Antimicrobial Exposure Assessment Task Force II (AEATF II)

Standard Operating Procedures for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program

Interim Draft Document

May 21, 2007

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INTRODUCTION

This document presents key AEATF II Standard Operating Procedures (SOPs), specifically from SOP Chapters 5, 8, 10 and 11, that support the example study protocol, *A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using Trigger Spray and Wipe or Ready to Use Wipes for Cleaning Indoor Surfaces (Draft Version, 5/21/07).* AEATF II SOPs from Chapters 5, 8, 10 and 11 concern the quality assurance unit, matrix samples, field study procedures, and human subject management, respectively. Please note that some of the SOPs are draft versions.

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STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit **AEATF II-5A.0**
QA Personnel Administration

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) establishes guidelines for Antimicrobial Exposure Assessment Task Force II (AEATF II) Quality Assurance Unit (QAU) personnel matters such as training and maintaining employee records.

2.0 QA PERSONNEL TRAINING

2.1. All QAU personnel must have adequate training on procedures related to their assigned duties. Training is the responsibility of QAU management and will be properly documented.

2.2. Personnel shall maintain a résumé or CV, or a record of training, as appropriate. Documentation of AEATF II SOP reviews will also be maintained. Any additional training shall be documented and will be placed in the training records.

3.0 QA PERSONNEL RECORDS

3.1. A personnel file is maintained for each AEATF II QAU member involved in AEATF II QA activities. These files are maintained by the QAU and will be archived at the AEATF II Archives upon completion of AEATF II activities.

3.2. Job descriptions will be maintained in the appropriate files. These documents shall describe the responsibilities of AEATF II QAU.

3.3. The following records of training and experience will be maintained:

a. Résumés or CVs reflecting education, academic or technical degrees, prior employment, and professional experience, and will be signed and dated.

b. A current job description indicating present responsibilities.

c. Current records of attendance and participation at quality assurance, scientific, or technical meetings or training seminars.

d. Records of training for AEATF II QAU functions (including SOP review documentation).

4.0 INDIVIDUAL RESPONSIBILITIES

4.1. It is the responsibility of each QAU individual to inform QAU management of any necessary changes or additions to the training file.

5.0 RECORD RETENTION

5.1. Job descriptions and résumés or CVs will be dated with each revision in order to determine which version was applicable during the performance of a specific function.

5.2. The information listed in 3.3 will be retained for the length of time set forth in the EPA GLPs §160.195(b).

6.0 RECORD REVIEW

6.1. Each personnel file will be subject to review by the QAU and/or AEATF II Technical Committee management on an annual basis, or as needed.

7.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit **AEATF II-5B.0**
AEATF II QAU Responsibilities

Approval

Technical Committee Chair: _____ Date: 9 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes the responsibilities of the Antimicrobial Exposure Assessment Task Force II (AEATF II) Quality Assurance Unit (QAU) with respect to the requirements of the AEATF II studies to be conducted.

2.0 QAU RESPONSIBILITIES

2.1. The QAU assures that the following regulations are adhered to:

a. EPA - Pesticide Programs; Good Laboratory Practice Standards 40 CFR part 160 (FR Vol. 54 No. 158: pp. 34067-34074)

2.2. The QAU will have direct interaction with the Study Director(s), contractors, Study Team Leaders and Technical Committee management for monitoring the level of GLP compliance (*i.e.*, assuring that the facilities, equipment, personnel, scientific methods, field practices and records are in compliance with the Good Laboratory Practices.)

2.3. The responsibilities of the AEATF II QAU are to:

a. Maintain a regularly updated copy of the master schedule for all studies conducted by the AEATF II.

b. Maintain copies of all protocols, amendments and standard operating procedures pertaining to all AEATF II studies that are expected to be performed in compliance with the GLPs, in the QAU archive files.

c. Perform facility inspections of the testing facilities and third party study directors who have been selected by AEAFT II Technical Committee management to perform AEATF II studies. The QAU of the testing facility is required to periodically inspect selected phases of each type of laboratory or field study conducted by the AEATF II, including a critical phase, associated raw data, and maintain properly signed and dated records of each inspection.

d. Immediately provide the Study Director, AEATF II designated study contractors, and AEATF II Technical Committee management with a written report of any problems or deficiencies found during inspections.

e. Provide written summaries of individual study inspections/audits to the Study Director(s) and AEATF II Study Team Leader as the Technical Committee management representative.

f. Review the study protocols and assure that no changes to approved protocols (amendments or deviations) are made without written acknowledgment.

g. Review the interim and final reports of each study conducted to assure that the report(s) accurately describe the experimental methods, raw data, observations, results, and procedures pertaining to the study.

h. Prepare and sign a statement, to be included in the final report, specifying the nature of the inspections, the dates of inspections/audits of the study and the dates that findings were reported to the Study Director and AEATF II management.

i. Maintain a QA study file, which is the repository of all Quality Assurance documents pertaining to ongoing AEATF II studies.

j. Conduct periodic study inspections performed by contract facilities.

k. Conduct GLP training for all contractor personnel involved with the AEATF II studies, as necessary.

l. Prepare, revise, and distribute all AEATF II SOPs; coordinate use of AEATF II member companies and contractor SOPs. Assure that the Study Director is aware of SOP deviations.

m. Assist in the preparation and review of data forms used on all AEATF II studies, as needed.

n. Oversee the GLP programs at contract laboratories by assisting the lab QAU with maintenance of facility records, study inspections, data and report audits, and GLP training, as needed.

o. Assist with regulatory agency inspections of the AEATF II studies and facilities.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit — **AEATF II-5C.0 QAU Records**

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 28, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes what records are to be maintained by the Quality Assurance Unit (QAU) for studies conducted by the Antimicrobial Exposure Assessment Task Force II (AEATF II).

2.0 PROCEDURE

2.1. The AEATF II QAU shall maintain all Quality Assurance records, with access strictly limited to QAU personnel. For each AEATF II field or laboratory study conducted, a separate file is maintained and indexed by AEATF II study number.

2.2. Each study file will contain the following items:

a. Protocol

b. Amendments/Deviations

c. Protocol/Amendment Acceptance pages (if applicable)

d. QA Study Inspection/Audit Log

e. Inspection/Audit reports and Summaries, and responses to findings

i. Protocol Reviews
ii. Data Audits
iii. In-Process or study conduct inspections
iv. Final Report Audits

3.0 QAU Record Retention

3.1. The QAU records will be retained in the QAU Archives until completion of all AEATF II activities, when all records will be transferred to the AEATF II archives for retention for the length of time set forth in the EPA GLPs, §160.19

4.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-5D.0 QA Master Schedule

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes what information is recorded on the QAU Master Schedule, how it is to be maintained, the authorized personnel, and capabilities of the master schedule system.

2.0 PROCEDURE

2.1. The QAU shall prepare and maintain a Master Schedule on a computerized spreadsheet for all AEATF II studies conducted. Verified hard copies of the master schedule will be maintained in the QAU archives until transferred to the permanent AEATF II archives for retention for the length of time set forth in the EPA GLPs §160.19

2.2. The master schedule is indexed by test substance, AEATF II study number, and study initiation date. It contains, but not limited to, the following information:

a. Test substance name or code number

b. Sponsor

c. Study number

d. Type (nature) of study

e. Test system

f. Study initiation date

g. Current status (Protocol Signed, Field Phase, Analytical Phase

[continuation of field sample analysis], Report Phase, Terminated, Completed)

h. Study Director

i. Contract facility or field cooperator

2.3. Studies are to be entered on the Master Schedule at the time of study initiation, or when the approved protocol is received by the QAU.

2.4. The Master Schedule is to be updated, printed, and signed and dated as needed.

2.5. The Master Schedule is a strictly confidential document and is to be treated as such by all personnel.

2.6. The output of the Master Schedule may be customized, as required by the AEATF II Technical Committee management. Confidential information may be printed at the direct request of the AEATF II. The standard output for the hard copy, will contain the information noted in section 2.2.

2.7. The AEATF II Master Schedule will be maintained on an electronic spreadsheet The spreadsheet will be backed-up on a floppy disk, CD-ROM, or other appropriate storage media. Copies (includes electronic copies for e-mailing) of the printout will be distributed to the AEATF II Technical Committee Chair and Study Team Leaders or any other appropriate personell when requested.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-5E.0 Protocol and Amendment Review

Approval

Technical Committee Chair: _____ Date: 09 Dec 05

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes how the Antimicrobial Exposure Assessment Task Force II (AEATF II) study protocols and amendments will be reviewed and maintained by the AEATF II QAU.

2.0 PROCEDURE

2.1. When the AEATF II QAU has received the protocol, it is reviewed for compliance with applicable GLP and AEATF II SOP requirements. The Study Director, Study Team Leader, and QAU for AEATF II shall approve the protocol. Subsequent protocol amendments may also be reviewed by the QAU for compliance with applicable GLPs and AEATF II SOPs but do not require QAU sign-off.

2.2. Any issues or concerns are brought to the attention of the Study Director and Study Team Leader for consideration. If an agreement cannot be met between the Study Director, and the Study Team Leader, then the AEATF II QAU and/or Technical Committee Chair may be asked to settle the issue.

2.3. The protocol review is filed in the QA study file.

2.4. The Study Director and Study Team Leader shall make all intentional or planned changes to the approved protocol in writing as protocol amendments. Changes will be submitted to the QAU for review and archiving. Any unplanned changes in a study protocol without this prior approval are to be reported as deviations to the Study Director and documented in the study data.

2.5. The QAU will maintain copies of all protocols and amendments for the

duration of the studies. Upon completion, all original protocols and amendments (maintained by the Study Director), will be transferred to the permanent AEATF II archives for storage per §160.19.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-5F.0 Inspection/Audit Types and Frequency

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes inspection/audit frequency to be followed by the Quality Assurance Unit (QAU) for field and laboratory inspections, data and final report audits, documentation, and reporting of the inspections/audits conducted for the Antimicrobial Exposure Assessment Task Force (AEATF II).

2.0 IN-PHASE INSPECTION PROCEDURES

2.1. The AEATF II QAU may periodically inspect selected phases of each study, as required. Frequency of inspections will be determined on a study-by-study basis by the Study Team Leader and AEATF II QAU. The AEATF II QAU will maintain written (signed/dated) records of each inspection.

2.2. The AEATF II QAU or contractor QAU will inspect each study at least once, during conduct of a critical phase. The AEATF II QAU may perform inspections of studies contracted to any test site/laboratory at any time. (Please refer to SOP AEATF II-5.G.)

2.3. The inspection phases of a particular study will be determined by the nature of the study. The phases of a GLP study can generally be defined as (but not limited to) the following:

a. Method Validation
b. Test Substance Administration
c. Test System Observation
d. Sampling
e. Receipt, Log-in, Identification and Storage of Samples
f. Subsampling and Sample Preparation

g. Analytical Standard(s) Preparation
h. Extraction
i. Analysis by Instrumentation

3.0 DATA REVIEWS

3.1. The AEATF II QAU may review data generated on any AEATF II study at anytime. (Please refer to SOP AEATF II-5.H.)

3.2. All raw data should be thoroughly reviewed by the contract facility's QAU; however, the AEATF II QAU will review any data not reviewed to the satisfaction of the AEATF II QAU prior to inclusion in the final report.

4.0 REPORT AUDITS

4.1. The final report, analytical reports and/or contractor reports will be reviewed at the completion of the AEATF II study for compliance with all applicable GLPs, study protocol, and SOPs. (Please refer to SOP AEATF II-5.J.)

5.0 REPORTING INSPECTION/AUDIT RESULTS

5.1. A record of inspection dates, study number, phases inspected, date reported to the Study Director and Management, and the identity of the person performing the inspection will be maintained in each QA file. This record is available for EPA inspection since it does not contain confidential information such as actual inspection findings. (Please refer to SOP AEATF II-5.C.)

5.2. Results of individual study inspections will be reported to the contract facility management, and the Study Director, AEATF II's Study Team Leader and QAU and other designated AEATF II personnel. The inspection report will note findings and suggested actions to be taken to address or correct the errors. (Please refer to SOP AEATF II-5.K.)

5.3. If corrective action is required, the Contract Facility Principal Investigator (P.I.) or the Study Director (or designate) should respond within fifteen working days. Corrective actions taken by supervisory or contract facility personnel (P.I.) will be acknowledged by the Study Director.

5.4. Any significant problems found during the course of an inspection, which are likely to affect the study integrity, are to be brought to the attention of the Study Director and AEATF II management immediately, through telephone conversations, faxes, email, or direct discussion at the test site. Such issues will still be written in the inspection report, even if corrective actions were already taken.

6.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit **AEATF II-5G.0**
Study Inspections

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes the procedure the AEATF II QAU will follow when performing an inspection on any portion of an ongoing study conducted for the Antimicrobial Exposure Assessment Task Force (AEATF II) at any designated test site or laboratory facility.

2.0 PROCEDURE

2.1. The designated QAU personnel will schedule inspections with the appropriate Study Director, contractor management, and the principal investigator (if required) for each study to be inspected.

2.2. The QAU will allow adequate time for travel to the site/facility in order to observe critical operations of the study. (Please refer to SOP AEATF II-5.F.)

2.3. The QAU will have the appropriate study protocol/amendments, analytical methods, and SOPs available during the inspection for reference.

2.4. Notes may be taken during the inspection for reference during the inspection report preparation. Checklists and inspection forms may be used at the QAU's discretion.

2.5. During an inspection, the QAU will determine whether the GLP and protocol requirements for that phase have been met and whether the procedure is performed in accordance with applicable AEATF II or contract facility SOPs (unless superseded by the AEATF II protocol). In addition to these verifications, study aspects are also inspected (as applicable) for, but are not limited to, the following:

a. Reagents and solutions labeled per GLP

b. Maintenance and calibration logs of all equipment used during the procedure

c. Documentation of test substance receipt and distribution

d. Verification of study calculations

e. Contamination prevention procedures

f. Samples labeled per protocol or SOP requirements

g. Proper storage of chemicals and samples

h. Health and Safety procedures are observed

i. Complete documentation of each procedure performed

j. Training records of study participants

k. Availability of SOPs for study personnel

2.6. The QAU should also verify that the contract facilities for study conduct are adequate. The following aspects will be considered (as appropriate):

a. Is application or testing equipment of appropriate size, design, and construction?

b. Are the field sites of appropriate size and location?

c. Does the design of the analytical facilities allow for separation of test systems samples and isolation of individual projects?

d. Are environmental conditions and instrumentations appropriate for the protocol? Is there documentation?

e. What is the source of water (carrier) used? Does the water quality and composition meet protocol requirements, if any?

f. Are there adequate areas for storage of supplies and equipment? Are these areas separate from the test system location?

g. Are samples collected per applicable SOPs and the study protocol?

h. How are test substances received, stored, distributed? Are environmental conditions of storage areas monitored? Are the storage areas secured? Who is responsible? Who has access?

i. Where are mixtures stored? Are storage conditions monitored?

j. Do laboratory areas appear to be adequate? Is there ample space for sample preparation and instrumentation?

k. Are raw data and specimens appropriately archived?

l. Do contract facility archives meet GLP requirements? (if required)

2.7. Any deviations from the GLPs and/or the study protocol shall be noted and immediately (within reason) be conveyed to the Study Director. Should the deviation be serious enough to warrant the termination of the study, the QAU shall inform all study personnel of the problem and wait for the sponsor and the Study Director to decide upon appropriate action(s).

2.8. An inspection report will be generated as described in SOP AEATF II-5.K.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/06	Original Document

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit — **AEATF II-5H.0 Data Audits**

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes the procedures to be followed by the Quality Assurance Unit (QAU) when auditing study data generated during Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

2.0 PROCEDURE

2.1. Study notebooks/files are reviewed for compliance with the EPA GLPs and the AEATF II study protocol; *i.e.*, the data are reviewed for documentation of performance of test requirements as described in the protocol.

2.2. Documentation of procedures performed or reference to appropriate AEATF II or contractor SOPs is verified.

2.3. Study notebooks/files are reviewed for proper data entry and error documentation per GLPs and SOPs.

2.4. Documentation of test substance application is reviewed, including application calculations, preparation and administration procedures, and test substance receipt, storage and distribution.

2.5. Proper documentation and Study Director acknowledgment of any SOP or AEATF II protocol deviations are verified.

2.6. Exact copies of original data must have been clearly identified as such, and has been signed/dated at the time of copying by the person verifying the copies.

2.7. Data forms are reviewed for completeness; *i.e.*, each assigned space must have a data entry, or be addressed if no entry was made.

2.8. Computerized calculations or spreadsheets are checked against raw data numbers and all calculation equations and methods are verified.

2.9. Computerized data (summary or transcribed) are checked for proper identification (*e.g.*, study, data type) and calibration (*e.g.*, efficiencies and standards) procedures.

2.10. Calibration and equipment logs are randomly checked, as well as test, reference, and control substance receipt and use logs.

2.11. Printouts from analytical instruments (GC, HPLC, *etc.*) are checked for proper documentation of run conditions and column information, and proper identification (project number, sample number, treatment level, instrument operator, injection amount), as well as random verification of integration summaries.

2.12. Data reviewed may be copied. All errors found or comments made by the QAU may be directly noted on any prepared copies. Any additional notes may be taken for later reference in preparing the inspection report.

2.13. All reviewed data copies and notes taken will be maintained in the QAU files.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-5I.0 Facility Inspections

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit **AEATF II-5I.0**
Facility Inspections

Approval

Technical Committee Chair: _____ Date: 9 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes, in general terms, what the Quality Assurance Unit (QAU) is to inspect during an Antimicrobial Exposure Assessment Task Force (AEATF II) facility inspection.

2.0 PROCEDURE

2.1. During a facility site visit an extensive inspection is made to assess the facility's compliance with the EPA Good Laboratory Practice Standards. The inspection includes a review of:

a. personnel training records
b. equipment maintenance procedures and records
c. standard operating procedures
d. health and safety equipment
e. test substance receipt, distribution, and storage
f. QA records, as appropriate
g. Archives
h. test system sample handling

2.2. An appropriate checklist may be used as a guideline during the facility inspection to assure that all aspects of the GLP requirements have been reviewed.

2.3. The QAU will schedule the inspection with the facility after obtaining the authorization from the AEATF II management to inspect the facility.

2.4. Facility inspections should be performed at any laboratory that has not been inspected by a Task Force member company within the last twelve (12) months, or whenever there is a question concerning the facility's integrity.

2.5. In order to maintain the highest level of compliance, facility inspections of contracted facilities should be performed at least annually.

2.6. The QAU will allow sufficient time to completely inspect the contract facility, including timeliness in arriving and departing the facility. All QAU personnel will conduct the inspection in an open and professional manner.

3.0 REPORTING INSPECTION FINDINGS

3.1. Deficiencies and recommended corrective actions are reported, in writing, to AEATF II management, Study Director(s), other appropriate AEATF II personnel, and the contract facility QAU and management.

3.2. The original inspection report will be sent to the facility. The original inspection report, with responses and the signature(s) from the facility, will be returned to the QAU, when it will be forwarded to the AEATF II management for signature(s).

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit — **AEATF II-5J.0 Report Audits**

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes the procedures that the Quality Assurance Unit (QAU) will follow for auditing draft, summary, progress, field, analytical and final study reports generated for the Antimicrobial Exposure Assessment Task Force (AEATF II).

2.0 QUANTITY OF REPORTED DATA TO BE AUDITED

2.1. The quantity of data (reported values *vs.* raw data) reviewed will depend on the type of study and the nature of the data. The greater the number of errors found within the reviewed data, the more extensive the audit may be.

2.2. The quantity of reported data reviewed will be at the discretion of the QAU. A minimum of 25% of all data (specific values or information) will be reviewed for each study, with the option to review up to 100% of all reported data. As much data as feasible will be reviewed during each audit.

2.3. The data points (tables, appendices) chosen for review will be at the discretion of the QAU. However, the QAU will choose enough data points to be reasonably assured that the data are accurately reported. For example, the QAU may choose to verify every 5th data point in a set of analytical data or may review all of the presented data in a table. (*i.e.*, computer generated data need not be reviewed as thoroughly as hand-recorded data)

2.4. If a significant number of data errors are found (*e.g.*; >5%) the QAU will either review the data completely (*i.e.*, 100% verification) or reject the report, or any portion thereof (table, appendix, text), until corrections have been made by the author(s).

3.0 REPORTS

3.1. The QAU is given a photocopy or electronic copy of each report prepared for each AEATF II study conducted and all supporting data, as necessary.

3.2. The AEATF II protocol should be read prior to report auditing for QAU familiarity with the study purpose and requirements.

3.3. Raw data not audited during the conduct of the study should be reviewed for GLP, AEATF II protocol and, AEATF II and/or contract test facility SOP compliance. Items to be reviewed include, but are not limited to: transcription of data to spreadsheets and worksheets, and verification of calculations. Additionally, equipment calibrations and test substance logs should be checked. (For example, if samples were weighed on a particular day, the QAU would check to see that the balance was calibrated on that day, and that the calibration weights bracketed the sample weights.)

3.4. The report should be read prior to auditing for familiarity with format and contents.

3.5. The report is reviewed to assure that all AEATF II protocol requirements have been met and that any differences are specified in the report.

3.6. The compliance statement will be reviewed for true and accurate reflection of the study conduct.

3.7. The contents (procedures, results, *etc.*) of the report are verified against the raw data or appropriate phase report. All descriptions, methods and procedures described in the report must be documented in the raw data. Routine procedures must be referenced in the data to the AEATF II and/or the contract test facility SOPs. Study specific procedures should be documented in the raw data.

3.8. Report tables are checked for accuracy of numerical data transcriptions. Computerized calculations and statistics are randomly checked.

3.9. Calculations are checked for accuracy. Selected data points on graphs are verified.

3.10. The table of contents is verified against headings and titles in the report.

3.11. The report is reviewed for compliance with the applicable EPA GLP requirements.

3.12. The report format must be checked for consistency with applicable EPA Data Reporting Guidelines and PR Notice 86-5, as necessary.

3.13. The report is checked for clarity, readability, spelling, *etc.*

4.0 Report Audit Findings

4.1. The QAU findings may be made directly on the copy of the report. A copy of the audited report with findings indicated will be kept by the QAU.

4.2. At the completion of the audit, any findings, questions, or raw data errors as well as recommended actions will be noted.

4.3. The audited report and Quality Assurance (QA) Inspection Report will be returned to the Study Director or appointed personnel for corrections and finalization.

4.4. Once the Study Director has addressed the QA findings, and the AEATF II Study Team Leader has reviewed the responses, the QA Inspection Report and the audited copy of the report will be returned to the QAU to be maintained in the QAU files as a record of the audit.

4.5. Prior to issuing the final report, the QAU may perform a post-audit inspection to assure all corrections have been made and any additions to the report are accurate.

5.0 Quality Assurance Final Report Statement

5.1. Upon acceptance of the final report by the AEATF II Study Team Leader, the QAU will prepare and sign a statement to be included with the final AEATF II study report which specifies the inspections conducted, dates of inspections/audits, and the dates findings were reported to the AEATF II Study Team Leader (sponsor representative) and the Study Director(s).

6.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

Chapter 8 – Matrix Samples

AEATF II-8A.1 Whole Body Sampling – Inner Dosimeters

Approval

Technical Committee Chair: _____ Date: 08 Mar 06

AEATF II QAU: _____ Date: 3/16/06

Effective Date: March 10, 2006

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from inner whole body dosimeters worn by workers (test subjects) during the Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

1.2 The inner dosimeter will be used as a collection medium and may be analyzed, as specified in Section 7.0 of this SOP. The inner dosimeter will be worn over the test subject's own undergarments and directly underneath the specified work clothing and personal protective equipment (PPE), if appropriate.

2.0 MATERIALS REQUIRED

2.1 The following materials are typically required for using and collecting whole body dosimeter samples from each worker/replicate:

a. 100% cotton, white, long underwear (inner) - with long sleeves, round neckline and no elastic.

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

c. Cutting utensils, (e.g. 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. Sample bottles, if needed

j. Cooler with dry ice, or freezer

k. Plastic bags

3.0 USE OF WHOLE BODY DOSIMETER

3.1 The test subject(s) will be given a new inner dosimeter prior to initiation of each study replicate. The workers will be allowed to change in a clean "privacy area". Disposable gloves should be worn by the test subject and the field 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 outer dosimeter 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 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 The field 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, outer dosimeter, and inner dosimeter collection. Remove garments in a manner to avoid cross-contamination.

4.4 Ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each replicate.

4.5 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.

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

4.7 Remove and discard any buttons from clothing.

4.8 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.

4.9 Inner dosimeter samples may also be placed directly into separate glass jars in preparation for method extraction. Sample jars need to be large enough to hold the required amount of solvent for extraction. Each jar will be labeled with sample identification and sealed with its Teflon-lined lid. Each jar will be placed into separate ZipLoc bags for shipping.

4.10 There shall be six (6) inner dosimeter samples per replicate as outlined in section 4.5.

5.0 SAMPLING INTERVALS

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

6.0 FIELD STORAGE

6.1 Place samples collected during the study 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.

7.0 ANALYSIS OF INNER DOSIMETER SAMPLES

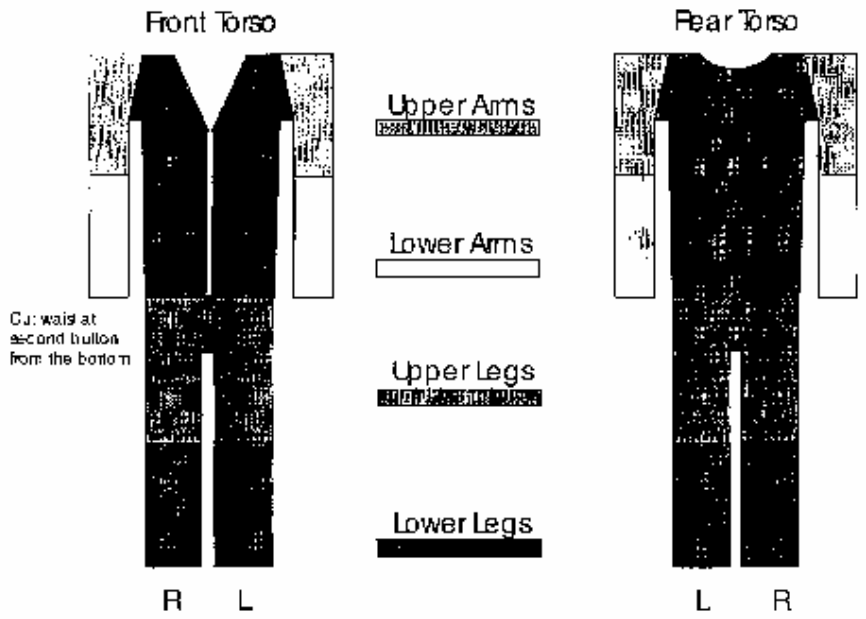
7.1 Inner dosimeter samples will be analyzed if the analyte is detected in its corresponding outer dosimeter segment. If there are no detects in the outer dosimeter section, the corresponding inner dosimeter section will not be analyzed unless authorized by the Study Director. If inner dosimeter samples are not analyzed, they must be retained under frozen conditions until notified by the Study Director of sample disposition.

8.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	3/10/06	Added requirement to section 4.9 that jars be placed in Ziploc bags for shipping.

Attachment

Diagram of Inner Dosimeter



Effective Date : May 14, 2007

Approval

Technical Committee: _____ DATE
CHAIR

AEATF II QAU: _____ DATE

Effective Date: May 14, 2007

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for collecting pesticide residues from workers bare hands during the Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

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**)

b. Anionic detergent solution (Aerosol® OT solution - sodium dioctyl sulfosuccinate) or other suitable solvents for use on human skin demonstrated to completely dissolve milligram quantities of active ingredient in 500 mL for each hand wash (e.g., approximately 0.1 mg active ingredient / ml solvent based on 95th percentile hand loading from EPA's Pesticide Handlers Exposure Database).

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 (ethanol, isopropanol), alcohol/water mixture, acetone, *etc.*)

j. Paper towels

k. Cooler with dry ice or freezer

l. Plastic bags

3.0 HAND WASH SOLUTION PREPARATION

3.1 The desired solution concentration is 0.01% v/v Aerosol® OT (AOT)* to water (500 mL for each handwash).

3.2 Pipette an appropriate amount of AOT solution into the water. Document brand of water (if store bought) and where purchased. If the water is not store bought, document the source.

3.3 Store the solution in glass jars. 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 500 mL AOT solution aliquots.

*Aerosol OT is **not** to be used with quaternary ammonium biocides (quats). For quats, a solution of 50% ethanol or isopropanol in water should be used.

4.0 WASHING PROCEDURE

4.1 Upon removal of the workers' personal protective equipment (PPE) and shoes/socks, the test subject will be taken to a designated clean sampling area for hand wash collection.

4.2 Hand washes must be completed before the face/neck wipe samples are collected. Prior to collection of the hand wash sample, carefully push up the outer dosimeter shirt sleeves. Change gloves, and carefully push up the inner dosimeter cuffs from the worker's wrists.

4.3 Have the test subject place both hands over a bowl, and pour approximately 400 mL of hand wash solution over the subject's hands for approximately 30 seconds. The subject will scrub their

hands while the wash solution is slowly poured over the workers' hands.

4.4 The worker shall then immerse their hands in the 400 mL of wash solution in the collection bowl and scrub their hands (front and back) in the solution for a minimum of 30 seconds.

4.5 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 hand wash solution is poured over the workers' hands to rinse. Allow the hands to drain for approximately five seconds.

4.6 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 hand wash sample). Each jar will be placed into separate ZipLoc bags for shipping.

4.7 Clean the bowl with an alcohol solvent (e.g., ethanol or isopropanol) 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 soap and water prior to the exposure period. If washing facilities are not available, a hand wash sample will be collected and discarded.

5.2 Hand wash samples should be collected whenever the worker would normally wash his/her 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 workers' outer shirt and push up the sleeves before washing hands.

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

6.0 Field Storage

6.1 Place samples collected during the study 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.

History of Changes

Revision	Date	Description of Change
0	12/26/05	Original Document
1	3/10/06	Added requirement to section 4.6 that jars be placed in Ziploc bags for shipping.
2	5/14/07	Update terminology

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8C.1
Dermal Face/Neck Wipe Samples

Approval

Technical Committee Chair: [signature] Date: 08 Mar 06

AEATF II QAU: [signature] Date: 3/16/06

Effective Date: March 10, 2006

1.0 PURPOSE AND SCOPE

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

2.0 EQUIPMENT REQUIRED

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

a. 100% cotton gauze (8 layer, 4" x 4" pads, split into two 4 layer pads per wipe sample)

b. Anionic detergent solution (Aerosol® OT - sodium dioctyl sulfosuccinate)* prepared as follows:

i. Pipette an appropriate amount of AOT solution into the water. Document brand of water (if store bought) and where purchased. If the water is not store bought, document the source.

ii. Store the solution in glass jars. The shelf life of the 0.01% Aerosol® OT solution at room temperature is 48 hours.

* Aerosol OT **CANNOT** be used with quaternary ammonium biocides (quats). For quats, a solution of 50% ethanol or isopropanol in water must be used.

c. Syringe or pipette

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

e. Aluminum foil

f. Plastic bags

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

h. 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. Open the gauze pad package and separate the pad into two pads of 4 layers each. Use one 4 layer pad for each of the two wipes that will constitute a single sample.

3.2 Dispense approximately 4 mL of the wiping solution (0.01% Aerosol® OT except for quats) on the gauze pad with the syringe or pipette (or other appropriate means of moistening the pad).

3.3 Thoroughly wipe the test subject's face/neck (front & back) with the moistened pad.

3.4 Repeat steps 3.2 and 3.3 again, for a total of two dermal wipes per sample. Wrap both wipes in aluminum foil (only if using a sealable bag) and place in the prelabelled bag otherwise place both wipes in a prelabeled jar, close the top, and place in frozen storage. If a jar is used, place each jar into a ZipLoc bags for shipping.

4.0 SAMPLING INTERVALS

4.1 Prior to the exposure replicate, 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 replicate 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.

6.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	3/10/06	Added requirement to section 3.4 that jars be placed in Ziploc bags for shipping.

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8D.0
Collection of Air Samples
Using OVS Tubes

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 Antimicrobial Exposure Assessment Task Force (AEATF II) 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.

2.0 MATERIALS REQUIRED

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

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 clips 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 replicate. 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.

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 AEATF II 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 is 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 replicate to ensure it is functioning properly.

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

4.10 Should a pump malfunction during a replicate, 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 sampling period, 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 replicate, 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 replicate, 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.

8.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-8E.0 Fortification of Matrix Samples

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples **AEATF II-8E.0**
Fortification of Matrix Samples

Approval

Technical Committee Chair: _____ Date: 07 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the methods by which worker exposure monitoring matrices, (*i.e.*, outer dosimeters, inner dosimeters, hand washes, face/neck wipes, 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 Antimicrobial Exposure Assessment Task Force (AEATF II).

2.0 EQUIPMENT/REAGENTS REQUIRED

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

a. Exposure monitoring matrix samples (outer and inner dosimeter material cut according to applicable SOP, moistened face/neck wipes, hand wash solutions, and OVS tubes).

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

c. Appropriate pipettes (*e.g.* 1.0 mL graduated 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) or solvent solution (if required by the analytical method). Refer to the SOP AEATF II-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)

3.0 SPIKING MATERIALS

3.1 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.

4.0 SPIKING TECHNIQUES

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

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

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

4.4 **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.

4.5 **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.

4.8 **Spiking using vialed spikes:** 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 that may be removed easily from the vial and will not interfere with analysis of fortified matrices.

5.0 SPIKING PROCEDURES

5.1 Dosimeters (inner and outer)

a. The dosimeters shall 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. Dosimeter sections may also be placed directly into a glass jar and fortified as directed.

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. The spiking material will be added to outer dosimeters; ensure the fortification is added to a dosimeter that has been folded to provide at least 4 layers of cloth. This insures that all the material is absorbed by the cloth.

d. When spiking with vialed solutions, 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 places 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. Outer dosimeters will be left uncovered for the duration of the weathering period.

5.2 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 vialed solution will be unscrewed from the vial and discarded without rinsing. The vial contents will be added to a 500 mL Aerosol OT (AOT) sample (or solvent solution) 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.

5.3 Face/Neck Wipes

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

b. When spiking with vialed solutions, 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.

5.4 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.

6.0 FORTIFICATION SAMPLE IDENTIFICATION AND HANDLING

6.1 Refer to SOP AEATF II-8F for the procedures to uniquely identify fortification samples.

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

6.3 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.

7.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-8F.0 Sample Identification

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the procedures to uniquely identify field samples collected during Antimicrobial Exposure Assessment Task Force (AEATF II) worker exposure studies.

2.0 NUMBERING PROCEDURE

2.1 All samples (exposure and fortification) will be identified by the protocol (AEATF II study) number and a unique identification number that describes the type of sample. Individual sample numbers (replicate numbers) may not be reused should a replicate be started and then cancelled, even if no samples were collected for analysis. Additional replicate number(s) will be added to the sample list to account for the lost replicate(s).

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

SN-XX-NN-YY-ZZ

2.3 The identities of the code pairs are listed on the following page.

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

SN: The last two digits of the AEATF II 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 worker replicate number

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

YY: A code for the type of the samples

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

ZZ: Unique 2 Character Codes For All Samples

Fortifications (FF samples only)		Dosimeters (FS samples only)	
Tx*	- travel spike	LA	- lower arms
Lx*	- low spike	UA	- upper arms
Mx*	- mid spike	FT	- front torso
Hx*	- high spike	RT	- rear torso
Cx*	- control sample	UL	- upper legs
		LL	- lower legs

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

Air – Handwash - Face/Neck Wipe Samples (Worker FS, AR, HW & FW samples only)
Sequential number to denote multiple samples (if more than one sample is collected) from the same replicate. -01 is the first sample collected, -02 is the second, *etc.* If only one wash or wipe sample is collected, then –01 will be the only sample number used. If more than one must be collected during the replicate, 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 AEA01 - worker sample - worker rep. 2 - inner dosimeter - lower legs

01-WS-02-OD-LA: Study AEA01 - worker sample - worker rep. 2 - outer dosimeter - lower arms

05-WS-05-HW-01: Study AEA05 - worker sample - worker rep. 5 - first hand wash collected (*i.e.* worker used the bathroom before end of rep.)

05-WS-05-HW-02: Study AEA05 - worker sample - worker rep. 5 – second hand wash collected, in this instance at the end of the worker activity

05-WS-03-AR-01: Study AEA05 - worker sample - worker rep. 3 - air sample

05-WS-09-FW-01: Study AEA05 - worker sample - worker rep. 9 - face/neck wipe

11-FF-01-ID-L2: Study AEA11 - Field fort. - first study day - inner dosimeter - second low level

22-FF-03-FW-H1 Study AEA22 - Field fort. - third study day - face/neck wipe - first high level [this may be the second day of fortifications for AEA22]

22-FF-03-FW-H2: Study AEA22 - Field fort. - third study day - face/neck wipe - second high level

3.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-8G.1 Whole Body Sampling – Outer Dosimeters

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8G.1
Whole Body Sampling –
Outer Dosimeters

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: 3/16/06

Effective Date: March 10, 2006

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 (test subjects) during the Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

1.2 The outer dosimeter (shirt and pants) will be used as a collection medium and will be analyzed. The outer dosimeter will be worn directly over the test subject's inner dosimeter. Personal protective equipment (PPE) will also be worn, if appropriate.

2.0 MATERIALS REQUIRED

2.1 The following materials are required for using and collecting whole body outer dosimeter samples from each worker/replicate:

a. 100% cotton long-sleeved work shirt

b. 100% cotton pants

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

d. Scissors

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

f. Sealable bags or other suitable bags or sample container

g. Aluminum foil wrap

h. Disposable paper or plastic mat

i. Hangers, if appropriate

j. Cooler with dry ice, or freezer

k. Plastic bags

3.0 Use of Whole Body Dosimeter

3.1 The test subject(s) will be given clean, new outer dosimeters prior to initiation of each study replicate. The workers will be allowed to change in a clean "privacy area". Disposable gloves should be worn by the test subject and the field personnel to minimize contamination.

3.2 Care should be taken to provide clothing of adequate fit (e.g., cut the excess off the pant legs). The shirt should be tucked into the pants during the exposure replicate. The inner dosimeter arm and part cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles).

4.0 Collection Procedure

4.1 The worker will remove his/her shoes and applicable PPE prior to entering the clean sampling area. The worker will be taken to a designated "privacy area" for removal of 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 field 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, outer dosimeter, and inner dosimeter collection. Remove garments in a manner to avoid cross-contamination.

4.4 Ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each replicate.

4.5 Cut the shirt into four (4) sections:

a. Right & left upper arms (shoulder to elbow)

b. Right & left lower arms (elbow to cuff)

c. Front torso (cut at side seams)

d. Rear torso (cut at side seams)

4.6 Cut the pants into two (2) sections:
a. Right & left upper legs (waist to knee)

b. Right & left lower legs (knee to cuff)

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

4.8 Remove and discard any plastic buttons from clothing.

4.9 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.

4.10 Outer dosimeter samples may also be placed directly into separate glass jars in preparation for method extraction. Sample jars need to be large enough to hold the required amount of solvent for extraction. Each jar will be labeled with sample identification and sealed with its Teflon-lined lid. Each jar will be placed into separate ZipLoc bags for shipping.

4.11 There shall be six (6) outer dosimeter samples per replicate as outlined in section 4.5 and 4.6.

5.0 SAMPLING INTERVALS

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

6.0 FIELD STORAGE

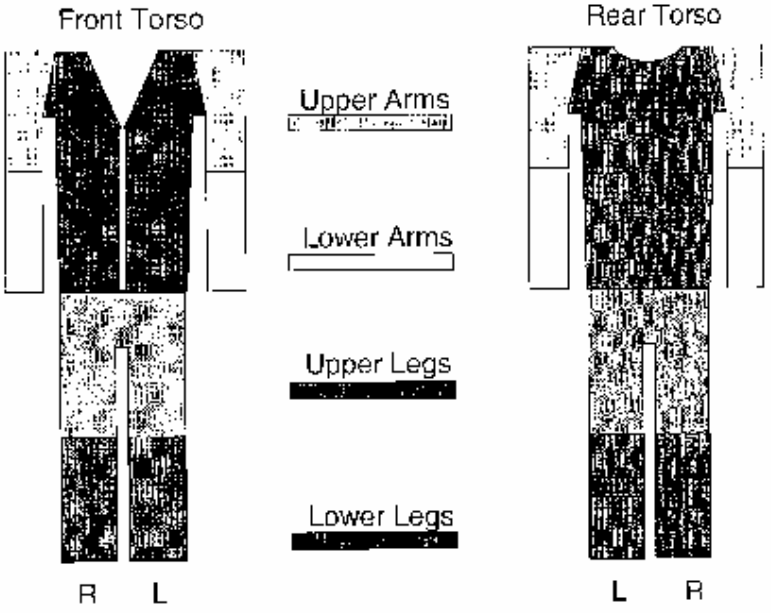
6.1 Place samples collected during the study in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical). If dry ice is not available, the Study Director must be notified before sample collection and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

7.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	3/10/06	Added requirement to section 4.10 that jars be placed in Ziploc bags for shipping.

Attachment

Diagram of Outer Dosimeter



Chapter 10 – Field Study Procedures

AEATF II-10A.0 Rotameter Calibration

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations — **AEATF II-10A.0 Rotameter Calibration**

Approval

Technical Committee Chair: _____ Date: 9 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 Antimicrobial Exposure Assessment Task Force (AEATF II) 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 at least 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.

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations

AEATF II-10B.0
Packing, Handling, and Shipping of Samples

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of procedures for handling the Antimicrobial Exposure Assessment Task Force (AEATF) test system [matrix] samples collected at the field test sites. This SOP also covers storage, packing, and shipping procedures.

2.0 SAMPLE HANDLING AND STORAGE

2.1 All samples will be collected as directed by the study protocol or appropriate SOP to prevent degradation and/or contamination.

2.2 Place "dry" field samples (*e.g.*, body dosimeters) in appropriate labeled containers, then "immediately" place in an ice chest with dry ice or in a freezer for transport to the analytical facility or for long-term storage (>12 hours).

2.3 All liquid samples should be placed in appropriate jars with lids. Allow sufficient headspace when freezing these samples to prevent cracking or breaking from expansion.

2.4 Field fortification sample and solution, control sample and field generated sample containers are to be stored separately (a physical separation of the containers themselves must be complied with, either in separate boxes or plastic bags) in ice chests and/or freezers. These samples must be kept separate during shipping. All samples from workers are to be boxed and shipped separately from those listed in this section. This should minimize the potential for cross-contamination.

3.0 SAMPLE PACKING AND SHIPPING

3.1 Samples, when packed for overnight shipping, should be placed on dry ice in insulated containers (boxes or coolers). Be sure to add enough dry ice to keep the samples frozen for at least 36 hours. Samples packed for transport by freezer truck service will be boxed and stored frozen until picked up by freezer truck.

3.2 Before shipping, all sample numbers should be checked against a sample list to provide an accurate chain of custody form for the analytical laboratory. A copy of the signed form will remain in the raw data logbook. Chain of custody documents will be included with the shipment to the analytical laboratory. See the attached example.

3.3 All samples in bottles should be placed in sealable bags and wrapped with protective wrapping materials (*e.g.*, bubble wrap or newspaper) to minimize breakage. Bottles must be securely packed in each shipping container so that there is minimal or no movement. Additional bubble wrap or paper may be placed in the sample shipping container to provide cushioning.

3.4 If samples must be shipped via a commercial overnight freight carrier, they are always shipped on a priority basis. For local studies, samples will be transported on dry ice, in a cooler, from the field to a laboratory freezer.

3.5 An effort should be made to ship samples to arrive at the designated facility on a weekday. Do not ship samples over a weekend unless a freezer truck service is being used.

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

Attachment

Sample Shipping Form
(example)

Antimicrobial Exposure Assessment Task Force
Sample Shipping Chain of Custody

AEATF Study No.	Sample Type:	Priority:	Page
AEATF99	OVS Tubes	Overnight	1 of 1

Ship To:	Ship From:
Analytical P.I. Analytical Laboratory Address City, State Zip Code	Study Director Facility/Company Address City, State Zip Code

Carrier	Waybill/Airbill No.	Date Shipped/Initials:
FedEx	N123 456 7	02/07/06 RF

Approximate Amount of Dry Ice Included:	Conditions of Samples when Packed:
15 lbs.	Frozen, kept in freezer on-site

Comments:
Air samples from trials 1 to 10, two coolers in shipment

List of Samples Shipped:	Received:	List of Samples Shipped:	Received:
Cooler 1:		Cooler 2:	
AR-DS-01-01	✓		
AR-DS-01-02	✓		
AR-DS-01-03	✓	See attached sample list in cooler 2 for samples in cooler 2	
AR-DS-01-04	✓		✓
AR-DS-01-05	✓		
AR-DS-02-01	✓		
AR-DS-02-02	✓		
AR-DS-02-03	✓		
AR-DS-02-04	✓		
AR-DS-02-05	✓		

Date Received:	Received By/Company:
02/08/03	J.Doe/Analytical Lab, Inc.

Condition Received:
Frozen, dry ice still present in cooler

Destination of Samples at Analytical Facility:	Date Placed in Storage/Initials:
Freezer 1-A	2-08-06/JD

Do not ship samples over a weekend unless on a freezer truck.

AEATF II-10C.0 Worker and Study Observations

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations — **AEATF II-10C.0 Worker and Study Observations**

Approval

Technical Committee Chair: _____ Date: 9 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

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 AEATF II 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. Record the following information, at a minimum:

a. Prepare a sketch map of the working area giving key details such as compass points, mixing area, treatment area, and sampling 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. Ventilation system will be described in the raw data.

5.0 Calibration and Equipment Details

5.1 Details of application equipment will be recorded in the field notebook. Application equipment will be calibrated, and calculations recorded, as defined in the study protocol.

6.0 Subject Observations

6.1 Use the appropriate form in the field notebook to record the times and descriptions of all activities other than mixing, loading, and/or application activities; *e.g.*, resting, lunch, washing hands, driving vehicles, *etc.*

6.2 Describe clothing and personal protective equipment (PPE) worn and location function/site condition. Record any instances of removal of protective equipment during the monitoring period.

6.3 Record start and stop time for the activities. Record the productivity of each worker during the activities (*e.g.*, amount of product handled, area covered, etc.).

6.4 Record any actions that might explain any unusually high or low exposure values for any of the body parts (*e.g.*, spills, working with nozzles, contacting wet surfaces, *etc.*).

7.0 History of Changes

Revision	Date	Description Of Change
0	12/28/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations

AEATF II-10D.0
Application Equipment
Operation Verification

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 (mop, handheld sprayer, *etc.*) prior to being used in Antimicrobial Exposure Assessment Task Force (AEATF) worker exposure studies.

1.2 This SOP will cover various commercial application equipment that may be used on AEATF worker exposure studies. Since the AEATF will measure handler exposure (applicator) under expected working conditions using standard industry practices, no modifications or maintenance will be performed by the AEATF to the equipment. In order to maintain an acceptable level of scientific integrity, the AEATF 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 AEATF 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 function of the equipment has been checked within the six months prior to the AEATF 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 AEATF 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 AEATF application. All results and calculations will be documented in the study file.

6.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

AEATF II-10E.0 Worker Sample Collection Sequence

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations **AEATF II-10E.0**
Worker Sample Collection Sequence

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 Antimicrobial Exposure Assessment Task Force (AEATF) exposure studies.

2.0 COLLECTION SEQUENCE

2.1 Upon completion of the standard replicate, the worker shall return to the appropriate staging area.

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) worn on the head, which may be a respirator or glasses.

2.4 The worker will then remove any body PPE (e.g., apron, coveralls, or gloves) they may be wearing and their shoes, then the worker may enter the clean sampling area.

2.5 The researcher will collect hand wash samples, according to SOP 8.B.

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

2.7 After collection of the face/neck wipes, the researcher will remove the outer and inner dosimeters from the worker, according to SOP 8.J and 8.A, respectively.

2.8 At this point, all worker samples will have been collected and the worker shall dress in their street clothes and may be dismissed.

2.9 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-replicate 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.

3.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations — **AEATF II-10F.0**
GPI Electronic Digital Flow Meter

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides the steps to properly operate, calibrate and maintain the Great Plains Industries, Inc. (GPI) Electronic Digital Meter for recording application solution amounts during Antimicrobial Exposure Assessment Task Force (AEATF II) worker exposure studies.

2.0 EQUIPMENT REQUIRED

2.1 The following equipment is needed to calibrate the flow meters:

a. GPI Electronic Digital Meter

b. "Calibrated" Bucket/Container or equivalent

c. Water Source

d. GPI Electronic Water Meter Operations Guide and Owner's manual

3.0 CALIBRATION VERIFICATION PROCEDURE

3.1 If necessary, prepare the meter according to the manufacturer's directions by installing two lengths of pipe (20" and 5", minimum) on the inlet and outlet ends, respectively.

3.2 Attach the water source to the inlet pipe. Secure the connection and ensure that there are no leaks.

3.3 Zero the meter by pressing and holding the DISPLAY button for three seconds. The meter should read zeros on the display.

3.4 Turn on the water source and fill the container to the predetermined volume mark. Use a continuous, full stream for the flow. Turn off the water.

3.5 Record the reading on the meter. Compare to the predetermined volume and calculate the percent difference.

3.6 Repeat steps 3.3 to 3.5 a minimum of three times for each meter until all meters to be used have been calibrated. Each meter should be within 5% of the expected volume.

3.7 If the reading on the meter is consistently greater than 5% of expected, then the meter must be electronically calibrated according to the manufacturer's directions. Refer to the Calibration section in the Owner's manual, pp. 10-13. After electronically calibrating the meter, recheck the meter as described above.

4.0 OPERATION

4.1 A complete description of operation controls is described in the Owner's Manual, Operations section, pp. 6-10.

4.2 Turn the meter on by pressing and releasing the DISPLAY button. The meter will automatically turn on when liquid flows through it. The meter will automatically turn off after approximately four minutes of non-use.

4.3 To clear the batch totals display, press and hold the DISPLAY button for three seconds. The cumulative total cannot be cleared, except by removing the batteries.

4.4 To select a calibration curve, hold the CALIBRATE button while pressing and releasing the DISPLAY button until the desired calibration curve shows on the display. The factory calibration curve should be selected. If a field calibration curve is necessary, then follow the manufacturer's directions for creating a field calibration. See the Owner's Manual, Calibration, pp. 10-13. Document this action in the raw data.

4.5 If the display is dim or non-existent, then the batteries are too weak to operate the meter properly.

5.0 MAINTENANCE

5.1 A complete description of maintenance procedures is described in the Owner's Manual, Maintenance section, pp. 14-16.

5.2 During daily or routine use, these meters are maintenance-free.

5.3 The meter should be cleaned after each use to prevent and debris from accumulating on the interior, which can degrade accuracy and damage the turbine. Dried material should be cleaned with a penetrating lubricant, such as WD-40®. Do not submerge the meter.

5.4 If the reading is dim or blank, replace the batteries. Remove the cover by unscrewing the four face screws. Lift-off the faceplate, remove the old batteries, clean the battery terminal, and replace with fresh batteries. Replace the faceplate, and retighten the four screws.

5.5 If the meter fails to operate properly, cannot be adequately calibrated, or otherwise does not operate, then the meter should be removed from service, and either returned to the manufacturer for repair, or be replaced. Do not attempt to repair or modify the internal structures.

5.6 Record battery replacements as "routine" maintenance. Records cleaning procedures and "routine" maintenance. Record non-functioning returned for repair or replacement and "non-routine" maintenance.

6.0 REFERENCES

6.1 For complete and detailed information on the operation, calibration, and maintenance procedures refer to:

6.1.1 GPI Electronic Digital Meter Owner's Manual No 920685-8

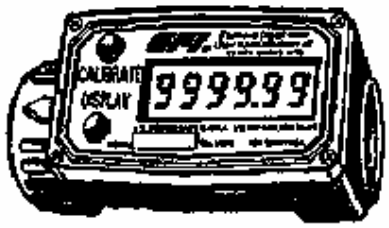
6.1.2 GPI Operations Guide for Electronic Digital Meter No 920731-2

6.2 Great Plains Industries, Inc.
5252 East 36th Street North
Wichita, KS 67220-3205
TEL: 316-686-7361 toll-free: 1-800-835-0113
FAX: 316-686-6746
www.gplains.com/gpi

7.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document

8.0 REFERENCE DIAGRAMS



AEATF II-10G.0 Personal Air Sampling Pump Calibration

STANDARD OPERATING PROCEDURE

Chapter 10: Field Operations

AEATF II-10G.0
Personal Air Sampling Pump Calibration

Approval

Technical Committee Chair: _____ Date: 09 Dec 2005

AEATF II QAU: _____ Date: 12/9/05

Effective Date: December 26, 2005

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 Antimicrobial Exposure Assessment Task Force (AEATF II) worker exposure studies.

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 replicate. 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 replicate OVS tube has been removed by the field sample collection personnel.

5.0 History of Changes

Revision	Date	Description Of Change
0	12/26/05	Original Document

Chapter 11 - Human Subject Management

AEATF II-11A.0 - Pregnancy Testing – DRAFT VERSION

Effective Date : May 14, 2007

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: 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 (or subject) who is being considered for participation in an Antimicrobial Exposure Assessment Task Force (AEATF II) exposure study. AEATF II policy does not permit pregnant workers to participate in its 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 potential female volunteer will be told during the consent process that any woman who is pregnant or nursing is ineligible to participate in an AEATF II exposure study.

2.2 Within 24 hours prior to study participation, any woman <50 years of age who has signed the ICF for participation will be asked to take a urine pregnancy test (over-the-counter variety).

a. The pregnancy test kit will be provided by AEATF II.
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 volunteer to the bathroom and wait outside while the volunteer 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 state her desire to continue or withdraw from participation in the study.

a. If the potential worker or subject chooses to withdraw from the study.
   i. She will be allowed to do so without stating a reason and will be compensated for her time and inconvenience.
   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 volunteer will be promptly discarded.

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

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

Effective Date : May 14, 2007

APPROVAL_____ DATE_____

APPROVAL_____ DATE_____

Last Revision Date: 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 Antimicrobial Exposure Assessment Task Force (AEATF II) worker exposure study.

1.2 Since workers wear an extra layer of clothing during AEATF II 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-induced illness, procedures for preventing heat-induced illness, early signs and symptoms of heat-induced illness, and what to do if heat-induced illness becomes apparent or suspected. AEATF II Study Directors will use this information to brief field personnel prior to each exposure study conducted by the Task Force.

1.3 This SOP describes the measures to be taken to minimize the risk of heat-related illness to workers during their participation in an AEATF II field study, measures to be taken if a worker is affected by heat-related illness, and how AEATF II researchers will monitor environmental conditions (ambient temperature and humidity).

1.4 The Study Director will identify any workplace plans to handle heat-related illness, and discuss the AEATF II procedures with the employer and workers. The Study Director shall gain agreement from the employer and workers to utilize the AEATF II procedures during the conduct of the study. This will be documented and included in the raw data.

2.0 INTRODUCTION

2.1 There is potential for heat stress to workers under certain conditions of temperature and humidity. For workers who participate in AEATF II

studies, this potential increases because an additional layer of clothing (inner dosimeters) is required and the required outer layer (outer dosimeter) may be hotter than clothes normally worn by the worker.

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-induced 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 off. 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 water or sports drinks should be consumed before and regularly during work.

4.0 PREVENTION PROCEDURES

4.1 The Study Director shall make pre-study arrangements to provide access to local emergency medical assistance if necessary during the conduct of an AEATF II study while workers are being monitored. The Study Director shall conduct periodic observations of workers during the study and will advise subjects any signs of heat-related illness.

4.2 During all AEATF II studies, the Study Director and field personnel share responsibility for awareness of heat illness. The following procedures should 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.

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

c. 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.

d. 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. There is no need to take hand washes or stop inhalation monitoring during a water break.

e. Observe workers during the monitoring period and be aware of the signs and symptoms listed below in Attachment A.

f. Require workers to take rest breaks when any signs or symptoms outlined below are present.

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 A: Heat Illness Symptoms and Treatment Chart.

6.0 FIELD PERSONNEL RESPONSIBILITIES

6.1 During all AEATF II studies, the Study Director and field personnel share the responsibility for awareness of heat illness. This section stresses the importance that symptoms be recognized and responded to promptly and appropriately.

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 AEATF II representative will provide instruction to field personnel, 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 volunteer 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 volunteers 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 personnel 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 ensure coordination with local emergency response or medical professionals to provide medical coverage if needed. This should include at least identifying and locating the closest facility, calling or visiting the facility, and determining the best way to get

emergency medical assistance. If possible the staff of the medical facility should be informed when and where the research will be conducted, and that any subjects needing medical attention will be brought to that facility.

7.3 The Study Director will make the final decision for conducting the study during conditions of elevated heat stress potential. The Study Director may elect not to initiate the study or to terminate the study operations on that particular day based on stop criteria outlined in Section 11.0.

7.4 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.

7.5 The study observers will record on their Observation Form that they have looked for signs of heat illnesses. Recordings will be made periodically and whenever they are informed that a Heat Index Category has changed.

7.6 If a study observer believes a worker is showing signs of heat-related illness, he/she will take immediate steps to mitigate effects as outlined in Attachment A and reports to the Study Director immediately.

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

8.0 FIELD RESEARCH RESPONSIBILITIES

8.1 Assure that adequate cool drinking water or sports drinks are available to study participants.

8.2 Assure that shady areas are available during breaks.

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

8.4 The National Weather Service (NWS) Heat Index Chart will be referenced as the basis for this section of the SOP. The Heat Index Chart 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. (Ref. 14.1) See Attachment B for a copy of the Heat Index Chart.

9.0 HEAT INDEX CATEGORIES

9.1 The following table summarizes the HI Categories, and relates category to ambient temperatures. However, as discussed in Section 10, heat index is a function of both temperature and humidity as shown in Attachment B and reflects how the body perceives heat. At high heat and low humidity, it actually "feels" cooler than the ambient temperature, while higher humidity can make a lower ambient temperature feel hotter. The relationship between heat and humidity feel reflects the evaporative cooling the body can obtain from perspiration.

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

10.0 DETERMINATION OF HEAT INDEX

10.1 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.

10.2 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.

10.3 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. 14.2)

10.4 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. 14.3)

11.0 CRITERIA FOR FIELD MONITORING INITIATION AND STOP CRITERIA

11.1 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 ≥130° F [54° C], or ≥120° F [49° C] when working in direct sun (EXTREME DANGER Category). These are the beginning of the range of temperatures at which heat stroke is highly likely. (Ref. 14.4) The Study Director, at his discretion, may choose not to initiate monitoring, regardless of the HI.

11.2 The Study Director will exercise the requisite vigilance to heat stress conditions, sections 11.4 through 11.13. The degree of vigilance adjusts to changing environmental conditions (heat index based on temperature and humidity) which may affect worker risk to heat stress. In addition, the the Study Director, or if present at a study, the on-site medical professional, will periodically observe workers when conditions exist for potential heat related illness.

11.3 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, if present at a study, with regard to suspected cases of heat-related illness.

11.4 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.

11.5 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.

11.6 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), the Study Director should either STOP THE WORKER EXPOSURE MONITORING or 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.

11.7 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 AEATF II policy to provide medical coverage and to seek medical help immediately if symptoms develop.

11.8 If the Study Director believes that a worker may be suffering heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The Study Director should also consult with the on-site medical professional, if present at a study. 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 subject as appropriate. Take measures to relieve symptoms until professional medical care arrives.

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

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

11.9 If the HI falls between 105° - 129° F [41 - 54° C], or between 95° - 119° F [35 - 48° C] when working in direct sun (DANGER Category), either STOP THE EXPOSURE MONITORING or the Study Director should pay particular attention to **likely** signs of heat cramps and heat exhaustion or **possible** signs of heat stroke with prolonged exposure.

11.10 If signs of heat cramps occur, treat as recommended in section 11.7, above.

11.11 If the Study Director believes that a worker may be suffering from heat exhaustion or heat stroke, immediately STOP THE WORKER EXPOSURE MONITORING. The Study DIrector should also consult with the on-site medical professional, in present at a study. 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 subject as appropriate. Take measures to relieve the symptoms until professional medical care arrives. See sections 11.8 a. & b. above.

11.12 If the HI reaches 130° F [54° C], or 120° F [49° C] when working in direct sun, STOP THE WORKER EXPOSURE MONITORING, as heatstroke is **highly likely** with continuous exposure. (REF. 14.4)

12.0 EXPENSES

12.1 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 AEATF II unless such expenses are covered by the worker's individual or employer sponsored insurance.

13.0 INCIDENT REPORTING

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

14.0 REFERENCES

14.1 The Heat Index Chart used as a reference in this SOP is taken from the Washington State Department of Labor and Industries "Application of

Standards to Address Heat Related Illnesses in the Outdoor Environment" dated July 13, 2006. It is from the National Weather Service HI Chart, but provides a wider range of ambient temperature and humidity combinations, allowing for greater ease of use in the field.

14.2 The National Weather Service suggests a heat index adjustment of an additional 10-15°F [6 - 8° C] for sunny conditions. Given the following assumptions, an adjustment of 10°F [6° C] is reasonable under the conditions of AEATF II worker exposure studies:

a. Workers who participate in these studies perform this work as part of their normal job, including in hot environments.

b. Workers are fully acclimatized.

c. Anticipated work activities are generally moderate workloads. A useful guide is the EPA "A Guide to Heat Stress in Agriculture", *Table 5 - Approximate Workload Levels*)

d. Baseline (single layer) clothing is worn by the study participant.

e. If an additional layer of clothing, such as the inner dosimeter, is worn, the heat index will be adjusted upward by adding another 10 ºF to the ambient temperature on the left side of the chart.

14.3 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.

14.4 National Weather Service – Apparent Temperature Categories indicates that heat stroke is highly likely at 130° F [54° C] (or 120° F [49° C] adjusted for sunny conditions). This temperature is also used by the University of Florida in its *Heat Stress Policy* as a criterion for discontinuing work.

14.5 The National Weather Service issues advisories based on specific heat index temperatures occurring up to 3 hours per day. ***"HEAT ADVISORY ISSUED WITHIN 12 HOURS OF THE ONSET OF THE FOLLOWING CONDITIONS: Heat Index of at least 105° F*** [41° C] ***but less than 115° F*** [46° C] ***for less than 3 hours per day."*** It is on this basis that the CAUTION and EXTREME CAUTION Categories apply if HI temperatures fall into either of those categories for 3 successive hours. However, the degree of risk for more serious heat-related illness increases in the DANGER and EXTREME DANGER Categories. Therefore, the

DANGER Category applies if temperatures fall into its category for only 2 successive hours, and the EXTREME DANGER Category applies if only one measurement falls into its category, resulting in immediate discontinuance of the study. This guidance is intended to reduce the amount of time a higher risk category is monitored before precautions are taken.

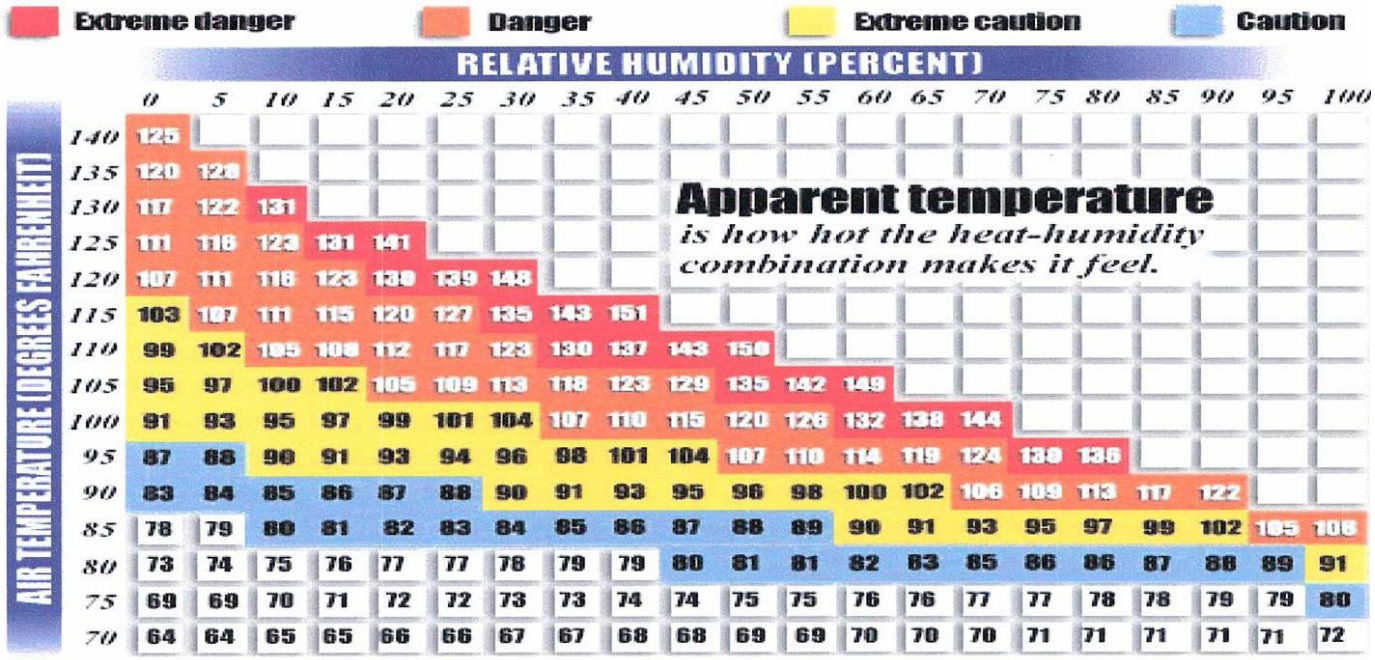
14.6 Controlling Heat Stress Made Simple. September, 1995. GPO Document Number 055-000-00474-9 prepared by the United States Environmental Protection Agency and the Occupational Safety and Health Administration.

Attachment A: 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.

NOAA's National Weather Service Heat Index

Heat Index	*General Effect of Heat Index on People in Higher Risk Groups*
80 to 89° - Caution	Fatigue possible with prolonged exposure and/or physical activity
90 to 104°- Extreme Caution	Sunstroke, heat cramps and heat exhaustion possible with prolonged exposure and/or physical activity
105 – 129° – Danger	Sunstroke, heat cramps or heat exhaustion likely, and heatstroke possible with prolonged exposure and/or physical activity
130° or higher – Extreme Danger	Heat/Sunstroke highly likely with continued exposure



Attachment B: Heat Index Chart

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APPROVAL_____ DATE_____

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Last Revision Date: N/A

2.0 PURPOSE AND SCOPE

1.1 This SOP describes the procedure(s) to be followed in the event that a subject requires emergency medical attention during his/her participation in an Antimicrobial Exposure Assessment Task Force (AEATF II) exposure monitoring study.

1.2 The user of this SOP should be familiar with the SOP AEATF II-11B.0, "*Controlling Heat Stress"*, as there are possible overlaps in procedures.

1.3 The Study Director will determine if test site plans are in place to handle on-site emergencies. As an adjunct to existing plans, the Study Director will discuss the AEATF II procedures with the on-site test facility manager and subjects or workers. If there is not existing on-site plan, the AEATF II procedures will take precedent. The Study Director shall gain agreement to utilize the AEATF II procedures during the conduct of the study. This will be documented and included in the raw data.

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) which may be used in event of a medical emergency during the study.

a. Specific information about the facility, including the address, telephone number and direction to/from the field site will be obtained.

2.2 As deemed appropriate by an on-site, specifically designated individual (e.g., emergency medical technician) or Study Director, a member of the study team will call 911 (or other local emergency number) and allow paramedics to respond and continue to treat the subject as appropriate.

2.3 As deemed appropriate by the Study Director, and with consent from the worker, the worker may be taken by ambulance to the nearest emergency medical facility, such as a hospital or minor injury clinic. If the illness or injury is believed to be associated with high morbidity or mortality, e.g., broken bones, heat stroke, etc., the subject will be taken for emergency care even without their consent.

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

2.4 If a test subject is taken to a medical emergency facility for examination or care, a member of the study team will accompany the subject to the facility so the Sponsor can stay informed through discussions with the physician or other medical professional that is involved.

3.0 HEAT-RELATED ILLNESS

3.1 A worker who becomes ill due to heat stress will likely be treated on-site as a non-emergency. Treatment for heat stress will include but not be limited to providing the worker a shaded area to rest, plenty of fluids to drink, and other treatments listed in SOP AEATF II-11B.0.

3.2 If the Study Director determines that a heat-related medical emergency is taking place the Study Director will summon the on-site medical professional to take measures to relieve symptoms and provide appropriate medical care. As deemed appropriate, a member of the study team will call 911 (or other local emergency number) to request additional medical assistance.

4.0 FOLLOW-UP OF EMERGENCY OR HOSPITALIZATION EVENT

If a worker is taken to a medical facility for treatment related to his/her participation in the study, the Study Director will complete the records by indicating that the worker was treated and released. This includes whether or not the worker refused treatment.

5.0 MEDICAL RECORDS

Medical records will not become part of the research records.

6.0 EXPENSES

Expenses associated with the reasonable and appropriate treatment for illness or injury incurred as a result of participating in this study will be paid for by AEATF II to the extent such expenses are not covered by the worker's own insurance or by a third party.

7.0 INCIDENT REPORTING

7.1 Any medical emergency event will be reported by the Study Director or a member of the study team to the Sponsor (AEATF II) and the Institutional Review Board.

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 AEATF II's SOP *AEATF II 11-D.0 Potential Referable Findings Procedures*.

Effective Date : May 31, 2007

APPROVAL_____	DATE_____
APPROVAL_____	DATE_____
Last Revision Date: 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 AEATF II study as required by FIFRA Section 6(a)(2) .

2.0 DEFINITIONS

2.1 Study Director – The contractor who is appointed by the AEATF II 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 Sponsor's Representative – The AEATF II 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. This subcommittee consists of Task Force members, study director, field contractor and consultants that helped design the study.

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. Protocol Committee chair
c. Task Force Managing Director
d. 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)
e. Task Force counsel

2.5 New findings – This is any potentially adverse data that are generated by AEATF II 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 AEATF II to submit a 6(a)(2) report since the Task Force is not a registrant. However, the AEATF II may make a 6(a)(2) submission on behalf of all Task Force members when the finding involves AEATF II studies and results.

3.3 If AEATF II 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, AEATF II 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 AEATF II reporting on their behalf.

3.6 Any AEATF II 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 AEATF II.

3.7 Regarding the use of surrogate compounds, the AEATF II, 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 AEATF II 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, Sponsor's Representative, 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 AEATF II 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 AEATF II 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 AEATF II 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.