the experiment, if applicable

d. Signature or initials of person generating data

e. AHETF Study number

f. System description (*e.g.*, GC column type, oven temperatures, weather station brand/model, mobile phase, flow rates, HPLC unique instrument number, *etc.*) This system description can be added to the first page of an analytical data set if documentation exists indicating this information pertains to the entire data set.

3.2 The first printout from automated systems is considered the original raw data.

4.0 SCIENTIFIC/TECHNICAL REVIEW OF RESULTS

4.1 It is the responsibility of the Study Director, or his/her designate, or the contract laboratory management to ensure that all results on data forms, notebooks and automated printouts are accurate. All mistakes should be noted and corrected by the personnel who recorded the data.

4.2 The AHETF Quality Assurance Unit (QAU) may review the raw data at any given time.

Data Corrections

Chapter 9: DOCUMENTATION
AHETF-9.F.O.

Effective Date : February 1, 2003

APPROVAL David Johnson DATE 01-22-03

APPROVAL William Ottley DATE 1-28-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the procedure for making proper changes and/or corrections to raw data generated in all Agricultural Handlers Exposure Task Force (AHETF) studies.

2.0 PROCEDURE

2.1 Changes to the raw data are made by drawing a single line through the original entry so as to not obscure the entry then adding the correct entry. The change and/or correction must be initialed and dated by the individual making the change, and an explanation (either written out or coded) must be given for the change. The following codes and their definition can be used:

WL	=	Inadvertently recorded in wrong location
CC	=	Changed for greater clarity
WO	=	Write over. (Personnel inadvertently wrote over the error instead of drawing a line through the error). Cross out the error and re-enter the correct data.
SP	=	Spelling error
CE	=	Calculation error

RE = Recording error

NI = Entry not initialed and dated at time of entry

FC = Form change (*i.e.* incorrect unit contained in column header)

RO = Rounding error

2.2 Codes, other than those defined in section 2.1 may be used, if clearly explained (defined) in the notebook or data file.

2.3 Error codes should be circled to distinguish the code from the individual's initials, and placed as close to the correction as possible. If this is not possible, the error should be footnoted and explained elsewhere on the page.

2.4 Errors that cannot be explained with an appropriate defined code must be explained in detail on the page at the time of correction.

2.5 The field and laboratory facilities may follow the examples in this SOP or use their own internal SOPs on data correction.

Raw Data Handling

Chapter 9: DOCUMENTATION
AHETF-9.G.O.

Effective Date : February 1, 2003

APPROVAL David Johnson DATE 01-22-03

APPROVAL William Ditty DATE 1-28-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the methods to follow when contract facilities forward raw data to the Agricultural Handlers Exposure Task Force (AHETF).

2.0 PROCEDURE FOR THE SHIPPING OF RAW DATA

2.1 The contract facility will assemble all original data plus a detailed itemized list of all data/material being sent, and prepare it for shipping via acceptable carrier (*e.g.*, one providing tracking accountability such as Federal Express). An appropriate Chain of Custody Form will accompany the data. (Refer to the attached example).

2.2 The facility will produce true copies of the original data, which will be subject to QA review (if necessary).

2.3 The true copies will be shipped to the AHETF QAU, Study Director or other designee for report preparation and review. Originals will be shipped directly to the AHETF archives. Copies and originals may not be shipped together or at the same time *(i.e.*, one complete set must be secured by the contractor or AHETF while the other is in transit).

2.4 Data should be sent via overnight carrier, or transferred to the Study Director, committee member, or designated personnel for hand delivery.

2.5 Upon receipt of the shipment, the data package will be inspected. The condition of the data package will be noted and acknowledgment of receipt will be noted on the Chain of Custody form.

2.6 The AHETF Task Force Manager, Study Monitor, or designate will review the copies and the report for scientific accuracy and regulatory compliance. The copies will be maintained as long as the data are required for report preparation or review. Upon completion of the final report, but prior to finalization (Study Director signature), all original raw data will be placed in the AHETF designated archives.

3.0 RETURN POLICY

3.1 All original data and contractor report(s) should be sent directly to the designated archives. The contract test facility will be responsible for the condition of the data until it has been received by the AHETF archives.

3.2 True copies of the raw data will be maintained by the Study Director or AHETF Quality Assurance Unit (QAU). All original raw data will be maintained in the AHETF archives after study completion. The AHETF will authorize all transfers and distributions of AHETF study data.

3.3 No contract laboratory may retain copies of AHETF study data unless authorized in writing by the AHETF. Raw data packages will consist of original AHETF data, and true copies of lab/facility specific data (*i.e.*, temperature records, SOPs, personnel records, maintenance logs, *etc.*).

Attachment

Chain of Custody Form

(example)

Agricultural Handlers Exposure Task Force

Data Chain of Custody

AHETF Study No.	Data Type:	Priority:	Page:
AHE99	*Analytical raw data*	*Overnight*	*1 of 1*

Ship To:	Ship From:
AHETF Archives *Archivist* *Address* *City, State Zip Code*	*Study Director* *Facility/Company* *Address* *City, State Zip Code*

Shipper/Carrier:	Airbill No.	Date Shipped/Initials:
FedEx	*123-456-7A*	*10/16/02 mm*

Comments:

3 boxes packed with raw data

Shipped:	Description of Materials Sent:	Received:
	Box 1:	
✓	*Field notebook*	✓
✓	*Test substance records*	✓
✓	*Application video*	✓
	Box 2:	
✓	*Analytical data 7-1-97 to 8-19-97*	✓
	Box 3:	
✓	*Analytical data 8-26-97 to 9-15-97*	✓
✓	*Final report*	✓
✓	*QA records (in separate envelope)*	✓

Date Received:	Received By/Company:
10/18/02	**J.Doe/Archives, Inc.**

Condition Received:

Good, sealed boxes. 3 boxes received.

Preparation of True Copies

Chapter 9: DOCUMENTATION
AHETF-9.H.O.

Effective Date : February 1, 2003

APPROVAL David Johnson DATE 01-22-03

APPROVAL William Ott DATE 1-28-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the process for making true or exact photocopies of original raw data to be used in place of the original data by the Agricultural Handlers Exposure Task Force (AHETF).

1.2 All original study data will be retained by the AHETF and all original facility records will be the responsibility of the individual contractors; however, copies of these data may need to be produced to complete study files, facilitate preparation of the report(s), or be used in auditing the final report(s).

2.0 PROCEDURE

2.1 The necessary data will be photocopied by the contractor. All copied pages of raw data will be immediately reviewed by the persons making the copies for clarity and completeness.

2.2 Any pages that are poorly copied (*i.e.,* smeared, unclear, too light or dark, missing text, *etc.*) are not acceptable, and must be re-photocopied.

2.3 Individual pages will be certified as a true, exact, or certified copy, either with an appropriate rubber stamp or written by the person(s) verifying the copied pages. The person's initials (or a signature) and the date verified must be noted on the copied page(s).

2.4 Whole sections of data (*e.g.,* chromatogram sets, entire data notebooks, *etc.*) must be verified completely, but only the cover page of the set need contain the true copy designation and the person's initials and date. In addition, the cover page must indicate the total number of pages in the set and clearly state that all pages contained in the set are true copies. All pages in such a set must be paginated or otherwise marked to ensure they remain together.

2.5 True copies must be handled as raw data (when replacing the original data), and are subject to all AHETF and GLP handling and retention requirements.

2.6 True copies may be discarded by the AHETF or contractors only when the original raw data are properly archived and there is no longer a need for such copies. Verification must be obtained from the Study Director, Task Force Manager, AHETF QAU, or designated archive facility(s) before disposal.

2.7 Copies of data made for transfer of information within the AHETF need not be authenticated. Only copies of data intended to replace the original raw data must follow the above listed procedures.

Phase Report Template

Chapter 9: DOCUMENTATION
AHETF-9.I.0.

Effective Date: January 15, 2005

APPROVAL Shirley Stanford DATE 1-18-05

APPROVAL David Jackson DATE 01/28/05

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the process for use and completion of the standardized phase report template designed for the contract facilities conducting field and analytical studies for the Agricultural Handlers Exposure Task Force (AHETF). Contents and required elements for individual reports are detailed in SOP AHETF-4.A.

1.2 Due to government requested specifications for electronic submissions of study reports, the original document may be created in any recent version of Microsoft® Word® (i.e., Office 2003, 2002, 97). However, the conversion of the file into Adobe® Portable Document Format (PDF) must be done to Adobe® 5.0. Later versions must have the PDF file saved to the 5.0 format.

2.0 REPORT FORMATTING

2.1 The electronic template is preformatted as described in this section. No changes shall be made to the formatting unless otherwise approved by the AHETF. Requests for changes to the formatting should be directed to the appropriate Study Director. This template was modeled after the EPA OPP – Electronic Submission and Review Specifications.

2.2 Times New Roman (the default font requested by the USEPA for electronic submissions) or an equivalent font, shall be used for all text, tables, and figures. The standard size will be 12 pt. with no text smaller than 8 pt. Italicized fonts should be avoided and script fonts may not be used. This is the default font requested by the USEPA for electronic submissions.

2.3 Boldface should be used for highlighting section titles and key words and phrases in the text. Underlining should be avoided. Shading in tables may be used if no greater than 40% or reversed text (white text on a black background) may be used. Single lines are preferred to double lines.

2.4 Line spacing should be 1.0 and not greater than 1.5. Line height should be set to automatic. All documents should be set to automatic kerning.

2.5 Margins should be at least 1.25" on the left and no less than 0.75" on the right. Top and bottom margins should be set between 0.75" and 1.00". For field and analytical reports to be appended to the final summary report, the top and bottom margins may be adjusted to accommodate additional pagination.

2.6 Each page, except the cover page, must have a header and/or footer with the AHETF study number and pagination. The header and/or footer may contain a single line at its bottom edge to set it off from the text. The header and/or footer text shall be in 10 pt.

2.7 Text alignment should be set to either left or full justification (preferred), and must be consistent throughout the report. Subsections and paragraphs should be indented on the left, with no hanging indentation (even left alignment at each outline level). Tab stops should be no less than 0.25" per level and no greater than 0.50" per level.

2.8 Titles and section headings should be larger than the body text. These items should be set to no larger than 14 pt. and should be set in boldface. Individual sections shall be identified by a whole number, with subsections being identified by that number and a sequential decimal, then by a lowercase letter.

2.9 Tables and figures should be identified by Arabic Numerals, such as "Table 1." or "Figure 7." Appendices shall be identified by capital letters, such as "Appendix A." All tables, figures and appendices must have a descriptive title.

2.10 Where superscripts are necessary to designate a footnote, these should be letters and not numbers.

2.11 Optically scanned copies of data may be included in an appendix, as necessary. Copies should be copied at their original size (1:1 if 8.5" x 11.0" or smaller). If oversized pages are to be copied, they should not be reduced less than 80% of original size. All information must be legible. Contrast must be adjusted so that no areas are too dark or light. Any unreadable copies will be rejected, and must be re-scanned or removed and excluded from the report.

3.0 ELECTRONIC FORMATS

3.1 All report and manipulated data must be presented to the AHETF in an electronic format. To maintain consistency from all contractors, each report document must be in Microsoft® Word® for Windows® 97 or compatible format. All spreadsheet data must be in Microsoft® Excel® for Windows® 97 or compatible format. Macintosh® formatted data are not acceptable. This template was created using EPA's Specifications for Creating PDF® Version of Study Reports.

3.2 All signed pages will be optically scanned separately and stored in PDF® format. These signed pages need to be inserted into the final phase report file.

3.3 Electronic submissions to the EPA must be in Adobe® Acrobat® PDF format version 5.0. Later versions of Acrobat® may be used; however, the output must be in the 5.0 format. EPA's website (http://www.epa.gov/oppfod01/eds/softset_study.pdf) contains a guidance document entitled, "Software Settings for the Creation of PDF Files for Electronic Submission." This document should be referred to when setting the PDF conversion settings. All documents will be converted versus distilled.

3.4 All data should be electronically available. All word processing files, spreadsheets, photographs, and optically scanned figures must be submitted to the AHETF on a CD-ROM, along with the completed PDF® phase report. One original signed hard copy of the phase report will also be submitted.

4.0 COMPLETION OF ELECTRONIC TEMPLATES

4.1 It is imperative to complete the electronic template in the prescribed manner in this SOP. Failure to follow the specified techniques will result in an incoherent electronic version of the phase report.

4.2 After all reviews have been completed, the report must be converted to Adobe® PDF® then printed. This will serve as the final original document. As different printers produce slightly different formatting, it is important to edit the document layout with an Acrobat® compatible printer as the selected printer.

4.3 Cutting and pasting from an old document presents problems both in appearance and in the conversion process. If you need to do this, do not copy a whole section but by paragraph. Use the styles box to keep text in the proper formatting, if necessary.

4.4 Refer to your "STYLE" bar to see the applicable formatting. The "STYLES" have been preset to wrap a paragraph to the correct position without placing a hard return then tabbing or spacing over. Do not space to align (this will not convert to PDF format cleanly).

4.5 All paragraphs in the templates are defaulted to be full aligned (per SOP). Cutting and pasting from another document may change the default alignment and you will need to follow the steps noted above in §4.3. You will then need to manually change the alignment for pasted sections.

4.6 Spacing between paragraphs and sections is also embedded using styles so no extra lines need to be added.

4.7 Starting with an existing document and trying to add these new styles, one may get it to look right when printed, but electronically it has too much extraneous formatting and cannot be converted properly. This also increases the document size.

4.8 All "<>" are placeholders for information. All print in italics are places needing appropriate text inserted, usually encased by < >. Some examples are given in italics. Delete "<>" marks from completed sections.

4.9 Do not alter the template margin settings.

4.10 On the field and analytical templates, landscaped pages have a text box that will contain the footer information. The verbiage "AHETF Template <date>" that appears on portrait pages was purposely omitted from landscaped pages on the templates. This verbiage will need to be replaced with appropriate report information on all footer sections for the draft and final reports.

4.11 On the field and analytical templates, within Microsoft® Word® change the document properties to reflect the author of the report and a descriptor of the report (i.e., AHE06 - Acephate Method Validation or similar verbiage). This is changed by selecting the file menu, then properties, and choosing the summary tab.

4.12 Manually add the final hard page breaks only after all other formatting and changes have been completed, and then convert to PDF format.

4.13 It is recommended not to change any format setting in the templates, as it may affect several sections throughout the document. Local formatting may be adjusted manually, as necessary.

4.14 Extra figures, spreadsheets, tables, photographs, etc. should be converted into PDF format separately from the text in the template, then combined, in proper order in Adobe® Acrobat® before completion.

5.0 CONVERTING PROCESS

5.1 EPA's website contains a guidance document entitled, "Software Settings for the Creation of PDF Files for Electronic Submission." This document should be referred to when setting the PDF conversion settings. Unlike printing direct to Distiller, the use of PDFMaker allows for the creation of tagged PDF files, preservation of bookmarks and links, and conversion of metadata from the original Word document.

5.1.1. No passwords shall be used. The encryption level will be set to 128-bit. Permissions will be set to enable content access for the visually impaired and allow content copying and extraction. Changes allowed will be limited to comment authoring, form field fill-in or signing and printing will be fully allowed.

5.1.2. "Cross-document links" and "convert internet links" should all be enabled. Set link destination magnification to "inherit zoom." The Comments - Notes, Text Boxes – Article Threads, Page labels, cross-reference & ToC links and footnote & endnote links should all be selected.

5.1.3. Convert word headings to bookmarks should be chosen.

5.1.4. Set the document open options to "Bookmarks and Page", "Page Number" as "1" and open magnification to "default." Set link appearance type to "thin visible rectangle," highlight to "invert", line style as "solid" and color to "blue".

Rotameter Calibration

Chapter 10: FIELD OPERATIONS
AHETF-IO.A.O.

Effective Date : October 15, 2003

APPROVAL _____ DATE 09-27-03

APPROVAL _____ DATE 09-26-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly calibrate a rotameter used for measurement of the air flow rate through an OVS air sampling tube used to collect air monitoring samples during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the rotameters:

a. Personal low-volume air-sampler pump(s) (*e.g.*, SKC, or equivalent)

b. Tygon® tubing or equivalent

c. Appropriate calibration device or primary air flow meter (*e.g.,*BIOS DryCal®, Kurz Mass flow meter, Buck Calibrator, bubble meter and stopwatch, or equivalent)

d. Field rotameter with an appropriate measurement range

3.0 CALIBRATION PROCEDURE

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

3.2 Verify calibration of a rotameter once a year or if rotameter operation becomes suspect.

3.3 Start by calibrating five individual air-sampler pumps to five individual flow rates using a primary air flow meter (*e.g.* BIOS DryCal®, calibrated according to the SOP for the appropriate flowmeter). Select five flow rates that span the scale of the rotameter being calibrated.

3.4 Evaluate the rotameter calibration by attaching, one at a time, the five air flow calibrated air-sampler pumps from 3.3 to the rotameter. Hold the rotameter perpendicular to the ground and after the rotameter has been allowed to stabilize, a reading from the middle of the ball can be taken and recorded.

3.5 If any reading deviates more than ±5%, the rotameter will be discarded and replaced with a new rotameter.

Worker and Study Observations

Chapter 10: FIELD OPERATIONS
AHETF-10.C.3.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: January 1, 2006	Previous Version Number: 10.C.2.

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes procedures for the necessary observations to be performed during the field phase of the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 The SOP was revised to include more details on what observers should be looking for in relation to worker health status.

2.0 FIELD NOTEBOOKS

2.1 To standardize and facilitate data collection, a field notebook will be provided to the field contractors prior to the exposure-monitoring period. The notebook will provide the necessary forms for study data collection. Instructions for the use of notebook will be located at the front of notebook.

2.2 The provided notebook will contain the AHETF study number and contractor project number on each page. If additional pages are inserted into the field notebook, this information must be included on the inserted pages.

3.0 SITE DETAILS

3.1 Record site details on the appropriate forms in the field notebook.

The Principal Field Investigator (PFI) should record the following information, at a minimum:

a. Prepare a sketch map of the working area giving key details such as compass points, orientation of rows in test plot, mixing/loading area.

b. Record on the form the study number, site reference, date and initials.

c. Attach a copy of a map with the nearest town circled and give details from there.

d. If details of the location change (*e.g.,* move to a different location for application), prepare a new sketch showing the new conditions.

4.0 ENVIRONMENTAL CONSIDERATIONS

4.1 Outdoor environmental conditions, including but not limited to, wind speed, wind direction (relative to the test site and direction of application), air temperature and relative humidity will be monitored and recorded locally by means of a weather station at each trial site during worker monitoring, or by reference to data from the nearest NOAA weather station. Measuring equipment for on-site weather stations will be calibrated per the contractor's SOP.

4.2 Indoor environmental conditions, including but not limited to, air temperature and relative humidity will be monitored and recorded by means of calibrated measuring devices located within the designated test areas. Measuring equipment for indoor monitoring will be calibrated per the contractor's SOP. The ventilation system will be described in the raw data.

4.3 At all test sites, environmental conditions that could pose a potential heat-related illness threat will be diligently monitored as part of the AHETF program to minimize potential heat stress on workers. Refer to SOP AHETF-11.G.

5.0 EQUIPMENT DETAILS AND OPERATION VERIFICATION

5.1 Details of application equipment will be recorded in the field notebook. Application equipment operation will be verified, and calculations recorded, as defined in the study protocol and SOP AHETF-10.D.

6.0 WORKER OBSERVATIONS

6.1 Each dedicated worker's observer must use the appropriate form in the field notebook to record the times and descriptions of all activities including mixing, loading, and/or application activities; resting, lunch, washing hands, driving vehicles, *etc*.

6.2 Describe clothing and personal protective equipment (PPE) worn and crop/site condition. Document all clothing worn, including PPE prior to the start of observations during the work period. Note any clothing defects and bring to the attention of the Study Director, Principal Field Investigator (PFI), or AHETF personnel on-site. Record any instances of removal of protective equipment during the monitoring period.

6.3 Be sure that the air sampling pump has been turned on before the worker enters the mixing/loading areas, begins any activities for the day, or uses any application equipment. If the PFI has not turned on the air sampling pump immediately after the worker was dressed, it is the observer's responsibility to turn the pump on and record the start time in the field.

6.4 Record start and stop time for all activities. Record the productivity of each worker during the activities (*e.g.*, specifically the amount of product handled, if known). It is recommended that all study personnel synchronize their watches prior to the start of the day's activities.

6.5 Record any actions that might explain any unusually high or low exposure values for any of the body parts (*e.g.,* spills, maintenance of equipment, keeps gloves on, *etc.*).

6.6 Pay attention to the workers' hands during the exposure monitoring period, this includes time handling the test substance, donning/removing PPE, standing around waiting, or performing non-study related activities. Look for hand contact to contaminated equipment or clothing associated with contact to the head/face, other workers, personnel, *etc*.

6.7 Periodically note the workers' clothing. Look for new rips or tears, perspiration, chemical spills/stains, or anything that appears out of the ordinary. Also check and document the operation of the personal air sampling pump. Document as "Pump Running" not "Pump On".

6.8 Report any unusual or unauthorized activities observed (eating without handwash, not wearing PPE during chemical exposure, *etc*…) to the Study Director, PFI, or AHETF QAU.

6.9 Record observations pertinent to the worker assigned. For example, when observing a loader, it is not necessary to note the specifics of the application equipment. This information can be cross-referenced later.

6.10 Monitor the health status of the worker, especially under conditions of temperature and humidity which may promote a heat-related illness. Refer to SOP AHETF-11.G for specific warning signs and condition criteria. Record any reactions a worker may exhibit and any remedial actions taken.

6.11 Keep observations brief and to the point. Don't use worker names; rather use their ID for the study. Don't record long explanations of activities unless absolutely necessary to explain what is occurring. Document what activities are directly related to handling the test substance.

6.12 The observations made will be reviewed and placed in the field report at the conclusion of the study. Try to write neatly and clearly while describing the activities observed. Be as succinct as possible. Typically 3-5 pages of notes should be collected during an average work period.

6.13 Observe the worker for the entire time period of the exposure monitoring , from when the worker is dressed at the start of the day until he/she enters the staging area for sample collection; this includes during lunch breaks, performing other daily activities, and during interim sample collections. This does not include observing the worker during restroom breaks. If the worker cannot be seen during application, this should be noted, and is to be expected at times. If the observer needs to take a break, get another researcher to monitor the worker during the observer's absence.

6.14 Do record the names of non-study compounds observed being handled during the monitoring period. Use generic terms like anti-foam agent, surfactant, insecticide, *etc*. in observation notes and document chemical or trade names, if known, in the specific loading/application procedures.

6.15 A pre-study explanation of required observations may be conducted before the conduct of the study commences. The AHETF QAU and/or Study Director will be responsible for providing additional training on this SOP. The AHETF Study Director will determine if research personnel would benefit from such training on a per study basis.

Application Equipment Operation Verification

Chapter 10: FIELD OPERATIONS
AHETF-IO.D.O.

Effective Date : October 15, 2003

APPROVAL _____ DATE 09-27-03

APPROVAL _____ DATE 09-26-03

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

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps for the Study Director, or designee, to follow when assessing the operability of application equipment (groundboom, aerial, airblast, handheld, *etc.*) prior to being used in Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP will cover various commercial application equipment that may be used on AHETF worker exposure studies. Since the AHETF will measure handler exposure (applicator) under expected working conditions using standard industry practices, no modifications or maintenance will be performed by the AHETF to the equipment. In order to maintain an acceptable level of scientific integrity, the AHETF will perform several steps to assess the operational capabilities of the application equipment.

2.0 EQUIPMENT RECORDS REVIEW

2.1 The Study Director will obtain copies of pertinent maintenance and calibration records provided by the equipment owner. These copies will be maintained by the AHETF in the appropriate study file.

2.2 The Study Director, or designee, will review the equipment records prior to the application. The records should indicate reasonable maintenance has been conducted by the equipment owner/operator, and that the output of the equipment has been checked within the six months prior to the AHETF study.

3.0 VISUAL EQUIPMENT INSPECTION

3.1 The Study Director, or designee, will perform a general visual inspection of the application equipment. Visible signs of damage shall be noted. The overall condition of the equipment will be documented.

3.2 The Study Director shall point out any deficiencies or questionable parts of the equipment to the owner/operator. If deemed necessary, the owner/operator shall perform the needed repairs prior to the AHETF application.

3.3 All observations and corrective actions (if applicable) will be documented in the study file.

4.0 VERIFICATION OF GENERAL OPERATION

4.1 The output of the application equipment will be visually assessed prior to the application. This entails verifying that each nozzle (or other delivery mechanism) is discharging while the equipment is running and at operating pressure. This should be done without the test substance in the tank. Individual output from any nozzle may be collected and measured at the discretion of the Study Director. All observations or measurements made will be documented in the study file.

4.2 The overall operation of the equipment shall be verified. Any significant problems that interfere with the application shall be discussed before proceeding with the application. All observations and corrective actions (if necessary) will be documented in the study file.

5.0 APPLICATION EQUIPMENT OUTPUT

5.1 If deemed necessary by the Study Director, a complete measurement of each nozzle's output shall be completed, in duplicate, prior to the AHETF application. If the output is dependent upon the equipment's speed, then timed passes will be conducted over a known distance of similar terrain to the treated areas. All results and calculations will be documented in the study file.

Worker Sample Collection Sequence

Chapter 10: FIELD OPERATIONS
AHETF-10.E.2.

Effective Date : March 3, 2008

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

Last Revision Date: January 1, 2006 Previous Version Number: 10.E.1

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the sequence for the research personnel to follow when collecting worker samples from the field phase of the Agricultural Handlers Exposure Task Force (AHETF) exposure studies.

1.2 This SOP was revised to change the term "replicate" to monitoring unit or worker.

2.0 COLLECTION SEQUENCE

2.1 Upon completion of the monitoring period, the worker shall return to the appropriate staging area. Research personnel collecting dosimetry samples must change their disposable gloves (latex, vinyl, etc...) between each sample collected described as follows.

2.2 The research personnel will check the air pump flow rate using equipment and techniques described in SOPs 8.D and 10.A. The air sample will be collected according to SOP 8.D, and the air pump and lines removed from the worker.

2.3 The worker will then remove their own personal protective equipment (PPE), which may include chemical-resistant (CR) gloves, a respirator, glasses, hat or CR headgear. This headgear may contain head patch samples. If inner head patches were utilized during the study, the researcher will remove the inner head patch according to SOP 8.H.

2.4 If head patches were utilized in the study, the outer head patch will be collected by research personnel, according to SOP 8.H., after the worker removes their headgear.

2.5 The worker will then remove any body PPE (e.g., apron, coveralls, or gloves) and their shoes, then the worker may enter the clean, private area where they will remove their outer work clothes and socks.

2.6 If no sock dosimeters were used on the study, skip to section 2.7 and collect a hand wash sample. Otherwise, upon removal of outer garments (shirt, then pants, then outer socks) by the worker, the researcher will remove the sock dosimeters, according to SOP 8.I.

2.7 Immediately after the worker has removed his outer clothing and if the socks dosimeters (if used) have been collected, the researcher will collect hand wash samples, according to SOP 8.B.

2.8 After collection of hand washes, the researcher will collect face/neck wipe samples, according to SOP 8.C.

2.9 After collection of the face/neck wipes, the researcher will remove the inner dosimeter from the worker and process it, according to SOP 8.A.

2.10 At this point, all worker samples will have been collected and the worker shall dress in his/her street clothes and may be dismissed.

2.11 Any deviations to this procedure must be documented in the raw data and the Study Director informed of the changes and reasons. This sequence only applies to the post-monitoring period sample collection procedure. Interim samples that are collected will be done according to the specific matrix sample SOPs and identified according to SOP 8.F.

Personal Air Sampling Pump Calibration

Chapter 10: **FIELD OPERATIONS**
AHETF-10.G.1.

Effective Date : June 30, 2007

APPROVAL David Johnson DATE 04-02-08

APPROVAL [signature] DATE 02 APR 2008

Last Revision Date: October 15, 2003 Previous Version Number: 10.G.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly calibrate the personal air sampling pumps used to collect air monitoring samples during Agricultural Handlers Exposure Task Force (AHETF) worker exposure studies.

1.2 This SOP has been revised to change the term "replicate" to monitoring period or worker.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the sampling pumps:

a. Personal low-volume air sampling pump(s) (*e.g.*, SKC, or equivalent)

b. Tygon® tubing or equivalent

c. Appropriate OSHA Versatile Sampler (OVS) Tubes

d. Appropriate calibration device (*e.g.*, Kurz Mass flow meter, Buck Calibrator, bubble meter and stopwatch, or equivalent)

3.0 CALIBRATION PROCEDURE

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

3.2 Calibrate air sampling pumps before use in each monitoring period. Calibrations will take place on the day prior to or the same day the pumps are to be used.

3.3 Calibrate the pumps under actual use conditions, as the air temperature may affect the airflow (*e.g.*, calibrate outside rather than inside for exposure trials). Calibrate pumps with the appropriate OVS tube/ sampling train attached.

3.4 Follow appropriate contractor SOPs for the individual calibration methods for contractor equipment.

3.5 Adjust the airflow rate to appropriate 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 sampling pump and set aside. Repeat steps 3.4 and 3.5 until all needed sampling pumps (including backups) have been calibrated.

4.0 POST EXPOSURE FLOW RATE CHECK

4.1 Using the same methods to calibrate the air pump, measure the airflow with a new OVS tube. Document the results in the study file.

4.2 Check the post exposure flow rate after the worker's OVS tube has been removed by the field sample collection personnel.

Recruiting, Informing and Seeking Consent from Study Volunteers

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-11.B.1.

Effective Date : April 4, 2008

APPROVAL David Johnson DATE 04-02-08

APPROVAL DATE 02 Apr 2008

Last Revision Date: March 3, 2008 Previous Version Number: 11.B.0

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) defines general procedures for recruiting, informing, and seeking informed consent from workers in field studies being conducted by the Agricultural Handlers Exposure Task Force (AHETF). A more detailed study-specific recruitment plan will be developed for each field study and will be included in the study-specific protocol.

2.0 ETHICS 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 others working on behalf of the Task Force who interact with study participants, will have completed one or more ethics training courses. The only exception to this rule is that an interpreter, if used, does not need to have ethics training as long as they are accompanied by a researcher who has had ethics training. 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 PROTOCOL APPROVAL

3.1 Growers and 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, 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 RECRUITMENT OF WORKERS

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

4.1 The first phase typically involves contacting and selecting growers and/or commercial application companies that can provide the necessary crop/site, equipment, workers, and need for pesticide. This will often be done in a random manner, such as by calling from a randomized list of growers for a local area. During this first phase, employers are asked for permission to recruit their workers at a later date. 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 phase typically involves recruiting workers from a pool of eligible growers and/or commercial applicators identified in the first phase. These workers may be the growers, their employees, or employees of commercial applicators. The process is as follows:

a. Growers and/or commercial applicator companies will have been selected who are willing to cooperate with AHETF in the monitoring study and the SD will have determined they are acceptable. The grower or other responsible personnel will have given permission for the SD 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 providing a contact number for the SD. Note that growers themselves (if they are qualified handlers) may also be contacted at this time. The SD (or designee) organizes a meeting with only the interested workers present. This may be done one-on-one or with a group of interested workers.

4.3 The meeting with interested workers will consist of the following:

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

b. The SD (or designee) will explain the nature of the study and the general content of the protocol and Consent Form. Any materials used during this recruitment meeting will be approved by the IRB before use.

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

d. Informed Consent Forms will be available for review by potential volunteers. Workers will be urged to take a copy home for review.

e. Potential volunteers will be shown 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.

f. At the conclusion of the meeting, interested workers may either contact the SD (or designee) at a later time to express their intent to participate or may go through the individual private consent process at that time (described below in Section 7.0).

5.0 INCLUSION AND EXCLUSION CRITERIA

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

5.2 Participants in this study must meet the following inclusion criteria:

a. Be freely willing to participate

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 must be exempt from such training

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

e. Be at least 18 years old with a government-issued ID to verify age

f. Consider themselves to be in good general health with no medical conditions that could impact their ability to participate in the study

g. Be willing to follow all label and WPS requirements

h. Understand English or Spanish (*see below for further discussion of this topic*)

5.3 Potential subjects who meet the following exclusion criteria will not be allowed to participate in the study:

a. Are pregnant females

b. Are nursing mothers

c. Normally wear personal protective equipment (PPE) than is not required by the label, such as chemical-resistant clothing

d. Are employed by a pesticide manufacturers or a contractor to the AHETF

e. Do not understand English or Spanish

6.0 LANGUAGE REQUIREMENTS

6.1 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 their preferred version of the form. For workers whose preferred reading language is Spanish, AHETF obtains an IRB-approved translation of the Consent Form.

6.2 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. Reading ability will be self-reported by the worker. Each potential subject will decide for himself/herself whether or not they are comfortable reading the consent form. If not, an impartial witness will be used to read the form to them as described below.

6.3 When the need for a witness arises*, i.e.* if a worker has limited reading ability, an impartial witness will be used to verify that the worker has apparently understood the materials read to and discussed with them. Witnesses will have no association with researchers in this study nor will they be a part of the management of the grower where the research is being conducted. In addition, an impartial witness must have a general understanding of agriculture. The witness will also sign the Consent Form.

6.4 When study volunteers choose to have recruitment and consent discussions be done in Spanish, a bilingual researcher will be utilized. However, if all reasonable efforts to obtain a bilingual researcher have been exhausted, it is acceptable to instead utilize an interpreter. In this case, the SD (or designee) will conduct the discussions in English and the interpreter will translate the discussions into Spanish. The interpreter will also translate any questions from the volunteers into English so the SD

(or designee) can respond appropriately. If an interpreter is used, the SD (or designee) will ensure the interpreter knows enough about the research design and the content of the Consent Form to provide an accurate translation. If necessary, this will involve tutorial discussions from the SD (or designee). To test the understanding by the interpreter, the SD will ask him/her to explain some portions of the Spanish Consent Form, in English. Interpreters are not considered part of the research team and will not sign the Consent Form. An interpreter who assists in consent form communication between the SD (or designee) and the worker will not be permitted to serve as an impartial witness for that worker.

6.5 The following procedures will be followed with each individual wanting to participate in an AHETF study. The SD (or designee) will go through the entire consent process with the worker (see Section 7.0 below). The following paragraphs describe how workers with varying reading and language skills will be guided through the consent process. Attachment 11-B-2 provides a summary of the procedures described below.

a. Workers who understand English and are comfortable reading English will be provided a copy of the Consent Form in English, will be asked to read the Consent Form in its entirety and encouraged to ask questions of the SD or research staff pertaining to their participation in the study. A copy of the signed Consent Form will be provided to the worker.

b. Workers who understand English, but are not comfortable reading English will have the Consent Form read to them and will be encouraged to ask questions of the SD or research staff pertaining to their participation in the study. An impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (or designee) [see Section 7.0 below]. A copy of the signed Consent Form will be provided to the worker.

c. Workers who understand Spanish and are comfortable reading Spanish will be provided a copy of the Consent Form in Spanish, will be to read the Consent Form in its entirety and encouraged to ask questions of the SD or research staff pertaining to their participation in the study. Interpreters for

Spanish speakers will be provided only if all reasonable efforts to obtain a bilingual researcher have been exhausted. A copy of the signed Consent Form will be provided to the worker.

d. Workers who understand Spanish, but are not comfortable reading Spanish will have the Consent Form read to them and they will be encouraged to ask any questions to the SD or research staff pertaining to their participation in the study. Interpreters for Spanish speakers will be provided only if all reasonable efforts to obtain a bilingual researcher have been exhausted. A bilingual impartial witness will verify that the worker has apparently understood the materials read to and discussed with them. The witness may assess the worker's understanding by their answers to the questions asked of the worker by the SD (or designee) and relayed by the interpreter, if used; (see Section 7.0 below). A copy of the signed Consent Form will be provided to the worker.

7.0 INFORMED CONSENT PROCESS

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

7.2 The SD (or a researcher designated by the SD) 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.

7.3 Informed consent discussions will be conducted by the SD (or designee) in private with each worker and others that the worker may want to have present. Interpreters and witnesses may also be present as described above in Section 6.0. When a bilingual researcher is obtaining consent from a Spanish-speaking worker, the Study Director may also be present during the private meeting.

7.4 The SD (or designee) will inform the worker that he/she will receive $20, or the amount specified in the protocol, even if he/she decides not to participate following the discussion.

7.5 During the private meeting the SD (or designee) 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 receive an additional $80, or the amount specified in the protocol, if they decide to participate (don the dosimeters) but withdraw before the end of the monitoring period. Each worker will be provided a copy of the supervisor's signed form (described above) that states they will not suffer any consequence if they decide not to participate.

7.6 The SD (or designee) 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 and must be signed by the worker (and impartial witness, if present). The product label and Material Safety Data Sheet also will be explained. WPS requirements, especially proper use of clothing, personal protection equipment, etc., will be discussed. Refer to SOP AHETF-11.E for details.

7.7 The SD (or designee) will discuss the medical management plan with the prospective participants. Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. 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.

7.8 During the discussions between potential participants and the SD (or designee), ample time will be provided for questions and the SD will provide any additional information or clarification that is requested.

7.9 The IRB-approved Consent Form 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 SD (or designee) 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 SD (or designee) will provide a copy of the signed form to the worker.

7.10 An additional document, "Product Risk Statements", will be attached to the Consent Form. If the study is conducted in California, the "Experimental Subject's Bill of Rights" will also be attached. These documents will be reviewed, signed and dated by the worker, and copies will be provided.

a. In all situations, the SD (or designee) 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. (See Attachment 11-B-3)

7.11 The SD (or designee) will not sign the Consent Form unless he/she believes they have done everything possible to ensure that the process has been free of any element of coercion or undue influence, and that the worker understands the material in the Consent Form.

8.0 FOLLOW-UP PROCEDURES

8.1 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 will be mailed to the address provided by the participant(s) desiring it (the SD or designee will complete the form in Attachment 11-B-4). 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.

8.2 When the monitoring period is completed, or at the time a participant withdraws from the study, the SD (or designee) will remind the worker that he/she has received a copy of the signed Consent Form that has phone numbers for reporting any health changes the worker thinks may be related to his/her participation in the study. Worker inquiries of this nature will be forwarded to AHETF management to be resolved on a case-by-case basis.

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: _____

ATTACHMENT 11-B-2

Language Procedures

	Worker Understands English (and maybe Spanish, too)	Worker Understands Spanish (but not English)
Worker is Comfortable Reading This Language	SD (or designee) 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 not Comfortable Reading This Language	SD (or designee) Discussions in English SD (or designee) reads English Consent Form to worker Witness needed (English)	Bilingual researcher Discussions in Spanish* Bilingual researcher reads Spanish Consent Form to worker Witness needed (bilingual)

* If all reasonable efforts to obtain a bilingual researcher have been exhausted, an interpreter may be used as described in Section 6.

ATTACHMENT 11-B-3

Consent Form Understandability – Worker Feedback Form

Questions	Answered correctly?		Revisited material with apparent understanding?	
	Yes	No	Yes	No
INTRODUCTION				
Can you take an unsigned copy of this consent form home to think about? Yes				
Purpose				
What is the purpose of this study? To measure how much pesticide I might breathe or get on my skin.				
What job will you be performing in this study? Response will be site-specific				
Procedures				
What type of clothing will you wear underneath your normal work clothing? Long underwear				
When will you have your hands washed? At the end of the day, before eating and anytime I normally wash my hands (toilet)				
Products Handled				
Is the product you will be handling approved for use in the activity you will be performing in this study? Yes				
Risks & Discomforts				
Name two risks that you might have by participating in this study. Equipment, heat, product, embarrassment, eye/skin irritation, etc.				

Consent Form Understandability – Worker Feedback Form (Con't)

What are some early signs of heat stress? **Dizziness, being tired, irritability, lack of concentration**				
If you feel sick from too much heat, what do you do? **Tell a study investigator**				
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**				
How do you obtain a copy of your personal results from this study? **Ask Study Director for a copy**				
Benefits				
Will you benefit directly from participating in this study? **No**				
How will your employer benefit? **Free product**				
Section 7: 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 receive your normal pay from your employer if you participate in this study? **Yes**				

Consent Form Understandability – Worker Feedback Form (Con't)

Voluntary Participation / Withdrawal				
Can you employer help you decide whether or not you want to participate in this study? No				
When can you withdraw from the study? Anytime I want				
If you drop out of this study after it has already started, do you have to give a reason? No				
Will you normal pay be affected if you drop out? No				
What happens if you drop out of the study? I will go back to your usual activities.				
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				
Who do you call if you have questions about the study or think you have a study-related illness or injury? Study Director or AHETF				
Consent				
If you sign the CF, name one thing 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				

ATTACHMENT 11-B-4

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: _____

Chapter 11: **Worker Health Status**
HUMAN SUBJECT MANAGEMENT
AHETF-II.C.O.

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 The following SOP describes the procedure used during the informed consent process to determine the general health status of potential participants and whether they have any medical condition(s) which could impact their ability to participate in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

2.0 INTRODUCTION

2.1 The AHETF requires workers to be in good health and able to perform the work activity for which they will be monitored. The AHETF respects the medical privacy of the worker. As a result, the AHETF will make no effort to obtain worker medical records and will rely on self-reported health status.

3.0 PROCEDURE

3.1 The worker will be asked during the informed consent process if they consider their general health status to be good. Only workers who answer "yes" will be allowed to participate in the study.

3.2 The worker will be asked during the informed consent process if he/she has any medical condition(s) that could impact his/or ability to participate in the study. If needed, the Study Director will discuss with the worker what this question means. Only workers who answer “no” will be allowed to participate in the study.

Disqualification of a worker due to health concerns will not be documented in the raw data and all other data pertaining to this individual will be promptly discarded. However, they will be counted as having been screened for participation, as per IRB guidelines.

Chapter 11: **Pregnancy Testing**
HUMAN SUBJECT MANAGEMENT
AHETF-II.D.O.

Effective Date : 03/03/08

APPROVAL David Johnson DATE 3/3/08

APPROVAL [signature] DATE 3/3/08

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

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to assess the reproductive status of a female worker who is being considered for participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study. AHETF policy does not permit pregnant workers to participate in its worker exposure studies. Federal Regulations (40 CFR Part 26, §26.203) prohibit a pregnant or nursing female from participating in these studies.

1.2 These procedures are also intended to protect the worker's privacy with respect to her employer and co-workers concerning the outcome of the pregnancy test.

2.0 PROCEDURES

2.1 Each female worker will be told during the recruitment and consent processes that any woman who is pregnant or nursing is ineligible to participate in an AHETF worker exposure study. The worker will be informed that no additional remuneration will be provided for taking the pregnancy test (*i.e.*, $80, or the amount specified in the protocol), for the inconvenience of participating in the exposure monitoring will not be provided to a woman who has a positive pregnancy test result and who therefore cannot participate in the study).

2.2 Within 24 hours prior to study participation, any woman who is being

considered for participation will be asked to take a urine pregnancy test (over-the-counter variety).

a. The pregnancy test kit will be provided by AHETF.

b. The pregnancy test will be supervised by a female researcher who will explain how to take the test.

c. The researcher will escort the female worker to the bathroom and wait outside while the worker self-administers the test.

2.3 The outcome of the test will initially be known only to the worker.

2.4 After the test, the worker will be asked to state her desire to continue or withdraw from participation in the study.

a. If the worker chooses to withdraw from the study

i. She will be allowed to do so without stating a reason.

ii. The test results will not be revealed to the employer or co-workers.

iii. The test results will not be documented. Consent forms and all other records associated with the worker will be promptly shredded.

b. If the worker states the desire to participate

i. A female researcher trained in the interpretation of pregnancy tests will confirm that the pregnancy test is negative.

ii. The negative pregnancy test results will be recorded in the study raw data.

2.5 With the confirmation of a negative test result, the worker will be permitted to continue in the study consent process.

Pesticide Safety Precautions

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-11.E.0.

Effective Date : June 30, 2007

APPROVAL _____ DATE 27 MAR 08

APPROVAL _____ DATE 03-28-08

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

1.0 PURPOSE AND SCOPE

1.1 This SOP describes measures intended to promote pesticide hygiene measures, which may result in decreased risk for illness or injury during participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study. These procedures will be followed during the worker informed consent process and exposure monitoring.

2.0 TRANSLATION

2.1 If needed or requested by the worker, a translator will be provided during any discussions described below.

3.0 COMPLIANCE WITH SAFETY REQUIREMENTS

3.1 Material Safety Data Sheets (MSDS) and labels will be summarized and available during the informed consent process and available during the exposure monitoring.

3.2 The Study Director will discuss the pertinent sections of the MSDS and label, but will emphasize sections that relate to possible signs and symptoms of acute over-exposure to the product being used in the study.

a. For example, if the product is a cholinesterase inhibitor, specific signs and symptoms are stated. For example, "*Too much exposure to this product may cause nausea, dizziness, confusion, and difficulty breathing.* "

b. Workers will be advised that there may be risks from using the product, which are unknown at this time.

3.3 Additional information on the product label that will be discussed with the worker includes the use of personal protection equipment (PPE) required during product handling and other user safety recommendations.

a. Workers will be reminded of standard practices that need to be followed to reduce exposure to pesticides. For example, provisions of the Worker Protection Standard (WPS) will be cited such as the requirement to wear long pants and long-sleeved shirts and labeled specified PPE; and safety recommendations for washing hands before eating, drinking or using the toilet, and to remove clothing that gets drenched with pesticide, for example from an accidental spill.

3.4 During the study conduct, researchers will ensure compliance with safety requirements on the product label and with the WPS. For example, workers will be reminded to use the label-specified PPE and to follow use directions on the label.

a. Each worker will be observed by a researcher during the entire monitoring period.

i. Study observers will not advise workers on how to perform their work unless a safety issue is involved. The observer will then immediately notify the Study Director.

3.5 The Study Director may stop the worker's participation in the study if he/she is engaging in unsafe work practices such as not using label-specified PPE. The participant will still receive the $80 payment for his/her inconvenience and the Study Director will decide whether the exposure monitoring has been compromised and whether the matrices should be collected from the worker.

4.0 ADDITIONAL SAFETY PRECAUTIONS

4.1 AHETF will have an on-site contracted medical professional at each study as an added safety precaution (see AHETF-SOP-11.H for further details).

4.2 AHETF will have a portable on-site eye-wash station at every study in the event that exogenous substances (*e.g.*, dirt, droplets or splashes, etc.) get in the eye of study participants, study researchers, or other on-site individuals.

Adverse Events Reporting for Institutional Review Boards

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

Effective Date : March 3, 2008

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to address an unanticipated adverse event resulting from participation in an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study.

2.0 PROCEDURES

2.1 The investigator (the Study Director) must familiarize himself with the references cited in this document.

2.2 Investigators are required to report adverse events that meet both of the following criteria (definition is from the Western Institutional Review Board):

a. Event is **UNANTICIPATED** (An unanticipated event is any adverse experience where the nature, severity or frequency is not identified in the investigator brochure or described in the protocol. Events which are already cited in the investigator brochure or protocol are not unanticipated and do not have to be reported to WIRB),

AND

b. Event is **POSSIBLY RELATED** to the study design, procedures, or drug/device. If the adverse event is clearly not related to the study drug, device, procedures, or washout process, it would not represent a risk to other subjects in the research and, therefore, does not have to be reported to WIRB.

2.3 If these criteria are not met then the event does not have to be reported to the IRB.

2.4 The Study Director (SD) must submit the written report of any suspected adverse event that occurs during a study, even if the event is brought to his attention by another researcher. The report should fully describe the event and any pertinent information leading up to it and following it (e.g., observers and/or medical professional comments prior to the occurrence). The report should include all relevant information of any similar events that occurred previously in other AHETF-conducted studies.

2.5 The SD must submit the written report to the IRB within 10 business days of the occurrence of the potential adverse event.

2.6 The report should include all relevant information, including any similar events that occurred previously in other AHETF-conducted studies.

3.0 REFERENCES

3.1 Office for Human Research Protections (OHRP), Dept of Health and Human Services: Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events. January 15, 2007 (guidance on regulations at 45 CFR part 46).

3.2 U.S. Dept of Health and Human Services (DHHS): Guidance for Clinical Investigators, Sponsors, and IRBs – Adverse Event Reporting – Improving Human Subject Protection). April 2007.

3.3 Western Institutional Review Board (WIRB): A guide for Researchers. Version 1.5, October 2006. www.wirb.com. Download on May 3, 2007.

Identification and Control of Heat Stress

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

Effective Date : 03/03/08

APPROVAL David Johnson	DATE 3/3/08
APPROVAL	DATE 3/3/08
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

1.1 The purpose of this Standard Operating Procedure (SOP) is to provide information on the recognition of conditions that contribute to heat-related illness that may occur during the conduct of an Agricultural Handlers Exposure Task Force (AHETF) worker exposure study, measures to be taken to minimize the risk of heat-related illness to workers during their participation in an AHETF worker exposure study, measures to be taken if a worker is affected by heat-related illness, how AHETF researchers monitor environmental conditions during the conduct of worker exposure monitoring, and stopping rules related to heat-related illness

2.0 INTRODUCTION

2.1 There is potential for heat stress to agricultural workers under certain conditions of temperature and humidity. Since workers wear an extra layer of clothing during AHETF exposure studies in addition to any required PPE, the risk of heat-related illness may be increased. This document presents a summary of situations that increase the risk of heat-related illness, procedures for preventing heat-related illness, early signs and symptoms of heat-related illness, and what to do if heat-related illness becomes apparent or suspected. AHETF Study Directors will use this information to brief field investigators and field monitors prior to each exposure study conducted by the Task Force.

2.2 The Study Director will identify any employer response plans that address

heat-related illness. 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. This will be documented and included in the raw data.

3.0 RISK FACTORS

3.1 Heat stress is the build-up in the body of heat generated by the muscles during work and from the environment. Heat exhaustion and heat stroke result when the body is subjected to more heat than it can accommodate. The following factors can increase the risk of a worker experiencing heat-related illnesses:

a. **Weather**: increased temperature, increased humidity, direct sunlight, and low winds all contribute to heat stress. Keep in mind the effects of high temperatures and high humidity are more than additive.

b. **Workload**: the body generates more heat during heavy work than during light or moderate work, so activities involving lifting and/or walking contribute more to heat stress than sedentary tasks.

c. **Clothing and PPE**: the evaporation of perspiration on the skin helps cool a person so the more clothes a person wears, the slower the perspiration evaporates and the longer it takes to cool down. In addition, coated and non-woven synthetic garments (e.g., rainsuits) effectively block evaporation of perspiration and contribute to heat stress.

d. **Worker conditioning**: younger workers, well-rested workers, and physically fit workers are less likely to suffer heat illness than other workers. In addition, workers who are not acclimated to working in the heat are at much greater risk of heat illness. Most importantly, workers must remain adequately hydrated, which means liquids such as water or sports drinks should be consumed before and regularly during work.

4.0 PREVENTION PROCEDURES

4.1 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 workers are being monitored. The medical professional shall conduct periodic observations of workers during the study and will advise the Study Director regarding possible signs of heat-related illness.

4.2 During all AHETF studies, the Study Director, on-site medical professional, and the field investigators share responsibility for awareness and prevention of heat illness. The following procedures will be followed:

a. Post a copy of the poster titled "Controlling Heat Stress Made Simple" at each field site (for example, in the staging or dressing area) so workers and field investigators will remain aware of the issue and can refer to the information on the poster (which is similar to this document). Both the English and Spanish versions will be posted (see Reference 13.3).

b. Initiate worker exposure monitoring during the cool part of the day whenever practical

c. Ensure plenty of water and sports drinks are available for the workers.

d. Assure that shady areas are available during breaks.

e. Immediately before monitoring begins, remind the workers of the risk of heat stress, suggest they drink some liquid before they start work, and let them know how/where they can get liquid during the monitoring period.

f. Urge workers to drink liquid during the monitoring period and remind them that thirst does not give a good indication of how much liquid a person needs to drink. NOTE: Hand washes will not be taken during water breaks unless specifically required by the label or requested by the worker.

g. Observe workers during the monitoring period and be aware of the signs and symptoms listed in Attachment 11-G-1.

h. Require workers to take rest breaks when any signs or symptoms outlined below are present (see Attachment 11-G-1).

5.0 SIGNS/SYMPTOMS AND FIRST AID MEASURES

5.1 Researchers should be familiar with the signs, symptoms, and treatment of heat-related illnesses outlined in Attachment 11-G-1: Heat Illness Symptoms and Treatment Chart.

6.0 FIELD PERSONNEL RESPONSIBILITIES

6.1 During all AHETF studies, the Study Director, field investigators, and the on-site contracted medical professional share the responsibility for awareness of heat illness. The on-site medical professional is described in SOP AHETF 11.H (Emergency Procedures for Human Subjects).

6.2 The Study Director will have received training, such as by the American Red Cross or other recognized training organization, in the recognition of symptoms associated with heat-related illness and in what measures should be taken to relieve symptoms of heat-related illness. Documentation of training will be kept in their personnel file.

6.3 The Study Director or AHETF representative will provide instruction to the field investigators, including study observers and field monitors, regarding the recognition of signs and symptoms of possible heat-related illnesses and actions necessary if heat-related illness occurs. The basis for this instruction is outlined in Sections 3.0, 4.0 and 5.0 of this SOP.

6.4 During the consent process, the Study Director will provide the worker with information on early signs and symptoms of heat-related illnesses.

6.5 Just prior to monitoring, the Study Director will discuss heat-related illness with the participants and the need to immediately report to the individual observer or other researcher any illness or injury.

6.6 The Study Director will ensure that a copy of the poster entitled "Controlling Heat Stress Made Simple" is posted at each field study site (such as in the staging or dressing area). It will be visibly placed so workers and field investigators will remain aware of the issue and can easily refer to the information on the poster. Both English and Spanish versions will be posted.

7.0 RESPONSIBILITIES FOR CONTROL AND TREATMENT OF HEAT-RELATED ILLNESS

7.1 The Study Director is responsible for taking actions to minimize the risks of heat stress during field monitoring. These include:

a. monitoring environmental conditions (heat index based on ambient temperature and relative humidity) which may influence the risk of heat-related illness

b. when necessary, initiating specific steps intended to prevent or minimize the occurrence of various heat-related illnesses

c. when necessary, relieving symptoms of heat- related illnesses

d. determining, in consultation with the on-site medical professional, if medical treatment is required.

7.2 Prior to monitoring, the Study Director will identify and locate the closest medical facility. See SOP "AHETF 11-H – Emergency Procedures for Human Subjects" for additional information.

7.3 The Study Director will inform all study observers at the start of the study of the current Heat Index (Apparent Temperature) Category. The observer will be informed if or when the Heat Index Category subsequently changes.

7.4 The study observers will look for signs of heat illness and record their findings on their Observation Form. Recordings will be made periodically or when they are informed that a Heat Index Category has changed.

7.5 If a study observer believes a worker is showing signs of heat-related illness, he/she reports to the Study Director immediately. The affected

worker will be taken to a shady or cool location and checked by the Study Director and on-site contracted medical professional. A decision will then be made as to whether the worker will continue to participate in the study.

7.6 The Study Director, in consultation with the on-site contracted medical professional, will decide if and when to stop a worker's participation in the study. As per GLPs, the final authority to terminate a worker's participation in the study rests with the Study Director.

7.7 In response to indications that conditions are conducive to high temperatures and high relative humidity, the Study Director may elect not to initiate the study or to terminate the study operations on a particular day.

8.0 HEAT INDEX CATEGORIES

8.1 The National Weather Service (NWS) Heat Index Chart will serve as the basis for determination of the Heat Index Categories. The Heat Index Chart (calculated from a combination of ambient temperature and humidity; see next section for determination of the heat index) is divided into color-coded categories, each denoting a range of heat index (HI) temperatures at which heat-related illnesses can possibly or are likely to occur. See Attachment 11-G-2 for a copy of the Heat Index Chart.

8.2 The following table summarizes the HI Categories.

National Weather Service Heat Index (Apparent Temperature)		
CATEGORY	HEAT INDEX TEMPERATURE RANGE, °F	POSSIBLE ILLNESS
Not applicable	Less than 80	None anticipated
Caution	80-89	Fatigue **possible** with prolonged exposure and/or physical activity
Extreme Caution	90-104	Sunstroke, heat cramps or heat exhaustion **possible** with prolonged exposure and/or physical activity

Danger	105-129	Sunstroke, heat cramps or heat exhaustion **likely**, and heatstroke **possible** with prolonged exposure and/or physical activity
Extreme Danger	130 or higher	Heat/Sunstroke **highly likely** with continued exposure

9.0 DETERMINATION OF HEAT INDEX

9.1 The heat index determination requires readings of local ambient temperature and relative humidity. Appropriate meteorological instrumentation will be used to determine the HI, such as a portable monitoring device, a sling psychrometer or on-site weather station. Measurements will be recorded and included in the raw data.

9.2 Temperature and relative humidity readings will be applied to the Heat Index Chart to determine the HI. Match the measured readings to those on the Heat Index Chart. The Heat Index will be the temperature shown at the intersection of the measured temperature and humidity readings. If measured temperature and/or relative humidity readings are not shown on the Heat Index Chart, round the measured reading up until it corresponds to the next highest value shown on the chart.

9.3 The resulting HI will be increased by 10° F [6° C] **if the worker is working in direct sun**. This includes work performed in greenhouses taking direct sunlight. If working in shaded areas such as enclosed cabs, tractors with canopies, or shade houses, or during evening or prevailing cloudy conditions, then the heat index reading needs no adjustment. (Ref. 13.1)

9.4 It is not necessary to monitor the heat index if the ambient temperature is below 70° F [21° C]. However, certain combinations of ambient temperatures between 70-79° F [21 - 26° C] and relative humidity readings are equivalent to HI values found in the CAUTION Category if adjusted for working in direct sun. Therefore, once the ambient temperature reaches 70° F [21° C], begin monitoring the Heat Index at least every hour. (Ref. 13.2)

10.0 CRITERIA FOR FIELD MONITORING INITIATION

10.1 Worker exposure monitoring will be initiated as scheduled unless extremely hot conditions are present. Specifically, worker exposure monitoring will not begin if the HI is ≥ 120° F [49° C], or ≥ 110° F [43° C] when working in direct sun (DANGER Category). The Study Director, at his discretion, may choose not to initiate monitoring, regardless of the HI.

10.2 The field investigators will exercise the requisite vigilance to heat stress conditions, Sections 10.4 through 10.8. The degree of vigilance adjusts to changing environmental conditions (heat index based on temperature and humidity) that may affect worker risk to heat stress. In addition, the on-site medical professional will periodically observe workers for potential heat-related illness.

10.3 The symptoms of heat-related illness and measures to relieve symptoms as described in the following sections are based on EPA's "A Guide to Heat Stress in Agriculture", *Table 1 - Heat Illnesses and First Aid Measures*. They are not meant to be all-inclusive, but serve as general guidance for purposes of this SOP. The Study Director will be trained in the recognition of signs and symptoms of heat-related illness, and in determining measures needed to relieve symptoms, and he will exercise appropriate diligence under the specific conditions of a heat-related event. Additionally, the Study Director should consult with the on-site medical professional with regard to suspected cases of heat-related illness.

10.4 If the HI is < 80° F [27° C], or < 70° F [21° C] when working in direct sun, no specific vigilance is necessary. Observe for early signs of **possible** heat illness, such as fatigue.

10.5 If the HI falls between 80° - 89° F [27 - 32° C], or between 70° - 79° F [21 - 26° C] when working in direct sun (CAUTION Category), increase vigilance by specifically observing for **possible** signs of early heat illness, which can include fatigue, dizziness, irritability or decreased concentration, especially if the worker has been working for a while. Inquire periodically about how they feel. If symptoms arise, rest the worker in the shade for approximately 30 minutes until cool and give water or sports drink.

a. NOTE: If the worker develops heat rash, rest the worker, give water or sports drink. If the rash persists or bothers the worker, then STOP THE WORKER EXPOSURE MONITORING.

10.6 If the HI falls between 90° - 104° F [32 - 40° C], or between 80° - 94° F [27 - 34° C] when working in direct sun (EXTREME CAUTION Category), increase vigilance even further by observing for **possible** signs of: heat cramps, such as muscle spasms, heavy sweating, thirst; heat exhaustion, such as fatigue, headache, dizziness, fainting, heavy sweating increased pulse; heat stroke, such as headache, dizziness, irrationality, coma, rapid breathing. These conditions are possible if the worker has been working for a while. Inquire periodically about how they feel.

a. With signs of heat cramps, give access to plenty of water or a sports drink and assure that they are drinking. Have the worker rest in the shade until cool. STOP THE WORKER EXPOSURE MONITORING. Advise the worker to be aware of symptoms of heat exhaustion and heat stroke. Remind the worker of the AHETF policy to provide medical coverage and to seek medical help immediately if symptoms develop.

b. If the SD believes that a worker may be suffering heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The SD should also consult with the on-site medical professional. However, if the worker's condition is considered to be serious and to require additional 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 study participant as appropriate. Take measures to relieve symptoms until professional medical care arrives.

   i. Heat exhaustion: treatment includes providing rest in shade, giving plenty of drinking water or sports drink, splashing cold water on worker.

   ii. Heat stroke: treatment includes moving to shaded area, removing outer clothing and shoes; wrapping in wet sheet or towel and fan to cool worker.

10.7 If the HI falls between 105° - 119° F [41 - 48° C], or between 95° - 109° F [35 - 43° C] when working in direct sun (DANGER Category), increase vigilance even further by paying particular attention to **likely** signs of heat cramps and heat exhaustion or **possible** signs of heat stroke with prolonged exposure.

a. If signs of heat cramps occur, treat as recommended in Section 10.6.a. above.

b. If the SD believes that a worker may be suffering from heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The SD should also consult with the on-site medical professional. However, if the worker's condition is considered to be serious and to require additional 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 study participant as appropriate. Take measures to relieve the symptoms until professional medical care arrives. See Section 10.6.b. above.

10.8 If the HI reaches 120° F [49° C], or 110° F [43° C] when working in direct sun, STOP THE WORKER EXPOSURE MONITORING.

a. Stopping monitoring when the HI reaches 120° F should provide adequate protection to the worker. Based on the National Weather Service Heat Index Chart, (Attachment 11-G-2), this value is roughly in the mid-range of the DANGER category, and therefore does not interface with the HI values in the EXTREME DANGER category where heatstroke is highly likely with continuous exposure. It is reasonable to assume that using 120° F as the stop point will prevent the HI from ever reaching the EXTREME DANGER Category, including anytime during the period between readings.

b. Note: This stop rule does not apply if a worker is working in air conditioned equipment. However, the HI will continue to be monitored to evaluate circumstances should the worker need to go outside the cab (such as for equipment repair). If the worker must be outside the cab for a prolonged period of time (more than 30 minutes), he/she will be sent to an environment that does not exceed the HI of 120° F until conditions are such that work can be resumed. If work cannot be resumed, the worker monitoring will be terminated.

11.0 EXPENSES

11.1 Expenses associated with the reasonable and appropriate treatment for heat-related illness as a result of participating in this study will be paid for by AHETF unless such expenses are covered by the worker's own insurance or insurance provided by the employer.

12.0 INCIDENT REPORTING

12.1 Any incident of heat-related illness will be reported by the Study Director or member of the research team to the Sponsor (AHETF) and the Institutional Review Board. See SOP AHETF 11.F for additional details on reporting such events to the IRB.

13.0 REFERENCES

13.1 The National Weather Service suggests a heat index adjustment of an additional 10-15°F [6 - 8° C] for sunny conditions. The AHETF rationale for the adjustment of the heat index for sunny conditions is contained in Attachment 11-G-3.

13.2 A Guide to Heat Stress in Agriculture. May, 1993. Document EPA-750-b-92-001 prepared by the United States Environmental Protection Agency and the Occupational Safety and Health Administration. *A Basic Program to Control Heat Stress – Step 4*, recommends hourly measurements of temperature and humidity.

13.3 Controlling Heat Stress Made Simple. September, 1995. GPO Document Number 055-000-00474-9 prepared by the United States Environmental Protection Agency and the Occupational Safety and Health Administration.

ATTACHMENT 11-G-1: HEAT ILLNESS SYMPTOMS AND TREATMENT CHART

Illness	Signs and Symptoms	Treatment
Early Heat Illness	Mild dizziness, fatigue, or irritability; Decreased concentration; Impaired judgment	Loosen or remove clothing, Rest the worker in the shade until cool, and give water to drink
Heat Rash	Tiny, blister-like red spots on skin; prickly sensations (generally caused by plugged sweat glands)	Rest the worker in the shade until cool, give water to drink; if the rash persists and bothers the worker, stop the monitoring.
Heat Cramps	Painful spasms of leg, arm, or abdominal muscles; Heavy sweating and thirst	Loosen clothing, give water or sport beverages, and rest the worker in the shade until cool. Stop monitoring the worker.
Heat Exhaustion	Fatigue, headache, dizziness, muscle weakness, loss of coordination, fainting, collapse. Profuse sweating; pale, moist cool skin; excessive thirst; dry mouth; dark yellow urine. Fast pulse, if conscious. May also have heat cramps, nausea, urge to defecate, rapid breathing, chills, tingling of the hands or feet, confusion, giddiness, slurred speech, irritability.	Remove to cooler, shaded area ASAP and **stop monitoring**. Rest worker lying down. Give water, as much as the worker will drink. Loosen or remove clothing. Splash cold water on body. Massage legs and arms to increase circulation. If worker has collapsed, get evaluation by physician or nurse specified in the study protocol and Consent Form.
Heat Stroke	Often occurs suddenly and is a life-threatening medical emergency. Headache, dizziness, confusion, irrational behavior, coma. Sweating may slow down or stop. Fast pulse, if conscious. Rapid breathing. May also have convulsions, nausea, incoherent speech, very aggressive behavior.	**Immediately call emergency medical services.** Move to cooler, shaded area immediately and **stop monitoring**. Remove outer clothing/shoes. Wrap in wet sheet or towel and fan to cool worker. **Get immediate evaluation** from physician or nurse specified in the study protocol and Consent Form.

Attachment 11-G-2: Heat Index Chart

Heat Index Table

Temp °F	Relative Humidity (%)												
	40	45	50	55	60	65	70	75	80	85	90	95	100
110	136												
108	130	137											
106	124	130	137										
104	119	124	131	137									
102	114	119	124	130	137								
100	109	114	118	124	129	136							
98	105	109	113	117	123	128	134						
96	101	104	108	112	116	121	126	132					
94	97	100	102	106	110	114	119	124	129	135			
92	94	96	99	101	105	108	112	116	121	126	131		
90	91	93	95	97	100	103	106	109	113	117	122	127	132
88	88	89	91	93	95	98	100	103	106	110	113	117	121
86	85	87	88	89	91	93	95	97	100	102	105	108	112
84	83	84	85	86	88	89	90	92	94	96	98	100	103
82	81	82	83	84	84	85	86	88	89	90	91	93	95
80	80	80	81	81	82	82	83	84	84	85	86	86	87

Source: NOAA's National Weather Service

With Prolonged Exposure and/or Physical Activity:		
	Extreme Danger: Heat Stroke or Sunstroke likely	Danger: Sunstroke, muscle cramps, and/or heat exhaustion likely
	Extreme Caution: Sunstroke, muscle cramps, and/or heat exhaustion possible	Caution: Fatigue possible

Attachment 11-G-3: AHETF Rationale for the Heat Index Adjustment for Sunny Conditions

The Heat Index Chart developed by the National Weather Service (NWS) was primarily intended for public use (Ref: "Heat Stress Guidance" from the NWS). Portions of the public include susceptible groups such as children, elderly and infirmed. Underlying assumptions in the development of the heat index values included wearing long trousers and short sleeves, light wind, and shady conditions. To account for full sun conditions, the NWS recommends a heat index adjustment of an additional 10-15° F (6-8° C). That is, if people are in full sun an additional 10-15° F is added to the current Heat Index (HI) value which is calculated based on the current temperature and humidity.

In this SOP, heat index values were adjusted by 10° F (6° C) for full sun conditions. This adjustment is reasonable under the conditions of AHETF worker monitoring studies for the following reasons:

- Workers who participate in these studies perform this work as part of their normal job, including having familiarity with working in hot environments
- Workers who participate in these studies are adults in good health
- Workers who participate in these studies are acclimatized
- No impervious clothing will be worn.
- Mixing/loading and/or applying activities are generally moderate workloads (Reference EPA "A Guide to Heat Stress in Agriculture", *Table 5- Approximate Workload Levels*)
- Heat indices are monitored hourly with appropriate control measures in place
- Study investigators constantly observe workers for signs of heat-related illness and take control measures accordingly
- A medical professional is on-site during the monitoring period to observe for signs of heat-related illness and provide treatment if necessary, including calling for medical emergency assistance

AHETF study participants wear an inner dosimeter under their work clothing, thus increasing their risk of heat-related illness. However, it is believed that this increased risk if offset by the conditions listed above and the implementation of a heat stress management plan as described in this SOP. Furthermore, conditions of worker scenarios being monitored by AHETF should be put in perspective with other occupations involving hot working environments. For example, road construction activities often involve heavy workload levels, radiant heat from hot pavement, etc. It

may be reasonable under those conditions to increase the solar load adjustment by more than 10° F. However, for agricultural mixing/loading and application activities included in the AHETF monitoring program, a 10° F adjustment is considered to be adequately protective.

Emergency Procedures for Human Subjects

Chapter 11: HUMAN SUBJECT MANAGEMENT
AHETF-11.H.0.

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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.

2.0 PROCEDURES

2.1 Prior to initiation of exposure monitoring, the Study Director will determine the emergency 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 facility, including the address, telephone number and directions from the field site will be obtained.

b. Since monitoring of study participants can occur on a variety of nearby agricultural farms, a participant may be taken to another facility if it is closer or more convenient.

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 chemical) or injury.

2.2 If a study participant is injured or becomes ill (including heat related illnesses) during the study, 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.

2.3 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.

2.4 If a participant is taken to a medical emergency 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 COLLECTION OF DOSIMETRY MATRICES

3.1 No exposure samples will be collected from a participant taken to a medical facility.

3.2 The participant must withdraw from the study in order to receive medical treatment; he/she will still receive the remuneration ($80) from AHETF for their participation in the study.

4.0 FOLLOW-UP OF EMERGENCY OR HOSPITALIZATION EVENT

4.1 If a participant is taken to a medical facility for treatment related to his/her participation in the study, the Study Director will document whether 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 Expenses associated with reasonable and appropriate treatment for illness or injury incurred as a result of participating in this study will be paid for by AHETF unless such expenses are covered by the participant's own insurance or insurance provided through his/her employer.

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.