Antimicrobial Exposure Assessment Task Force II (AEATF II)

Aerosol Application Study

VOLUME 4

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

August 4, 2009

TABLE OF CONTENTS

INTRODUCTION

This document presents key AEATF II Standard Operating Procedures (SOPs), specifically from SOP Chapters 4, 5, 6, 7, 8, 10 and 11, that support the study protocol, *A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product using a Pressurized Aerosol Can for Indoor Surface Disinfecting (August 4, 2009).* AEATF II SOPs from Chapters 4, 5, 6, 7, 8, 10 and 11 concern the study reports, quality assurance unit, archives, test, control and reference substances, matrix samples, field study procedures, and human subject management, respectively.

A complete list of AEATF II SOPs (i.e., associated with all SOP Chapters) is provided below. Those being provided in this document, i.e., key SOPs supporting the example study protocol, are indicated as bold text.

Chapter 1 – Administration

AEATF II-1A.1 Organizational Structure
AEATF II-1B.1 Personnel Responsibilities
AEATF II-1C.1 Study Director Selection
AEATF II-1D.1 Inspection of AEATF II Facilities/Data
AEATF II-1E.0 Communication Directives
AEATF II-1F.0 Adverse Effects Reporting

Chapter 2 – Protocols

AEATF II-2A.1 Study Authorization and Approval
AEATF II-2B.1 Study Number Assignment
AEATF II-2C.1 Protocol Design and Preparation

Chapter 3 – Standard Operating Procedures

AEATF II-3A.1 SOP Preparation, Approval, Maintenance, and Distribution
AEATF II-3B.1 Use of AEATF II and Contractor SOPs

Chapter 4 – Study Reports

AEATF II-4A.1 Study Report Preparation
AEATF II-4B.1 Final Report Issuance (RETIRED)

Chapter 5 – Quality Assurance Unit

AEATF II-5A.1 QA Personnel Administration
AEATF II-5B.1 AEATF II QAU Responsibilities
AEATF II-5C.1 QAU Records
AEATF II-5D.1 QA Master Schedule (RETIRED)
AEATF II-5E.1 Protocol and Amendment Review
AEATF II-5F.1 Inspection/Audit Types and Frequency
AEATF II-5G.1 Study Inspections
AEATF II-5H.1 Data Audits
AEATF II-5I.1 Facility Inspections
AEATF II-5J.1 Report Audits

Chapter 11 – Human Subject Management

STANDARD OPERATING PROCEDURE

Chapter 4: Study Reports

AEATF II-4A.1
Study Report Preparation

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

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

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

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

2.0 REQUIRED INFORMATION

2.1 A final report for each protocol-driven study will be prepared by the appropriate personnel (*i.e.*, Study Director). Subcontractors will prepare their individual reports to be appended to the final report.

2.2 A final study report is a complete, comprehensive presentation of experimental methods, analysis and interpretation of results, and conclusions. Interim or phase study reports are limited reports issued during the conduct of a study or at the end of a specific phase of a study (*e.g.*, field phase report) that present only certain portions of the study results. Specifically, per GLP and Ethics Testing requirements, all reports must include, but are not limited to the following (note - all sections listed may not apply to interim/phase reports):

a. Name and address of the facility(s) performing the AEATF

II study and the dates on which the study was initiated and completed, terminated or discontinued.

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

c. Statistical methods employed in analyzing the data.

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

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

f. A description of the methods used.

g. A description of the test system used.

h. A description of the subject recruiting process and informed consent process.

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

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

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

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

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

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

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

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

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

2.3 A DRAFT report will be prepared before the final report. This copy will serve to evaluate the content and accuracy of the report. The draft final report will not be signed by any study personnel. The appropriate contract facility quality assurance unit should review the report before its completion. The draft final report may be audited by the AEATF II Quality Assurance Unit (please refer to SOP AEATF II-5.0.). In addition to undergoing a compliance and accuracy review by the QAU, each draft final report will be subjected to a technical review by members of the AEATF II.

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

3.0 REPORT ORGANIZATION

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

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

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

c. Good Laboratory Practice Compliance Statement

d. QA Statement(s)

e. Certification of Authenticity

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

g. Table of Contents

h. Text

i. Tables

j. Figures

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

l. Raw Data (submitter's option)

3.2 The report will be reviewed by the appropriate AEATF II representatives. After the study is signed by the Study Director and Quality Assurance Units, the AEATF II Sponsor representative will sign the Compliance (submitter) and Data No Confidentiality statements as sponsor representative. It is imperative that the raw data have been transferred to the designated archives at or before this stage, to comply with 40 CFR, Part 160, §160.185(a)(13) and §160.190(a).

3.3 After all necessary signatures are obtained, the report will be forwarded to the AEATF II Technical Committee Chair.

4.0 REPORT FORMATTING

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

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

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

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

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

4.6 Each page, except the cover page, must have a header or footer with the

AEATF II study number and pagination. The header or footer may contain a single line at its bottom edge to set it off from the text. The header or footer text shall be in 10 pt.

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

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

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

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

5.0 ELECTRONIC FORMATS

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

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

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

6.0 FINAL REPORT MODIFICATIONS

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

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

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

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

7.0 REPORT DISTRIBUTION TO AEATF II MEMBER COMPANIES

7.1 Current AEATF II member companies have access to all final reports and data. Written requests for copies of specific reports and data must be directed to the Technical Committee Chair.

8.0 REPORT PRESENTATION TO INDUSTRY AND ACADEMIA

8.1 Any information to be disseminated by the AEATF II to nonmember companies, professional societies, and academic researchers must be approved by the AEATF II Executive Committee, through the Technical Committee Chair.

7.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Revised to include the ethics requirements as set forth in 40 CFR, Part 26 for human subject testing Added information regarding distribution to AEATF II,

		Industry, and Academia Merged portions of SOP AEATF II-4B to this SOP

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit AEATF II-5A.1
QA Personnel Administration

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) establishes guidelines for Antimicrobial Exposure Assessment Task Force II (AEATF II) contract 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
1	7/15/09	Correct name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit — AEATF II-5B.1
AEATF II QAU Responsibilities

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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.

1.2 As required by the GLPs, the test facility is responsible for assuring the quality assurance for a study. The AEATF II QAU will perform and/or supplement the test facility QAU if needed, and perform oversight at the request and discretion of the task force.

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, 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 if requested by the task force are to:

a. Maintain copies (hard copy or electronic) 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.

b. 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.

c. 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.

d. Provide reports of findings from inspections of individual study inspections/audits to the Study Director(s) and AEATF II management.

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

f. 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.

g. 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.

h. Conduct periodic study inspections performed by contract facilities.

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

j. 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.

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

l. 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.

m. Assist with regulatory agency inspections of the AEATF II studies and facilities if requested.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Added section 1.2 Deleted requirement to maintain a master schedule Allow for copies of protocols, amendments and standard operating procedures be either hard copy or electronic

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5C.1 QAU Records

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 for inspections done by the AEATF II QAU

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
1	7/15/09	Corrected name of task force on side bar Specify audit logs only maintained for inspections done by the AEATF II QAU in section 2.2.d.

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5E.1 Protocol and Amendment Review

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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, 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 for consideration.

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

2.4. The Study Director shall make all intentional or planned changes to the approved protocol in writing as protocol amendments. If requested by the Task Force, 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
1	7/15/09	Corrected name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5F.1 Inspection/Audit Types and Frequency

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 Task Force 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, 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
1	7/15/09	Corrected name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5G.1
Study Inspections

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 and contractor QAU.

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	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Section 2.1 – change that inspections will be scheduled with the Study Director and contractor QAU

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5H.1 Data Audits

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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
1	7/15/09	Corrected name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5I.1
Facility Inspections

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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
1	7/15/09	Corrected name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit

AEATF II-5J.1 Report Audits

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

T ch i l

Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 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, the QAU 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 (sponsor representative) and the Study Director(s).

6.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Deleted reference to Study Team Leader

STANDARD OPERATING PROCEDURE

Chapter 5: Quality Assurance Unit AEATF II-5K.1
Inspection Report Distribution

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the procedure that the Antimicrobial Exposure Assessment Task Force (AEATF II) Quality Assurance Unit (QAU) will follow when raw data audit, study report audit, facility inspection, and field-site inspection reports are written and distributed to the appropriate AEATF II personnel. The routing of inspection reports for signature and review is described.

2.0 INSPECTION REPORTING PROCEDURES

2.1 Significant GLP, protocol, or SOP deviations, as determined by the QAU, will be reported/communicated (e-mail, phone call, etc) to the Study Director and Task Force.

2.2 The original, signed audit/inspection report will be sent to the Study Director or contractor/P.I. for a formal response. Copies (includes e-mailed electronic copies) of the report will be issued to the Study Director and Task Force and other designated AEATF II personnel (if necessary). Responses are requested to be returned within 15 working days.

2.3 Upon receipt of the responses, actions taken will be reported to the Study Director and Task Force. The Study Director will acknowledge receipt of the audit report by signing the report where indicated. The report will then be sent to other AEATF II personnel for additional signatures.

2.4 Once all required personnel have signed the audit report it will be returned to the QAU for subsequent archiving. Copies of completed inspection reports may be distributed to AEATF II personnel as needed.

2.5 The following personnel are required to sign the inspection findings audit report issued by the AEATF II QAU:

a. AEATF II QAU

b. Study Director

c. Study Director Management

d. AEATF II Management (if necessary)

e. Contractor (Principal Investigator/Management), if necessary

2.6 A summary of study inspection findings may be circulated to the AEATF II members. This summary may be prepared by the QAU and circulated through the AEATF II members on a monthly, or as needed, basis.

2.7 All AEATF II QAU Inspection Reports are confidential and will not be distributed to unauthorized personnel. Reports will be available to any Task Force representative upon request.

2.8 Final Report audit findings will be issued directly to the Study Director for comment and correction.

2.9 All inspection reports should be returned to the AEATF II QAU within fifteen days of receipt. All inspection reports will be maintained by the AEATF II QAU.

3.0 FACILITY INSPECTIONS

3.1 Facility inspections include any general inspection of a testing facility. Inspection reports will be generated and signed/dated by the QAU. Facility inspection reports will be distributed as described in section 2.0 of this SOP.

3.2 Inspection reports should be addressed and signed by the appropriate contractor personnel and returned to the QAU within 25 working days.

3.3 Facility inspections may be used by the AEATF II to decide if a facility is capable of conducting a GLP study for the AEATF II.

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Deleted reference to Study Team Leader

STANDARD OPERATING PROCEDURE

Chapter 6: Archives

AEATF II-6A.1
Storage of Raw Data

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how and where raw data are to be stored by the designated Antimicrobial Exposure Assessment Task Force II (AEATF II) archive facility.

2.0 AEATF II GENERAL ARCHIVING PROCEDURES

2.1 All raw data, documentation, protocols, correspondence collected during any AEATF II study will be reviewed by the Study Director or authorized personnel and submitted to the designated AEATF II archive facility. The Study Director will assure that this material is placed into temporary or permanent archive storage before study completion.

2.2 Certified copies of all raw data (refer to SOP AEATF II-9H.) should be sent to the AEATF II Study Director or Quality Assurance Unit before the transfer of original data to the designated archives. Once receipt of the copies has been verified, the original data may be sent directly to the archives. Under no circumstances, should the original data and certified copies be shipped simultaneously.

2.3 Non-study specific raw data (*e.g.*, facility records) and copies of raw data from completed AEATF II studies may be maintained in the contracted field or analytical facilities' archive, or if necessary, by designated AEATF II personnel. Original raw data should be sent directly to the permanent AEATF II archive facility.

2.4 Any temporary archive should be designed for orderly storage and expedient retrieval of all raw data, documentation, protocols, and final reports. Data should be kept in a secured area under ambient environmental conditions. Appropriate contractor SOPs will be followed.

2.5 Quality assurance documents will be **maintained separately** by the AEATF II Quality Assurance Unit (QAU). QA documents will be transferred to the designated permanent archive facility upon completion of AEATF II activities.

2.6 Once placed in permanent archival storage, all requests for data must be directed through the Task Force Manager. AEATF II technical personnel should **not** directly contact the archiving facility unless otherwise stated. (Please refer to SOP AEATF II-6B.)

3.0 AEATF II DATA STORAGE REQUIREMENTS

3.1 Conditions of storage are set up to reduce deterioration of the documents and provide for their security according to the EPA GLP requirements during their retention and the nature of the documents.

3.2 Any machine generated data that will degrade with time, such as fading of thermal paper, will be photocopied and certified as “copy(ies) of the original(s)” before being archived. *These copies are in addition to the complete set of certified copies to be prepared.*

3.3 Direct access to the archives for placing or retrieving data is limited to the designated Archivist or alternate.

3.4 Raw data, documentation, and other study records are to be retained in the AEATF II archives for, at least, the period during which the Antimicrobial Exposure Assessment Task Force II or other registrant holds any research or marketing permit to which the study is pertinent.

3.5 Original raw data may only be removed from the archive area when copies are needed, personnel wish to review data on-site, or data are being transferred to another location (please refer to SOP AEATF II-6B.).

3.6 All electronic and optical storage media will be retained as described above. Electronic and optical media may be defined as raw data, depending upon the type of data contained on electronic media (*e.g.,* video tapes, CD-ROM, original data collected onto a floppy diskette, audio tapes).

4.0 CONTRACTOR TO AEATF II ARCHIVES: DATA TRANSFER PROCEDURES

4.1 Upon receipt and acceptance of the certified copies of the raw data by the AEATF II Study Director or QAU, the contractor will be directed to send the original raw data to the designated archive personnel.

4.2 All original data must be sent to the AEATF II Archives from the contracted facilities by registered or certified mail, or by overnight courier (*i.e.,* Federal Express, UPS, *etc. . .*) with appropriate transmittal forms or chain of custody forms.

4.3 Data packages will be addressed to the attention of the AEATF II Archivist.

4.4 Data sets, as received at the archives, will be inspected for shipment damage. Any chain of custody forms will be completed and distributed as necessary. Copies or originals of such transmittal forms will be maintained in the archives.

4.5 Contents of the data package will be compared against the required chain of custody or contents list, as appropriate.

4.6 Appropriate Archive Facility SOPs will be followed for logging-in, handling, and storing archived materials.

5.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar

STANDARD OPERATING PROCEDURE

Chapter 7: Test, Control, and Reference Substances

AEATF II-7A.1 Test, Control, and Reference Substances Receipt and Shipment

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) presents the minimum requirements for the inspection, receipt and shipment of Antimicrobial Exposure Assessment Task Force (AEATF II) test, reference, and/or control substances by contracted performing laboratories.

1.2 This SOP is also intended as a guide for assessing the SOPs available at the contracted facilities, and shall be followed only when the contracted facility SOP is unacceptable. The SOP(s) followed will be documented in the study file.

2.0 TEST, CONTROL AND REFERENCE SUBSTANCE INSPECTION

2.1 The appropriate field and analytical facilities should have personnel who are responsible for all test, reference, and control substances used in exposure studies and analytical portions of all AEATF II studies.

2.2 The appropriate personnel should inspect each test, control, or reference substance shipment received for at least the following conditions:

a. Physical damage to the packaging.

b. Loss of substance (*i.e.*, half-full or empty containers).

c. Possible contamination of the substances (*i.e.*, unusual color, particulates, physical change).

d. Proper use of special shipping procedures designed to preserve the integrity of the substance; *i.e.*, substances shipped frozen should be frozen upon receipt.

2.3 Test, control and reference substance documentation submitted with the shipment should be examined and must correspond with the substances received. If labeling is unclear, inadequate, or nonexistent, the Study Director, or designated personnel shall be notified. The shipping facility should be contacted for clarification. The specific substance should be returned if it cannot be properly identified.

3.0 LOG-IN, TRANSFER, AND RETURN TEST, CONTROL AND REFERENCE SUBSTANCES

3.1 Test, control and reference substances should be checked in as they are received. Pertinent information including, but not limited to, receipt date, substance identification, amount received, carrier (if applicable), and shipment origination should be recorded in the contractor's receipt and inventory log, as appropriate.

3.2 The test, control and reference substance information should be entered into the contractor's facility's receipt log or appropriate document, which should include the receipt date, substance(s) name or ID, lot number, sender/ manufacturer, and amount received. The substances should be stored in the appropriate chemical storage area.

3.3 When a test, control and/or reference substance is sent to the field test sites the following information, as a minimum, should be recorded by the sender on a shipping log: the date sent, test substance name/ID, lot/batch number, amount shipped and destination. All appropriate shipping receipts will be retained and kept in the appropriate study file.

3.4 Should any remaining test substances be returned from the field test site to the AEATF II contractor, an appropriate facility will be designated to receive the unused test substance. The field contractors will be notified of which facility, and the responsible person will receive the incoming substance(s). The amount of material will be estimated [if unable to determine accurately] and indicated as such. These procedures will be followed until all of the test, control and reference substance(s) is (are) used, stored, or properly disposed of, per the facility's or appropriate SOPs.

4.0 SHIPPING TEST, CONTROL AND REFERENCE SUBSTANCES

4.1 The Study Director, Principal Investigator, or other designee will prepare the packages according to Department of Transportation (DOT) or IATA regulations, complete a packing list or chain of custody for chemical shipments, include an MSDS (if available), and ship them to the appropriate test sites.

4.2 The amount of substance to be shipped, the toxicity of the substance (oral LD_{50}, inhalation, and dermal toxicity), whether it is flammable or corrosive, and the common or chemical family name will be determined before shipment.

4.3 Proper packing methods, materials, and outer labeling will be determined and utilized.

4.4 When the substance(s) has been packed and is ready for shipment, the package and required paperwork will be reviewed by a second designated party. If any items are missing or incorrect, the faults will be corrected.

4.5 An appropriate shipping company will carry the test substance according to appropriate DOT or IATA regulations. No test substance will be sent via U.S. mail. Flammable materials **should not** be sent via air.

4.6 The recipient must be notified that the chemical is *en route*.

4.7 Appropriate contractor SOPs shall be followed for all chemical shipments made by each facility, unless otherwise noted.

5.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Delete reference to Study Team Leader Chapter title and SOP name modified

STANDARD OPERATING PROCEDURE

Chapter 7: Test, Control, and Reference Substances

AEATF II-7B.1 Test, Control, and Reference Substances Labeling

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides guidelines on how test, reference and control substances [referred to as "Test Substance" in this SOP] should be labeled once they are received by the designated test sites or performing laboratories.

1.2 This SOP is also intended as a guide for assessing the SOPs available at the contracted facilities, and will be followed only when the contracted facility SOP is unacceptable. The SOP followed will be documented in the study file.

2.0 LABELING

2.1 Every container of test, reference or control substance must have certain information directly attached to the container, even if it has been transferred or repackaged. Every container must be appropriately labeled and be easily identifiable at all times. The following type of labeling is recommended.

2.2 **Test Substance Label** - Test substance containers that are used for all AEATF II studies will be labeled with the following information, as per 40 CFR, Part 160, §160.105(c), and sponsor requirements:

a. Test substance name

b. CAS number or code number

c. batch number

d. expiration date (if applicable)

e. storage conditions (minimum $^{and}/_{or}$ maximum temp. preferred)

2.3 Storage containers are to be assigned to a particular test substance until properly disposed of. All test substance containers will be retained until the final report is complete, unless an exemption has been granted by the EPA.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Chapter title and SOP name modified

STANDARD OPERATING PROCEDURE

Chapter 7: Test, Control, and Reference Substances

AEATF II-7C.1 Disposal of Test, Control, and Reference Substances

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how test, control, and reference substances are to be disposed of by the contract facilities, the documentation required at the completion of an AEATF II study, and the AEATF II policy on container retention.

2.0 PROCEDURE

2.1 A reserve sample from each batch of test, control, and reference substance will be retained from each study more than four weeks in duration [EPA GLPs §160.105 (d)]. Storage time is only to be as long as the sample affords evaluation. Samples may only be discarded with written permission from the Study Director.

2.2 Samples of test, control, and reference substances that have been archived by AEATF II or stored at the facilities of the contract lab by the Study Director may be discarded after acceptance of the final report by the AEATF II. Written authorization must be obtained from the AEATF II Study Director or designate prior to disposal of any of the test, control, or reference substances.

2.3 Disposition of all substances must be recorded on an appropriate inventory log.

2.4 If the AEATF II study was conducted using a registered or experimental material from an outside source or AEATF II member company, the Study Director is responsible for assuring that the remaining test, reference, and control substances are returned to the supplier or manufacturer, if

requested, or disposed of. Written authorization must be maintained in the AEATF II study file upon the return or disposal of the test, control, or reference substances. Refer to SOP AEATF II-7A for shipping guidelines or follow the appropriate contract facility SOP(s).

2.5 Once Study Director approval has been obtained, the contract laboratories or field test sites will properly dispose of all materials per federal, state and local regulations.

3.0 CONTAINER RETENTION

3.1 Label requirements for container handling and disposal after use (*e.g.*, triple rinsing before disposal, or special conditions for disposal) will be considered part of the handling exposure period for each AEATF II study. Containers will only be retained by the designated facilities after handling activities have been completed.

3.2 All original test, control and reference substance containers used in each AEATF II study **will be retained** in compliance with the GLPs, unless the EPA grants an exemption. The location of the containers will be documented in the appropriate study file.

3.3 If a waiver for container retention is granted, then empty containers will not be retained; however, the following documentation must be maintained in the study data files:

a. Information of shipments pertaining to each container leaving the storage site (*e.g.*, shipping requests, bills of lading, carrier bills, monthly inventories, *etc. . .*).

b. Test substance receipt records at each testing facility or field site.

c. Complete usage logs of material taken from each container.

d. A record of the final destination of the container(s), including the place and date of disposal or reclaiming, and any appropriate receipts.

3.4 In addition, the AEATF II will be responsible for the following documentation:

a. A statement included in the final report indicating the compliance or noncompliance required by 40 CFR 160.12 describing that this exception to Good Laboratory Practices is in accordance with the conditions provided under the exemption.

b. An inventory of empty containers before disposal, including sufficient information to uniquely identify containers; the inventory will be periodically updated to indicate the arrival and disposal of empty containers. NOTE: this inventory is considered raw data.

c. The identity of the locations of each facility where test, control, and reference substances are stored; where empty containers are stored prior to disposal; where records of use, shipment, and disposal of containers are maintained; and the test, control, and reference substances were used in each study.

3.5 Individual study protocols will provide information regarding any GLP exemptions. Exemptions may be granted, based upon the design of the proposed studies, the length of time per study, and amount of material to be used.

3.6 Should the EPA request an inspection of the AEATF II studies, the EPA will be notified - within two (2) weeks of the inspection - of the locations described in 3.4 c. This information will be sent to:

Rick Colbert, Director
Agriculture and Ecosystems Division (2225A)
Office of Compliance - USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460
202-564-2320
colbert.richard@epa.gov

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Add name and address of the EPA contact. Correct numbering format. Chapter title and SOP name modified

STANDARD OPERATING PROCEDURE

Chapter 7: Test, Control, and Reference Substances

AEATF II-7D.1 Test, Control, and Reference Substances Chain of Custody

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how test, control, and reference substances will be identified and tracked for the Antimicrobial Exposure Assessment Task Force (AEATF II) during scheduled studies.

2.0 PROCEDURE

2.1 All test, control, and reference substances will be shipped and handled according to SOP AEATF II-7A.

2.2 Each test, control, and reference substance will be identified according to SOP AEATF II-7B.

2.3 A chain of custody (COC) form will accompany each shipment of a test substance after receipt from the supplier. The Study Director or designee will initialize a COC form upon receipt of any compound.

2.4 Attachment 7-D-1 is an example of an acceptable chain of custody form.

2.5 The form contains information on three phases of handling of the test, control, and reference substance: initial shipment to field site(s), usage information on study, and disposal/return information upon trial completion. Each section must be addressed appropriately, and in a timely manner.

2.6 A new form must be used for additional shipments of the test, control, and reference substance(s) for each study, or for the transfer of these

substance(s) to another test site, or for the use on another AEATF II study.

2.7 Copies of partially completed and fully completed forms should be sent to the Study Monitor upon completion of each stage of the study. The Study Director will maintain the original form as raw data.

2.8 The completed form(s) will be placed in the study file for archiving upon completion of the study.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Chapter title and SOP name modified

Attachment 7-D-1

Example Test, Control, or Reference Substance Chain of Custody Form

Antimicrobial Exposure Assessment Task Force
Chain of Custody

AEATF II Study No.:	Contents:	Priority:	Page:
Ship To:		Ship From:	
Shipper/Carrier:	Airbill No.:	Date Shipped/Initials:	
Comments:			

Shipped:	Description of Materials Sent:	Received:

Date Received:	Received By/Company:
Condition Received:	

American Chemistry Council - Antimicrobial Exposure Assessment Task Force II

STANDARD OPERATING PROCEDURE

Chapter 7: Test, Control, and Reference Substances

AEATF II-7E.1 Test and Reference Substance Analysis

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how test and reference substances will be characterized and documented for all Antimicrobial Exposure Assessment Task Force II (AEATF II) studies.

1.2 This SOP explains the concept of test and reference substance use in AEATF II exposure studies and describe the specific analyses to be determined on AEATF II test and references substances.

2.0 TEST SUBSTANCE DEFINITION AND USAGE

2.1 The USEPA defines "test substance" {§ 160.3 (7)} as "…a substance or mixture … added to a test system in a study, which…is the subject of an application for a research or marketing permit, …or, … a substance used in a study to assist in characterizing the toxicity, metabolism, or other characteristics..."

2.2 In respect to this definition, the AEATF II use of a "test substance" does not fall within this scope. The AEATF II is utilizing commercially available, registered products to provide an analytical marker in the determination of exposure routes to antimicrobial workers mixing, loading, $^{and}/_{or}$ applying biocides under typical working conditions.

2.3 The term "test substance" is used by the AEATF II to describe all registered biocides that may be used on an AEATF II study for the sole purpose of providing adequate detectable residues in the determination of an antimicrobial pesticide exposure profile.

3.0 ANALYTICAL INFORMATION AND DOCUMENTATION

3.1 The AEATF II will obtain a GLP determination of the percent active ingredient for each batch or lot of formulated test substance and a GLP purity analysis on all analytical reference substances used in an AEATF II study if the manufacturer does not provide it. These analyses can be obtained prior to or concurrently with the field-testing.

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Chapter title modified

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8A.2
Whole Body Sampling – Inner, Outer, and Sock Dosimeters

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

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

1.2 AEATF II studies may use whole body inner, whole body outer, and sock dosimeters. Whole body inner dosimeters, a 100% cotton union suit, are worn over the worker's own undergarments and directly underneath specified work clothing. Whole body outer dosimeters, a long sleeve shirt and long pants, are worn directly over the inner dosimeter. Sock dosimeters may include an inner sock dosimeter worn under the worker's own outer sock, or an inner sock dosimeter worn under an outer sock dosimeter. The dosimeters to be used will be specified in the study protocol. Whole body outer and outer sock dosimeters will be worn under personal protective equipment (PPE) as appropriate.

2.0 Materials Required

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

a. 100% cotton, white, long underwear (inner dosimeter), with long sleeves, round neckline and no elastic. Inner dosimeters will be pre-washed before use according to AEATF SOP 8H, unless otherwise directed by the protocol.

b. 100% cotton long-sleeved work shirt, and 100% cotton long pants (outer dosimeter).

c. 100% cotton, lightweight socks, ankle high. Sock dosimeters will be pre-washed before use according to AEATF SOP 8H, unless otherwise directed by the protocol.

d. Disposable gloves (e.g., latex)

e. Scissors

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

g. Aluminum foil

h. Sample containers (e.g., re-closable bags, glass jars)

i. Disposable paper or plastic drop cloths

j. Clothes hangers (optional)

h. Cooler with dry ice, or freezer

3.0 USE OF WHOLE BODY AND SOCK DOSIMETERS

3.1 The study protocol describes which dosimeters are to be used in each study. Participating workers will be provided with new, protocol described, inner, outer and sock dosimeters prior to initiation of the monitoring event.

3.2 Each worker will be allowed to put on the dosimeters in a clean “privacy area.” A researcher of the same sex as the worker will accompany the worker to provide instructions and assist the worker. Disposable gloves should be worn by the worker and the researcher when putting on dosimeters to minimize contamination.

3.3 Inner Dosimeter: The inner dosimeter:

a. Shall be worn over the workers' own undergarments and directly under the outer dosimeter (or outer work clothing if no outer dosimeter is used).

b. Shall be appropriately fitted to the worker. The inner dosimeter should not extend beyond the outer dosimeter at the wrists or ankles. If necessary shorten the inner dosimeter legs by cutting off the excess, and pull up the inner dosimeter arms so the inner dosimeter will not extend beyond the outer dosimeter during the performance of the activity.

c. Shall be underneath the sock(s) at the pant leg.

d. Should generally be over any lightweight clothing layer worn for warmth. Cold weather procedures should be discussed with the Study Director prior to exposure monitoring activities.

3.4 Outer Dosimeter: The outer dosimeter:

a. Shall be worn directly over the inner dosimeter.

b. Shall be appropriately fitted to the worker. If necessary, the pant leg may be shortened so it does not contact the floor during typical movement expected during the ME. Do not shorten the pant leg more than typical for the work clothing style as excessively short pant legs may expose the underlying sock or inner dosimeter in an atypical fashion.

c. Shall have buttons (front, sleeve, collar) buttoned as would be typical for the worker and clothing style. The shirt should be tucked into the pants.

3.5 Sock Dosimeter: The protocol may specify the use of inner sock dosimeters, or both inner and outer sock dosimeters:

a. Inner sock dosimeters shall be worn directly under the worker's own socks, or directly under the outer sock dosimeter. Inner sock dosimeters will generally be worn on bare feet, though a liner or other sock article beneath the inner sock dosimeter shall be permitted if the worker prefers.

b. Outer sock dosimeters are worn directly over the inner sock dosimeter, and shall be the outermost layer inside footwear.

c. Inner sock dosimeters are worn over the inner dosimeter at the pant leg. Outer sock dosimeters are worn over the inner sock dosimeters and under the outer dosimeter at the pant leg.

4.0 COLLECTION PROCEDURE

4.1 After completion of the monitoring event, the worker will return to the privacy area. A researcher of the same sex as the worker will accompany the worker in the privacy area to collect hand wash and face/neck wipe samples, and assist with removal and collection of dosimeter samples.

4.2 Where high pesticide residues on footwear is likely, footwear may be removed (with researcher assistance) outside the privacy area to minimize introduction of potentially high residues in the privacy area. Removal must be accomplished in a way which prevents accidental contamination of other workers, the study team or visitors, and does not contaminate other samples (e.g., sock dosimeters) en route to the privacy area. A clearly designated seating area with coverings disposed between workers may be used to protect the footwear removal area. A clean walking path can be created with disposable material (changed after each worker), or impervious booties may be worn on the feet. The researcher must evaluate potential for unintended cross contamination (e.g., inside of outer pant leg contaminated by shoes now contacts exposed sock or inner dosimeter after shoe removal) and employ appropriate measures (e.g., roll back and secure pant leg) on a case-by-case basis. The researcher should also consider the potential for residue transfer and loss to inside bootie surfaces.

4.3 The sequence for post monitoring event procedures is:

a. Remove the air sample pump and collect air sample.

b. Collect the hand wash sample.

c. Collect the face/neck wipe sample.

d. Remove shoes (if not removed as described in 4.2).

e. Remove socks and/or sock dosimeters.

f. Remove outer dosimeter (or outer work clothing).

g. Remove inner dosimeter.

4.4 Removal of the air sample pump and collection of the air sampling tube, the hand wash sample, and the face/neck wipe sample are covered in separate SOPs.

4.5 The researcher will wear disposable gloves throughout the sample collection process. Gloves shall be changed between handling of each clothing article (e.g., PPE, air sample pump, jacket, shoes, socks, sock dosimeters, outer dosimeters, inner dosimeters), and after each sample is collected.

4.6 Footwear: With the worker seated on a plastic, paper or foil drop cloth:

a. Fold the pant leg back on itself (but not beyond the knee) so the outer sock is exposed.

b. Remove the footwear, being careful not to touch the socks or dosimeters, and place footwear where it will not contaminate the privacy area or dosimeter samples.

c. Remove and dispose of gloves.

4.7 Socks and Sock Dosimeter: With the worker still seated and the pant leg folded back on itself as described above:

a. Remove the outer sock layer, by grabbing opposite sides of the top of the sock and peel the sock back on itself as it is removed. The sock will end up “inside out.” If the outer sock layer is a sock dosimeter, place socks directly on foil wrap or in the sample container.

b. Change gloves.

c. Remove the inner sock layer (if any) in the same manner.

d. Discard gloves.

4.8 Outer Dosimeter: There are several ways to remove the outer dosimeter, and the “best” method will depend on the worker’s age, body size, and comfort level with assistance undressing, as well as collection preference

of the particular researcher. A specific procedure is therefore not mandated, but the following shall be observed to prevent cross-contamination when removing the garments and collecting outer dosimeter samples:

a. Have the worker stand on clean plastic, paper or foil drop cloth large enough to prevent contact of dosimeter with floor surface. Arrange a plastic, foil or paper covered seating surface where the worker can sit without leaving the drop cloth.

b. Clearly explain to the worker the procedure to be used for removal of the dosimeter.

c. Remove the outer garments in a manner which minimizes the potential for cross contamination. Handle the garments as little as possible, while adequately protecting them from contact with other surfaces.

d. Hang the garments on a clothes hanger or otherwise support it away from contact with other surfaces until processed. If dosimeters from more than one ME will be removed before processing, identify the dosimeter without altering the dosimeter (e.g., clothespin with ME number on the hanger).

e. To process, ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each dosimeter.

f. Remove and discard any buttons from clothing.

g. If the protocol specifies collection of upper and lower body, no sectioning is required. Continue with Step J below.

h. Cut the shirt into four (4) sections using the six section graphic of Attachment A as a guide.

    1. Right & left upper arms (shoulder to elbow).
    2. Right & left lower arms (elbow to cuff).
    3. Front torso (cut at side seams).
    4. Rear torso (cut at side seams).

i. Cut the pants into two (2) sections using the six section graphic of Attachment A as a guide.

1. Right & left upper legs (waist to knee).
2. Right & left lower legs (knee to cuff).

j. Place each section of clothing directly on a separate piece of aluminum foil large enough to completely wrap the section. Wrap foil around the cloth, ensuring the edges are folded together to prevent the loss of any residues. Place a label on the aluminum foil, and place the foil wrap in a labeled re-closable bag. Alternately, the section may be placed directly in a separate suitable glass sample jar. Do not allow the section to contact any surface before placement on the foil or sample jar.

k. Remove and discard gloves.

4.9 Inner Dosimeter. There are several ways to remove the inner dosimeter, and the "best" method will depend on the worker's age, body size, and comfort level with assistance undressing, as well as collection preference of the particular researcher. A specific procedure is therefore not mandated, but the following shall be observed to prevent cross-contamination when removing the garments and collecting inner dosimeter samples. If an outer dosimeter is not used, remove outer clothing as described for the outer dosimeter above.

a. Have the worker stand on clean plastic, paper or foil drop cloth large enough to prevent contact of dosimeter with floor surface. Arrange a plastic, foil or paper covered seating surface where the worker can sit without leaving the drop cloth.

b. Clearly explain to the worker the procedure to be used for removal of the dosimeter.

c. Remove the inner dosimeter in a manner which minimizes the potential for cross-contamination. Handle the garment as little as possible, while adequately protecting it from contact with other surfaces.

d. Hang the garment on a clothes hanger or otherwise support it away from contact with other surfaces until processed. If dosimeters from more than one ME will be removed before processing, identify the dosimeter without altering the dosimeter (e.g., clothespin with ME number on the hanger).

e. To process, ensure that the scissors have been decontaminated with solvent prior to use. Scissors must be cleaned between each dosimeter.

f. Remove and discard any buttons from clothing.

g. If the protocol specifies collection of upper and lower body, continue with Step H. If the protocol specifies collection of dosimeters in six sections, skip to Step I.

h. Cut the inner dosimeter into two (2) sections

1. Lower Body (all sections below the waist*)
2. Upper Body (all sections above the waist*)

*Cut just below the second button from the bottom to separate the upper body from the lower body. Refer to Attachment A.

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

1. Right & left upper arms (shoulder to elbow)
2. Right & left lower arms (elbow to cuff)
3. Front torso (above the waist*)
4. Rear torso (above the waist*)
5. Right & left upper legs (waist to knee)
6. Right and left lower legs (knee to cuff)

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

j. Place each section of dosimeter directly on a separate piece of aluminum foil large enough to completely wrap the section. Wrap foil around the cloth, ensuring the edges are folded together to prevent the loss of any residues. Place a label on the aluminum foil, and place the foil wrap in a labeled re-closable bag. Alternately, the section may be placed directly in a separate suitable glass sample jar. Do not allow the section to contact any surface before placement on the foil or sample jar.

k. Remove and discard gloves.

5.0 SAMPLING INTERVALS

5.1 Inner, outer and sock dosimeters will be collected at the end of each monitoring event, unless otherwise instructed by the protocol.

6.0 FIELD STORAGE

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

7.0 ANALYSIS OF INNER DOSIMETER SAMPLES

7.1 Where used and unless otherwise specified in the protocol, whole body outer dosimeters and outer sock dosimeters will be analyzed. Whole body inner and inner sock dosimeters will not be analyzed unless analyte(s), above the limit of quantitation (LOQ), as defined in the analytical method for the study, are found in the corresponding outer dosimeter. For example, in studies where whole body dosimeters are sectioned in six parts, if the lower arm outer dosimeter for a particular monitoring event (ME) shows analytes above the LOQ, the lower arm inner dosimeter for that ME will be analyzed. If the rear torso outer dosimeter for a particular ME does not shows analyte(s) above the LOQ, the rear torso inner dosimeter for the ME will not be analyzed. Inner dosimeter samples not analyzed shall be maintained in GLP compliant storage under frozen conditions until the Study Director provides instructions for 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.
2	7/15/09	Correct name of task force on side bar Combined with SOP AEATF II 8G (outer dosimeters) and added sock dosimeters Editorial changes and clarifications throughout Removed the reference to Ziploc bags

SOP AEATF II-8A.2

Attachment A

Diagram of Inner Dosimeter

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8B.3
Hand Wash Samples

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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. A suitable detergent or solvent (e.g. Aerosol® OT, isopropanol, ethanol) 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 for storage of the hand wash sample.

f. Re-closable plastic bags, glass jars or plastic bottles suitable for short term (< 48 hrs) storage of bulk hand wash solution prior to use.

g. Disposable gloves (e.g. latex, nitrile).

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

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

j. Paper towels.

k. Cooler with dry ice or freezer.

l. Re-closable plastic bags.

3.0 HAND WASH SOLUTION PREPARATION

3.1 Unless otherwise specified by the protocol, the desired hand wash solution is 0.01% v/v Aerosol® OT (AOT) in distilled water. Aerosol OT solution is not to be used with quaternary ammonium biocides (quats). For quats, a solution of 50% ethanol or isopropanol in distilled water will be used. Each hand wash will require 500 mL of hand wash solution. Sufficient quantities should be made for the projected number of hand washes to be collected within the allowable shelf life of the prepared solution.

3.2 Pipette an appropriate amount of detergent or solvent into distilled water to make the desired solution. For example, 3.8 mL of 10% AOT in one gallon of distilled water or 4 mL of 10% AOT in 4.0 liters of distilled water will make the desired 0.01% AOT hand wash solution. Document the brand of water (if store bought) and where it was purchased. If the water is not store bought, document the source.

3.3 Store the bulk hand wash solution in glass jars, plastic bags, water jugs or suitable container(s). The shelf life of the 0.01% Aerosol® OT or 50% ethanol or isopropanol solution at room temperature is 48 hours. Re-closable plastic bags, glass bottles, or plastic bottles (e.g., Nalgene) may also be used for short-term storage of AOT solution aliquots to facilitate collecting hand wash samples in the field

4.0 WASHING PROCEDURE

4.1 Unless otherwise specified by the protocol, prior to each monitoring event, the worker will have their hands washed by a researcher according

to the procedure outlined in this SOP. This will serve to clean the hands as well as provide some practice for the hand wash procedure that will be used in the study. The rinsate will be discarded.

4.2 Hand wash samples will be collected in a clean area. The worker will remove any PPE prior to the hand wash procedure.

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

4.4 Have the worker place both hands over a bowl, and pour approximately 400 mL of the hand wash solution over the worker's hands for approximately 30 seconds. The worker will scrub their hands while the wash solution is slowly poured over the workers' hands.

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

4.6 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.

4.7 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 re-closable bags for shipping.

4.8 Clean the bowl with solvent between workers. For alcohol based hand wash solutions, use an alcohol solvent (e.g., ethanol, methanol or isopropanol). For other hand wash solutions, acetone may also be used. 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 prior to the monitoring event as described in 4.1.

5.2 Hand wash samples should be collected whenever the worker would normally wash their hands; (*i.e.*, before eating, before using the bathroom, *etc.*) unless specified differently in the study protocol.

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 arranged and documented 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 4.6 that jars be placed in Ziploc bags for shipping.
2	3/7/08	Update Anionic detergent solution in section 2.1.
3	7/15/09	Correct name of task force on side bar Allow the use of glass jars and plastic bottles for short term storage of bulk AOT solution. Provide example of dilution procedure. Allow pre monitoring event hand wash by hand wash procedure or with soap and water, as specified by protocol. Specify the use of an alcohol solvent for alcohol based hand wash solutions. Remove reference to Ziploc brand re-closable bags. Various edits for clarity.

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8C.2
Dermal Face/Neck Wipe Samples

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 pads (8 ply, 4" x 4" / 10 cm x 10 cm)

b. A suitable face/neck wipe solution (e.g., Aerosol® OT, isopropanol or ethanol in distilled water), prepared and stored as described in SOP AEATF 8B. Unless otherwise specified by the protocol, the same solution used for hand washes in a particular study shall be used for the face/neck wipes.

c. Syringe or pipette

d. Disposable gloves (e.g., latex, nitrile)

e. Aluminum foil

f. Re-closable bags or glass jars with Teflon-lined lids

g. Cooler with dry ice or a freezer

3.0 SAMPLING PROCEDURE

3.1 The field personnel collecting samples will wear clean, disposable gloves while collecting these dermal samples. Open the gauze pad package and separate the pads (two pads of 8 ply each). Use one 8 ply pad for each of the two wipes that will constitute a single sample.

3.2 Dispense approximately 4 mL of the face wipe solution on the gauze pad with the syringe or pipette (or other appropriate means of moistening the pad).

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

3.4 Thoroughly wipe the worker's face/neck (front & back) with the moistened pad, and place the pad on a small piece of aluminum foil (if using a re-closable bag as sample container) or directly into a glass jar.

3.5 Repeat steps 3.2 and 3.4 again, for a total of two dermal wipes per sample, placing the second pad on the same aluminum foil or in the same jar as the first pad. If using aluminum foil and re-closable bags, wrap both pads in the foil, place the foil wrap in a pre-labeled bag and place the sample in frozen storage. If using a glass jar; close the top, and place the jar in frozen storage. If a jar is used, place each jar into a re-closable bag for shipping.

4.0 SAMPLING INTERVALS

4.1 Unless otherwise specified by the protocol, prior to each monitoring event (ME) the worker will have their face and neck wiped by a researcher according to the procedure outlined in this SOP. This will serve to clean the face and neck as well as provide some practice for the face and neck wipe procedure that will be used in the study. The face and neck wipe will be discarded.

4.2 A face/neck wipe sample will be collected prior to eating, and at other times during the ME if/as directed by the study protocol.

4.3 After the ME is complete, a face/neck wipe sample will be collected from each worker after the hand wash sample, and before removal of whole body dosimeters. All face/neck wipes for a particular ME will be combined, resulting in one sample per ME. If using glass jars for the sample, all samples for a particular ME will be placed in the same jar. If using foil wraps, a separate foil wrap may be used for each face/neck wipe, with all foil wraps placed in the same labeled sample container (e.g., re-closable plastic bag). If more than two face/neck wipes are

performed for a particular ME (more than 4 pads/sample), the laboratory must be notified as to the total number of pads 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 or a portable freezer is not available, the Study Director must be notified before sample collection and other suitable storage conditions arranged and documented 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.
2	7/15/09	Corrected name of task force on side bar Revised accepted wipe solution. Additional revisions and clarifications

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8D.1
Collection of Air Samples Using OVS Tubes

Approval

This is an approved electronic copy of an AEATF II Standard Operating Procedure.

Signed copy is on file with Quality Associates, Inc.

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 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 protective OVS 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:

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. Protective OVS tube holder

c. Tygon® or equivalent tubing and clips for securing tubing to the worker

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

e. Air flow meter (*e.g.*, Kurz Mass Flow Meter, rotameter, bubble

flowmeter, DryCal or equivalent)

f. Re-closable plastic bags (*e.g.*, Ziploc® freezer bags)

g. Disposable gloves (e.g., latex, nitrile)

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 Calibrate each air-sampler pump to the target flow rate specified in the protocol (e.g., 2 liters per min (L/min) before use in each monitoring event. with the appropriate OVS tube/sampling train attached. Calibration will take place on the day prior to, or the same day the pumps are to be used. Document the flow rate and pump number in the raw data.

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

3.4 Turn off the air-sampler pump and set aside. Repeat step 3.2 until all needed sampling pumps (including backups) have been calibrated.

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 a calibrated personal air-sampler pump.

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 the air flow meter. Re-calibrate 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 air flow meter in the raw data.

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

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

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

4.10 Should a pump malfunction during a monitoring event, it will be replaced immediately with a new, calibrated pump (Section 3). Remove the OVS tube and tubing from the old pump and attach it to the new pump, check the flow rate with the air flow meter, document the flow rate, the pump number and start time in the raw data, and repeat steps 4.7 through 4.9. These activities will be documented in the raw data, including the time the malfunction was discovered and the elapsed time indicated on the failed pump (if available).

4.11 At the end of the sampling period, remove the protective OVS tube holder from the OVS tube, measure the terminal flow rate with the air flow meter, 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 ME, remove the OVS tube from the tygon tubing, 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 ME, unless otherwise instructed by the protocol.

7.0 FIELD STORAGE

7.1 Place samples collected during the study 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 or a portable freezer is not available, the Study Director must be notified before sample collection and other suitable storage conditions arranged and documented in the raw data.

8.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Additional clarification and revisions throughout.

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8E.1
Fortification of Matrix Samples

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This SOP describes the methods by which worker exposure monitoring matrices (e.g. inner, outer and sock dosimeters, hand washes, face/neck wipes, and OVS tubes) are to be fortified when producing field fortification recovery data for Antimicrobial Exposure Assessment Task Force (AEATF II) studies. Sock dosimeters referenced in this SOP are used only when specified by the study protocol.

2.0 BACKGROUND

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

2.2 It is important that field fortification samples simulate worker samples as much as possible. For example, some worker matrices collect residue throughout the entire monitoring period and are therefore subject to environmental conditions for several hours. To simulate this in field fortification samples, certain matrices are “weathered” in the field concurrently with worker samples. That is, they are fortified (generally before any worker monitoring starts) and exposed to the environment

until worker monitoring has been completed on that day. Samples that are weathered include: inner , outer and sock dosimeters, and OVS tubes. On the other hand, face/neck wipes and hand wash samples are collected at discrete times during the day and are not subject to environmental conditions during sample collection. Therefore, these sample types (both worker samples and field fortified samples) are not weathered, but are instead placed into storage immediately after fortification.

2.3 The field fortification process simulates two other conditions that worker samples experience. First, inner dosimeter and inner sock fortification samples are covered with a material similar to what covers the worker samples during the monitoring period. Second, OVS tubes have air drawn through them at the same rate that air is drawn through the worker air tubes.

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

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

3.0 EQUIPMENT/REAGENTS REQUIRED

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

a. Exposure monitoring matrices which correspond to those in use during the study. This may include outer and inner dosimeter material (each sectioned as appropriate), sock dosimeters, moistened face/neck wipes, OVS tubes, and hand wash solutions.

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

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

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

e. Distilled or deionized water

f. The solvent or detergent solution prepared for collection of hand wash and face/neck wipe samples (refer to AEATF SOP 8B), and/or another solvent solution if required by the analytical method.

g. Paper towels

h. Disposable gloves (e.g., latex, nitrile)

i. Aluminum Foil

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

4.0 SPIKING MATERIALS

4.1 Spiking materials may be in the following forms:

a. Active ingredient (a.i.) in an organic solvent

b. Formulated product in water

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

d. Pre-spiked OVS tubes.

5.0 SPIKING TECHNIQUES

5.1 There are two (2) basic procedures that may be used for the fortification of exposure matrices for the AEATF II. They are by syringe or pipette, and by vial.

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

5.3 The spiking material needs to be distributed over the largest amount of matrix area possible.

5.4 **Spiking a.i. in solvent:** A specified volume, typically 1 mL, of spiking solution will be drawn up into the syringe or pipette and then applied

appropriately to the matrix of choice.

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

5.6 **Spiking using entire solution vials:** Vials containing a known aliquot of a known concentration of spiking material will be sent to the field along with instructions on how to apply the spike to a matrix. The person doing the spiking will take a given spiking vial, unscrew the cap, and apply the contents to the matrix. The contents may be poured directly from the vial or removed via a Pasteur pipette (or equivalent). Use of a pipette may be desired for smaller matrices where more exact placement of material is necessary. The vial and pipette will sometimes be rinsed several times with the solvent (*e.g.,* deionized or distilled water, acetone, acetonitrile, *etc.*) that was used to prepare the solution and applied to the matrix or as directed by the analytical laboratory (see below). The vial shall be retained with the fortified sample. The cap should be discarded and should not be rinsed. Vials should be marked with a label that may be tied to the vial with string or is a self-adhesive label, which may be removed easily from the vial and will not interfere with analysis of fortified matrices.

6.0 SPIKING PROCEDURES

6.1 Inner, Outer and Sock Dosimeters

a. The dosimeters shall be placed on a piece of aluminum foil prior to spiking, and folded to ensure all the spiking solution is absorbed by the cloth.

b. Fold inner dosimeters to provide at least 6 layers of cloth.

c. Fold outer dosimeters to provide at least 4 layers of cloth.

d. Fold sock dosimeters to provide at least 4 layers of cloth.

e. Apply the spiking solution.

f. When spiking with entire solution vials, care must be taken with solvent rinse of the vial (see Section 5.6) as too much solvent will cause the spike to run through the fabric. Place the empty spiking vial on the aluminum foil with the matrix prior to folding the foil.

g. When using a syringe or pipette to apply the solution onto the

dosimeter, the tip of the syringe or 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.)

h. Weathered inner and sock dosimeters will be folded over after fortification and covered with a single layer of outer dosimeter material during exposure. Effort should be made to ensure that the spiking solution has been completely absorbed by the material prior to covering.

i. Weathered outer dosimeters will be left uncovered for the duration of the weathering period.

j. When fortification (or weathering) is complete, the sample will be wrapped in the same piece of foil it was spiked on, and placed in a labeled re-closable plastic bag. If samples are to be placed directly in glass jars, the foil it was spiked on shall be rinsed into the jar after the sample is placed in the jar.

k. Where glass sample jars are used, non-weathered dosimeters (travel spikes) may be placed directly into a glass sample jar and fortified in the jar as directed.

6.2 Hand Washes

a. Add 500 mL of the hand wash solution prepared for collection of hand wash samples to a clean sample jar of the same type used for field collected samples. Prepare one jar for each fortification sample.

b. When using a syringe or pipette to apply the spiking solution, the appropriate amount of spiking solution (typically 1 mL) will be added to the hand wash solution in the sample jar.

b. When spiking with entire solution vials, the cap to the vialed solution will be unscrewed from the vial and discarded without rinsing. The vial contents will be added to the hand wash solution in the sample jar, and the vial dropped into the jar. The jar will be capped, and the sample swirled or the jar inverted to ensure proper mixing of the spiking material with the sample matrix.

6.3 Face/Neck Wipes

a. Pre-wet two face/neck wipes (gauze pads) as described for field

samples in SOP AEATF II-8C.

c. If using a foil wrap and re-closable bag for the sample, place the two pads on a piece of aluminum foil large enough to completely wrap both pads.

d. When spiking with entire solution vials, empty the contents of the vial onto the gauze pads. Discard the cap (without rinsing), place the vial on the foil (without rinsing) and wrap the pads with the foil. Place the foil wrap in the re-closable bag. The vial will be rinsed as part of the extraction procedure.

e. When using a syringe or pipette to apply the spiking solution, the tip of the pipette or syringe may be used to help distribute the spike (typically 1 mL) in lines evenly over the surface of the wipe, if necessary. Wrap the sample as described above (no vial) and place in a re-closable bag

f. When using a sample jar instead of foil wrap and re-closable bags, place the moistened gauze pads directly in the sample jar, and fortify the pads in the jar as described above. Discard the cap (without rinsing) and place the vial (without rinsing) in the jar. Place the lid on the jar following fortification.

6.4 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 a.i. 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 a.i. 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 the monitoring event (ME).

7.0 FORTIFICATION SAMPLE IDENTIFICATION AND HANDLING

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

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

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

8.0 FIELD FORTIFICATIONS GUIDELINES DURING A STUDY

8.1 At least one field fortification set for each surrogate a.i. used on an AEATF exposure study should be prepared and collected at each cluster location (site) described in the protocol.

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

8.3 Additional field fortifications may be prepared at the Study Director's discretion, generally when environmental or other conditions between different days of the same cluster are significantly different.

9.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Additional clarification and revisions throughout.

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8F.1
Sample Identification

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 Monitoring Event (ME) numbers or codes may not be reused should a specific worker's monitoring period be started and then cancelled, even if no samples were collected for analysis. Additional ME number(s) will be assigned as necessary.

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

SN-XX-NN-YY-ZZ

2.4 The following is a list of the code pairs to be used:

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 (alternately, if multiple active ingredients are used in one study, the fortification of the matrices for the different active ingredients will be identified by a sequential number as follows: F1, F2, *etc*., in which the number designates a specific active ingredient. The specific active ingredient associated

with the numeric code will be documented in the raw data.

NN: For exposure samples - The two-digit worker ME number

For exposure field fortification samples - A two-digit number to denote he study day of fortification (***e.g.,*** day 01, 02, 03) depending upon the actual day of the study the samples are fortified on. Study days are sequentially numbered through the entire study (all clusters).

YY: A code for the type of sample

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

Additional sample types may be added and codes documented in the protocol, when necessary.

ZZ: Unique 2-Character Code Applied to All Samples

To Fortification Samples (FF samples only)	To Dosimeter Samples (WS samples only)
Tx* - travel spike	LB - lower body
Lx* - low spike	UB - upper body
Mx* - mid spike	LA - lower arms
Hx* - high spike	UA - upper arms
Cx* - control Sample	FT - front torso
Zx** - back-up air spike	RT - rear torso
	UL - upper legs
* - A sequential number will be noted for each control and fortified sample to note replicate samples.	LL - lower legs
	OS - socks, outer
	IS - socks, inner
** This designation will only be used for the back-up air sample fortifications	

To Air, Handwash, and Face/Neck Wipe Samples
(Worker AR, HW & FW samples only)

A sequential number to denote multiple samples (if more than one sample is collected) from the same ME. -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.

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

01-WS-02-ID-LL: Study AEA01 - worker sample – ME 2 - inner dosimeter - lower legs.

01-WS-02-OD-UB: Study AEA01 - worker sample - ME 2 - outer dosimeter - upper body.

05-WS-05-HW-01: Study AEA05 - worker sample - ME 5 - first (or only) hand wash collected (e.g. worker used the bathroom before end of ME).

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

05-WS-03-AR-01: Study AEA05 - worker sample - ME 3 – first (or only) air sample.

05-WS-09-FW-01: Study AEA05 - worker sample - ME 9 – first (or only) 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
1	7/15/09	Correct name of task force on side bar Changed “monitoring event” terminology. Added provisions for sock dosimeters, 2 section whole body dosimeters, back-up air samples, and multiple active ingredients in the same study.

STANDARD OPERATING PROCEDURE

Chapter 8: Matrix Samples

AEATF II-8H.0
Pre-Washing Dosimeter Garments

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of the procedure for pre-washing and storage of dosimeter garments before use in Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies.

1.2 The manufacturing process may leave residue in the fabric of dosimeter garments which interferes with analyses. Pre-wash of dosimeter matrices, or use of previously pre-washed matrices may occur at discretion of the Study Director. The use of pre-washed matrices and a description of the procedure used will be documented in raw data for the study (Section 5). Inner, outer and sock dosimeters are examples of matrices which may be pre-washed. The Study Director may elect pre-wash for some, all or none of these matrices.

2.0 DOCUMENTING PRE-WASHED PROCEDURES

2.1 Written documentation shall be prepared and maintained by the facility responsible for the pre-wash which identifies the date, location, and detergent used, and the personnel who performed the pre-wash. A reference to the SOP (including version number) used, or a complete description of the pre-wash procedure shall also be included. The Note to File shall be signed by the person responsible for the pre-wash (which may or may not be the person who actually washed the garments).

3.0 PRE-WASH PROCEDURE

3.1 The garments selected for pre-wash shall be washed in a typical residential or commercial washing machine, and dried in a typical residential or commercial dryer.

3.2 Follow washing machine operating instructions for proper loading. When no instructions are provided, adding dry garments until the washing machine drum is 50% full is recommended.

3.3 Wash the garments, in **warm** (not hot) water, **three** separate times (complete washing cycle) using a low suds detergent (*e.g.*, All) with an amount of detergent appropriate for the number of garments washed. The washing machine and/or detergent label will often contain instructions for the amount of detergent to use. Document the name of the detergent used. For each wash event, allow the washing machine to go through a complete wash, rinse, and spin cycle.

3.4 Run the washing machine through **two additional** wash cycles without detergent. This will help remove all of the detergent.

3.5 Dry the garments in the dryer. Follow dryer instructions using a **medium** heat setting to minimize shrinkage of some fabric types. The garments are now ready for use.

4.0 STORAGE OF PRE-WASHED DOSIMETERS

4.1 Dosimeters will typically be pre-washed in advance of the study and will need to be stored before use.

4.2 Fold and place a single garment in a re-sealable plastic bag (e.g., 10 in x 16 in for inner dosimeters) such that the size tag is clearly visible through the plastic bag. Close the bag and placed the bag in a suitable container for storage. If closed containers (e.g., cardboard boxes) where the number and size of contents cannot easily be determined, labeling of contents on the exterior of the container is recommended.

4.3 Store the containers in a clean storage area away from chemicals of any kind. *Note that many cleaning products contain chemicals which may interfere with analyses in Antimicrobial Exposure Assessment Task Force (AEATF II) exposure studies*

4.0 LABELING OF PRE-WASHED DOSIMETERS

5.1 Pre-washed dosimeters will be labeled with the following information:

a. The date the dosimeter was pre-washed.

b. The location where dosimeters were pre-washed.

c. The person responsible for the pre-wash.

d. The identity of detergent used.

e. The SOP followed (including version number) or a description of the pre-wash procedure.

5.2 In most cases, each bag containing a pre-washed garment should be labeled, though the container (box) of bagged dosimeters may be labeled when inventory control and use procedures are sufficient to identify the pre-wash procedure used (if any) for dosimeters in raw data of a study.

6.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	07/15/09	Original Document

STANDARD OPERATING PROCEDURE

Chapter 10: Field Study Procedures

AEATF II-10B.1 Packing, Handling, and Shipping of Samples

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 II) 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.*, whole body dosimeter sections in aluminum foil) 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 Untreated control samples, worker samples, field fortification samples and fortification solutions should be stored separate from one another in the field, during shipment, and during storage at the analytical laboratory At a minimum, untreated samples must be physically separated from treated samples by at least two boundary layers (*e.g.*, double bagged, separate boxes/partitions, *etc…*) while in the same cooler/freezer, but preferably would be stored in completely separate coolers/freezers. Efforts should be taken to keep field fortification samples, field

fortification solutions and dosimetry samples separate at all times; however, these samples may be stored and shipped together provided there is adequate separation and protection from potential cross-contamination. Untreated samples may not be shipped in the same container with worker samples, field fortification samples or fortification solutions. The Study Director shall make any decisions regarding the combining of samples in the same device.

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 or jars 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 may be transported in a cooler on dry ice, or in a portable freezer from the field to the laboratory.

3.5 Unless otherwise arranged with the laboratory, ship all samples to arrive on a weekday during normal business hours. Samples shipped by courier should be shipped on a Monday, Tuesday or Wednesday, as any difficulties in transit may result in Thursday or Friday shipped samples thawing over the weekend.

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Clarified language concerning separation of UTC, TRT and fortification samples. Edited for clarity. Chapter title modified

Attachment

Example Sample Shipping Form

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.

STANDARD OPERATING PROCEDURE

Chapter 10: Field Study Procedures AEATF II-10C.1
Worker and Study Observations

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 Field contractors will prepare a notebook containing data forms necessary for collection of required field data.

2.2 The 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 of the working area. Include compass points, mixing area, work/treatment area, and sampling collection area(s).

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

c. Include a map of sufficient detail to locate the test site. If not within a municipality, identify and provide directions from the nearest municipality.

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 For studies in which some or all of the activities are conducted outdoors, 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 For studies in which some or all of the activities are conducted indoors, indoor environmental conditions, including but not limited to, air temperature and relative humidity will be monitored and recorded by means of calibrated measuring devices located within the designated test areas. Measuring equipment for indoor monitoring will be calibrated per the contractor's SOP. The ventilation system will be described in the raw data.

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

5.0 CALIBRATION AND EQUIPMENT DETAILS

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

5.2 Details regarding engineering controls in test substance packaging or mixing/loading equipment will be documented in the raw data.

6.0 Worker OBSERVATIONS

6.1 Prior to exposure monitoring the Study Director will review the requirements for observing workers during exposure monitoring for AEATF exposure studies.

6.2 If possible, one researcher will be dedicated to observing one worker during the monitoring period. Each researcher assigned to this task must

be familiar with AEATF SOPs for worker observations and have completed appropriate ethics training, which must be documented in their training file. Each observer must use the appropriate forms in the field notebook to record the times and descriptions of all activities including any mixing, loading or application activities; resting, lunch, washing hands, driving vehicles, *etc*.

6.3 Describe clothing and personal protective equipment (PPE) worn and work environment conditions. Document all clothing worn, including PPE prior to the start of observations during the work period. Note any clothing defects and bring to the attention of the Study Director or, in his/her absence, the field team member in charge. Record any instances of removal of protective equipment during the monitoring period.

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

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

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

6.7 Periodically observe the workers' clothing. Look for new rips or tears, perspiration, chemical spills/stains, or anything that appears out of the ordinary. Also check and document the operation of the personal air sampling pump. Avoid use of the term "Pump On".

6.8 Report any unusual or unauthorized activities observed (eating without hand wash, not wearing PPE during chemical exposure, *etc. …*) to the Study Director or, in his/her absence, the field team member in charge.

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

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

6.11 The observations made will be reviewed and placed in the field report at the conclusion of the study. Try to write neatly and clearly while describing the activities observed. Be as succinct as possible. Typically 3-5 pages of notes should be collected during an average 8-hour work period.

6.12 Observe the worker for the entire time period of the exposure monitoring, from when the worker is dressed at the start of the day until he/she enters the privacy area for sample collection; this includes during lunch breaks, performing other daily activities, and during interim sample collections. This does not include observing the worker during restroom breaks. If the worker cannot be seen during application, this should be noted. Additional lighting may be employed if the worker's activities occur at night. If the observer needs to take a break, get another researcher to monitor the worker during the observer's absence. Observers will make every effort to minimize interference with the worker's normal activities, such as keeping a reasonable distance from the worker and avoiding unnecessary conversation. Observers should contact the Study Director, or in his/her absence, the field team member in charge if they observe any activity contrary to the study design, label requirements, or dangerous activities undertaken by the worker. Based on the event, the SD has the discretion to terminate the ME.

6.13 Do record the names of non-study compounds observed being handled during the monitoring period.

7.0 STUDY PHOTOGRAPHS AND VIDEO RECORDING

7.1 Photographs/videos should be taken of the work area, application and/or mixing equipment; and various study activities (***e.g.***, exposure sampling techniques, mixing techniques, test substance application, ***etc****….)*. No photographs/videos should be taken in which a worker can be readily identified. These would include photographs/videos of their faces or any uniquely identifying marks (***e.g.***, tattoos, scars, ***etc.***…). No photographs/videos of the worker dressing or undressing will be taken. If a photograph/video needs to be taken of a worker (e.g., to show a torn shirt sleeve), every effort will be made to capture the image without any identifiable features in the frame.

7.2 Any photographs/videos or photographic files that can be used to readily identify a worker shall be shredded, erased, or deleted and will not be maintained in the raw data file.

7.3 Photographs/videos will be used to show the condition of clothing before and after monitoring, and to provide visual documentation of the study for use by regulatory reviewers. All photographs/videos are the property of

the AEATF II and will be used to document the research conducted.

8.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Added provision for contractor supplied data notebooks, procedures to be used when taking photographs and video, procedures for safeguarding worker identities, and procedures pertaining to heat stress monitoring. Substantial revision of procedure for documenting observations to clarify information required, minimize observer interference with worker's normal work activities, and document any test substance package engineering controls Chapter title modified

STANDARD OPERATING PROCEDURE

Chapter 10: Field Study Procedures AEATF II-10E.1
Worker Sample Collection Sequence

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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 II) exposure studies.

2.0 COLLECTION SEQUENCE

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

2.2 The worker will then remove their own personal protective equipment (PPE). PPE may include a chemical resistant (CR) apron, CR gloves, CR headgear, a respirator, glasses or goggles.

2.3 In the event there is contaminated footwear, see SOP AEATF II-8A for information concerning removal of footwear prior to entering the privacy area. Otherwise, the worker then enters the privacy area for collection of samples.

2.4 The general sequence for post-monitoring event procedures is:

a. Remove the air sample pump and collect air sample as described in SOPs AEATF II-8D and AEATF II-10A.

b. Collect the hand wash sample as described in SOP AEATF II-8B.

c. Collect the face/neck wipe sample as described in SOP AEATF II-8C.

d. Remove shoes (if not removed earlier removed).

e. Remove socks and/or sock dosimeters as described in SOP AEATF II-8A.

f. Remove outer dosimeter (or outer work clothing) as described in SOP AEATF II-8A.

g. Remove inner dosimeter as described in SOP AEATF II-8A.

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

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

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Edited for clarity Chapter title modified

STANDARD OPERATING PROCEDURE

Chapter 10: Field Study Procedures AEATF II-10F.1
GPI Electronic Digital Flow Meter

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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. GFI 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. 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.

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 section. 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.

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. Record cleaning procedures as "routine" maintenance. Record non-functioning returned for repair or replacement as "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

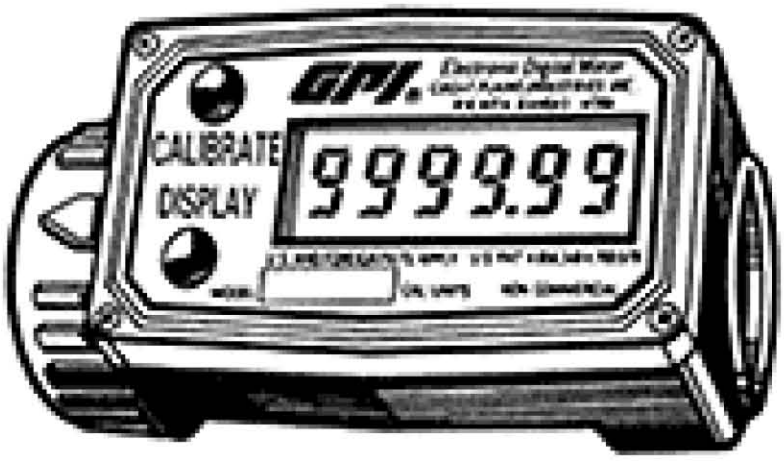
6.1.2 GPI Operations Guide for Electronic Digital Meter No 920731-2

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
1	7/15/09	Corrected name of task force on side bar Correct typographical errors. Removed Owners Manual page number references. Chapter title modified

8.0 REFERENCE DIAGRAMS



STANDARD OPERATING PROCEDURE

Chapter 10: Field Study Procedures

AEATF II-10G.1 Personal Air Sampling Pump Calibration

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

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, DryCal, 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 event (ME). 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 if the pumps are to be used predominantly outside). 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 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	12/26/05	Original Document
1	7/15/09	Corrected name of task force on side bar Add monitoring event terminology Removed requirement for post exposure flow rate check. Chapter title modified

STANDARD OPERATING PROCEDURE

Chapter 11: Human Subject Management AEATF II-11A.1
Pregnancy Testing and Nursing Status

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to assess the pregnancy and nursing status of a female worker (or subject) that is being considered for participation in an Antimicrobial Exposure Assessment Task Force (AEATF II) exposure study. Federal Regulations (40 CFR Part 26, §26.1203) prohibit regulated third parties from conducting research involving the intentional exposure of pregnant or nursing women.

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 PROCEDURE

2.1 Each potential female volunteer will be told during the consent process that federal regulations prohibit third parties from conducting research involving the intentional exposure of pregnant or nursing women. The female worker will be told that if she wishes to participate in the study she will be required to take an over-the-counter urine pregnancy test and that if the pregnancy test is positive, she will not be allowed to participate in the study, but she will be compensated for her time and inconvenience.

2.2 When an enrolled woman (i.e., a woman who has signed the ICF) arrives at the test site on the day of participation, she will be asked if she is pregnant or nursing. If she answers affirmatively to either question, she will be dismissed from the study, but compensated as outlined in the Informed Consent Form for volunteers who arrive at the study site at the designated time but are not monitored.

2.3 If she answers negatively to both questions, she will be asked to take an over-the counter type urine pregnancy test. Tests may be taken up to 12 hrs before participation. If she declines to take the pregnancy test, she will be dismissed from the study, but compensated as outlined in the Informed Consent Form for volunteers who arrive at the study site at the designated time but are not monitored.

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.

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

2.5 After the test, the worker will be asked to 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 retained to verify the screening process for participation per IRB guidelines.

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. A record will be made in study raw data stating ONLY that a pregnancy test was performed according to this SOP, and subject's participation in the study is in compliance with this SOP (i.e., subject is not pregnant).

2.6 With the confirmation of a negative test result, the subject will be permitted to continue in the study. Used test kits from all subjects will be retained in a sealed disposal container under the supervision of study investigators, and discarded with other study refuse from that site.

3.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	3/7/08	Original Document
1	7/15/09	Corrected name of task force on side bar Revised to clarify the appropriate regulation in Section 1.1 Added that a female volunteer may need more than one test in Section 2.2 Clarified that identities of individuals screened for participation will be retained per IRB guidelines in Section 2.4. Added in Section 2.2 provision to ask subject whether she is nursing or pregnant.

STANDARD OPERATING PROCEDURE

Chapter 11: Human Subject Management

AEATF II-11B.1
Heat Stress

Approval

Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 There is potential for heat stress under certain conditions of temperature and humidity. The potential for heat-related illness in workers who participate in AEATF II studies is increased 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. The purpose of this Standard Operating Procedure (SOP) is to:

a. Identify conditions that contribute to heat-related illness.

b. Explain measures to minimize the risk of heat-related illness.

c. Define responsibilities of study personnel for heat-related illness during exposure monitoring.

d. Describe how to calculate the Heat Index and determine the Heat Index Category, and explain how this is used to assess the risk of heat-related illness.

e. Provide criteria for stopping exposure monitoring activities when there is elevated risk of heat-related illness, and basic treatment information.

2.0 CONDITIONS THAT CONTRIBUTE TO HEAT-RELATED ILLNESS

2.1 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. 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.

3.0 MEASURES TO MINIMIZE HEAT-RELATED ILLNESS

3.1 Initiate outdoor exposure monitoring during the cool part of the day whenever practical.

3.2 If working outdoors, provide shade during breaks where possible.

3.3 When working indoors, consider measures to reduce the heat index without adversely impacting results of the study. For example, HVAC systems would normally be used; fans not typical of the work environment would normally not be used.

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

3.5 Urge workers to drink liquid during the monitoring period and remind them thirst does not give a good indication of how much liquid a person needs to drink.

3.6 Observe workers during the monitoring period and require workers to take rest breaks if any of the signs or symptoms outlined in Attachment A are observed.

3.7 Discuss the increased potential for heat-related illness with workers during the Informed Consent process, and review the signs and

symptoms of heat-related illness.

3.8 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. Impress upon workers the importance of reporting any health-related issues which arise during exposure monitoring to the nearest research team member

3.9 Post English and Spanish versions of the poster titled "Controlling Heat Stress Made Simple" so workers and research personnel will remain aware and can refer to the information.

4.0 RESPONSIBILITIES OF STUDY PERSONNEL

4.1 The Study Director is ultimately responsible for ensuring procedures outlined in this SOP are followed during AEATF II sponsored studies.

4.2 The Study Director (in consultation with any on-site medical professional) 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.

4.3 Responsibilities of study personnel include:

a. Recognize symptoms of heat-related illness;

b. Monitor environmental conditions for situations which pose elevated risk for heat-related illness and document monitoring activities, and;

c. Implement the plans specified in Sections 3 and 6 for minimizing the potential for, and addressing any heat-related illness which may occur during exposure monitoring.

4.4 <u>Recognizing symptoms of heat-related illness</u>:

a. All on-site research personnel will read this SOP, and become familiar with the signs, symptoms, and treatment of heat-related illnesses outlined in Attachment A: Heat Illness Symptoms and Treatment Chart.

b. The Study Director will ensure English and Spanish versions of the poster entitled "Controlling Heat Stress Made Simple" is posted at each field site. Posters will ideally be available at both dressing and work areas.

4.5 Monitoring environmental conditions.

a. The Study Director will monitor environmental conditions (heat index based on ambient temperature and relative humidity) which may influence the risk of heat-related illness. If the ambient temperature reaches 70º F, the Study Director will implement at least hourly checks of the heat index and will calculate the heat index category until the ambient temperature drops below 70º F. Section 5 of this SOP explains how to determine the heat index.

b. The Study Director will inform research personnel responsible for observing and documenting worker activities (Observers) of the Heat Index (Apparent Temperature) Category at the start of exposure monitoring, and of any changes in the Heat Index during the exposure monitoring period.

c. Observers will perform and record periodic checks for symptoms of heat-related illnesses, and record changes in the Heat Index Category communicated by the Study Director.

4.6 Plans to address heat related illness. The Study Director and/or Principal Field Investigator will:

a. Make arrangements to provide access to local emergency medical assistance if it becomes necessary during the conduct of an AEATF II study. Arrangements will be made prior to exposure monitoring and should consider the location and time of day of exposure monitoring activities.

b. Discuss procedures for heat-related illness monitoring and response with the employer (during workplace monitoring), and secure the employers agreement this SOP shall be followed during exposure monitoring activities in the workplace. This agreement shall be documented in raw data of the study.

c. Ensure a research team member trained to recognize and take measures to relieve symptoms of heat-related illness is present during exposure monitoring activities, unless a medical professional has been contracted for on-site supervision of subjects during the study. Training shall be from a recognized training organization (e.g., The American Red Cross) and documented in the team members training file.

d. Ensure study Observers know how to contact any on-site medical personnel, take immediate steps to mitigate effects of heat-related illness as outlined in Attachment A, and immediately report all observed symptoms of heat-related illness.

e. Make the final decision for starting or stopping the study during conditions of elevated heat stress potential (Section 6).

5.0 ENVIRONMENTAL MONITORING AND DETERMINING HEAT INDEX CATEGORY

5.1 The ambient temperature and humidity at the work area will be monitored throughout the exposure monitoring period. Appropriate meteorological instrumentation will be used and measurements will be recorded in the raw data.

5.2 The temperature and relative humidity readings will be applied to NOAA's National Weather Service Heat Index chart (Attachment B) to determine the Heat Index. The Heat Index will be the temperature shown at the intersection of the measured temperature and humidity readings. The chart is divided into color-coded categories, each denoting a range of heat index temperatures at which heat-related illnesses can possibly or are likely to occur

5.3 The National Weather Service Heat Index (Apparent Temperature) table below summarizes Heat Index Categories and identifies heat-related illness possible in each category. The Heat Index Temperature Range refers to the apparent temperature derived from the Heat Index Chart (Attachment B)

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

5.4 To determine the Heat Index and Heat Index Category:

a. Determine the ambient temperature and humidity.

b. **Add 10° F to the ambient temperature if the worker is working in (i.e., receiving) direct sun.** This includes sustained work in front of windows receiving direct sun when working indoors.

c. Find the intersection of adjusted ambient temperature and observed humidity on the Heat Index chart (Attachment B). The temperature reading in the block where ambient temperature and humidity intersect is the apparent temperature.

d. Consult the table in Section 5.3 to determine the Heat Index Category.

6.0 START/STOP CRITERIA AND TREATMENT

The symptoms of heat-related illness and measures to relieve symptoms 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 the Study Director on monitoring for heat-related illness, assessing and responding to symptoms of heat-related illness, and making decisions on when it is appropriate to start, and necessary to stop, exposure monitoring.

6.1 Worker exposure monitoring may be initiated as scheduled unless the Heat Index falls in the EXTREME DANGER Category, where heat stroke is highly likely. The Study Director, at his discretion, may choose not to initiate monitoring, regardless of the Heat Index.

6.2 If the Heat Index 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.

6.3 CAUTION Category. If the Heat Index falls between 80° - 89° F [27° – 32° C], or between 70° - 79° F [21° – 26° C] when working in direct sun, 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. 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

6.4 EXTREME CAUTION Category. If the Heat Index falls between 90° - 104° F [32° – 40° C], or between 80° - 94° F [27° – 34° C] when working in direct sun, 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.

a. Heat Cramps. STOP EXPOSURE MONITORING. **Give access to plenty of water or a sports drink and assure they are drinking. Have the worker rest in the shade until cool.** 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.

b. Heat Exhaustion. STOP EXPOSURE MONITORING. **Treatment includes moving worker to a shaded area to rest, providing plenty of drinking water or sports drink, and splashing cold water on the worker.** Consult with the on-site medical professional (if one was contracted for the study). If the worker's condition appears to be serious and 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.

c. Heat Stroke. STOP EXPOSURE MONITORING. In addition to the measures noted above for heat exhaustion, **treatment includes removing outer clothing and shoes and wrapping worker in wet sheet or towel and fan to cool worker.** Consult with the on-site medical professional (if one was contracted for the study). If the worker's condition appears to be serious and 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.

6.5 DANGER Category. If the Heat Index falls between 105° - 119° F [41° – 48° C], or between 95° - 109° F [35° – 43° C] when working in direct sun, 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. Treatment for heat cramps, heat exhaustion and heat stroke are described in Section 6.4.

6.6 If the Heat Index reaches **120° F [49° C], or 110° F [43° C]** when working in direct sun, STOP THE WORKER EXPOSURE MONITORING as heatstroke is highly likely with continuous exposure. Stopping monitoring when the Heat Index reaches 120° F should provide adequate protection to the worker. Based on the National Weather Service Heat Index Chart, (Attachment B), this value is roughly in the mid-range of the DANGER category, and therefore does not interface with the Heat Index values in the EXTREME DANGER category where heatstroke is highly likely with continuous exposure. It is reasonable to assume that using 120° F as the stop point will prevent the Heat Index from ever reaching the EXTREME DANGER Category, including at any time in the period between readings.

Note: This stop rule does not apply to an outdoor study (i.e., outdoor air temperature and humidity derives the Heat Index) if the worker is working primarily inside air conditioned equipment. If the worker must routinely be outside the air conditioned equipment for more than 30 minutes at a time, exposure monitoring will be stopped.

7.0 EXPENSES

7.1 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.

8.0 INCIDENT REPORTING

8.1 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-11D for additional details on reporting such events to the IRB.

9.0 REFERENCES

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

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

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

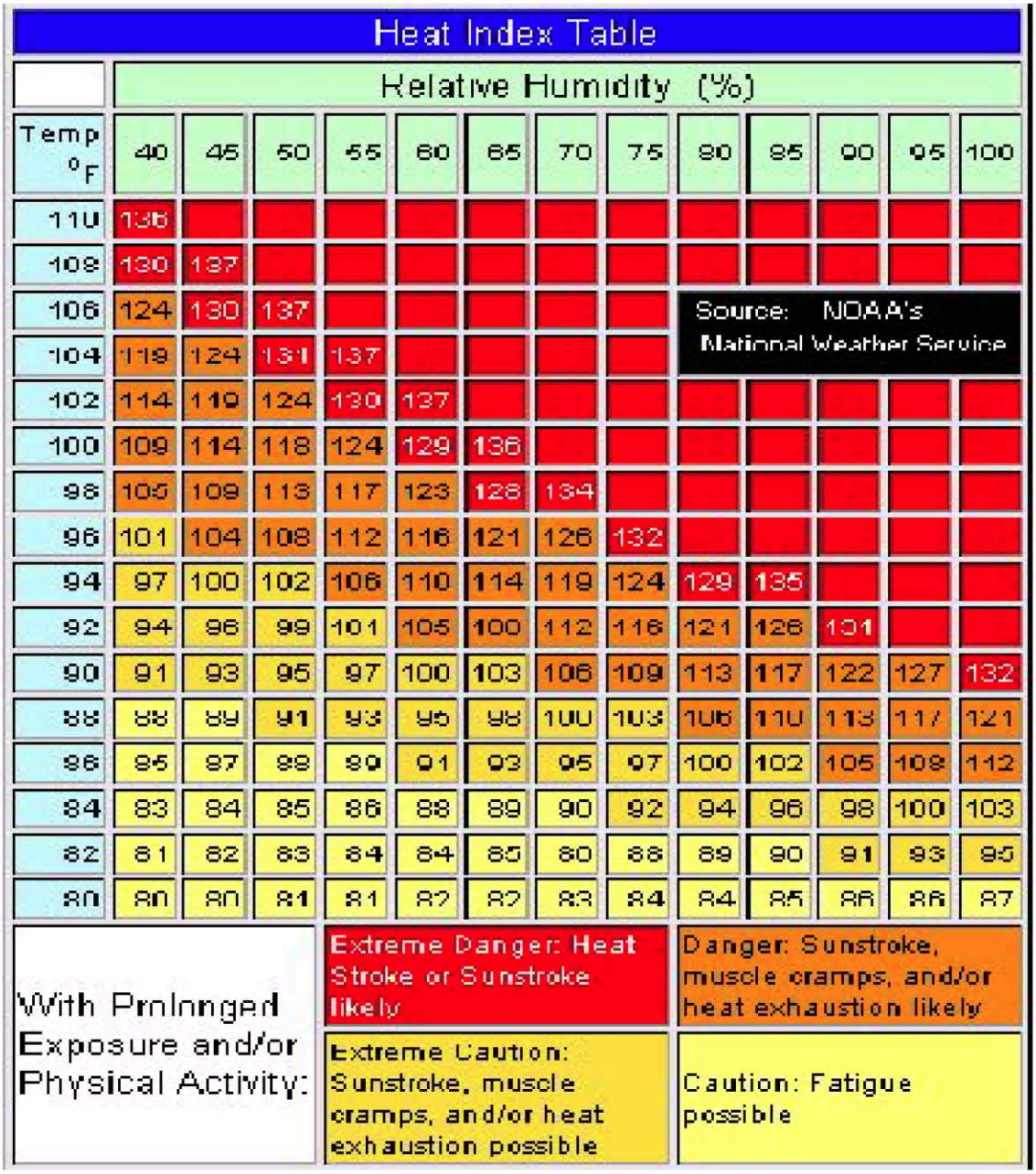
10.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	3/7/08	Original Document
1	7/15/09	Correct name of task force on side bar Revised section 1.1 to summarize full scope of the SOP Made definitions of work spaces consistent with indoor environment of AEATF II studies, Addition of section 3.3 Other edits and clarifications

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.

Attachment B: Heat Index Chart



Heat Index Table

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

Source: NOAA's National Weather Service

With Prolonged Exposure and/or Physical Activity:

Extreme Danger: Heat Stroke or Sunstroke likely

Danger: Sunstroke, muscle cramps, and/or heat exhaustion likely

Extreme Caution: Sunstroke, muscle cramps, and/or heat exhaustion possible

Caution: Fatigue possible

Attachment C: Rationale for Heat Index Adjustment for Sunny Conditions

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

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

- Workers who participate in these studies perform this work as part of their normal job, including having familiarity with working in hot environments
- Workers who participate in these studies are adults in good health
- Workers who participate in these studies are acclimatized
- No impervious clothing will be worn.
- Mixing/loading and/or applying activities are generally moderate workloads (Reference EPA "A Guide to Heat Stress in Agriculture", *Table 5- Approximate Workload Levels*)
- Heat indices are monitored hourly with appropriate control measures in place
- Study investigators constantly observe workers for signs of heat-related illness and take control measures accordingly
- A medical professional or researcher trained in treatment of heat illness (Section 4.6 c) is on-site during the monitoring period to observe for signs of heat-related illness and provide treatment if necessary, including calling for medical emergency assistance

AEATF study participants wear an inner dosimeter under their work clothing, thus increasing their risk of heat-related illness. However, it is believed that this increased risk if offset by the conditions listed above and the implementation of a heat stress management plan as described in this SOP. Furthermore, conditions of worker scenarios being monitored by AEATF should be put in perspective with other occupations involving hot working environments. A 10° F adjustment is considered to be adequately protective.

STANDARD OPERATING PROCEDURE

Chapter 11: Human Subject Management

AEATF II-11C.1
Emergency Procedures

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 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, and SOP AEATF II-11E, 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 or field investigator 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, an on-site member of the study team will call 911 (or other local emergency number) and allow Emergency Medical

Personnel (EMT) to respond and continue to treat the subject as appropriate.

2.3 As deemed appropriate by the EMT, 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.

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.

b. In consultation with the EMT, the study participant (worker) may refuse medical treatment.

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.

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.

3.2 If study personnel determines that a heat-related medical emergency is taking place they will summon the on-site medical professional, if available, 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.

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

4.0 FOLLOW-UP OF EMERGENCY HOSPITALIZATION EVENT

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

5.0 MEDICAL RECORDS

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

6.0 EXPENSES

6.1 Expenses associated with 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. This includes any deductible or out-of-pocket expenses, including co-payments.

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 per AEATF II's SOP AEATF II-11F.

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-1F.

8.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	3/7/08	Original Document
1	7/15/09	Corrected name of task force on side bar Section 2.3b was added to clarify a worker may choose to refuse treatment under certain circumstances. Section 3.3 was revised to clarify when medical management would preclude collection of exposure samples. Section 6.1 was revised to specify the costs covered by the AEATF as a result of an injury during a study.

STANDARD OPERATING PROCEDURE

Chapter 11: Human Subject Management AEATF II-11F.0

Adverse Events Reporting to IRB

Approval

Technical Committee Chair: _____ Date: _____

AEATF II QAU: _____ Date: _____

Effective Date: July 15, 2009

1.0 PURPOSE AND SCOPE

1.1 This SOP outlines the steps to be taken to address an unanticipated adverse event resulting from participation in an Antimicrobial Exposure Assessment Task Force (AEATF II) worker exposure study.

2.0 PROCEDURES

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

2.2 The Study Director, and/or their designees, are required to report adverse events that meet both of the following criteria:

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

AND

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

therefore, does not have to be reported to an IRB.

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

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

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

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

3.0 REFERENCES

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

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

4.0 HISTORY OF CHANGES

Revision	Date	Description Of Change
0	7/15/09	Original Document