

KTL/ULTRA/EU Environment and Climate contract No ENV4-CT97-0568

Preparation of Standard Operating Procedures (SOPs)

Identification code: SOP ULTRA /KTL-G - 1.0		APPROVALS			
Full SOP Working SOP # pages_____		Coordinator: __/ __/ __ _____			
Issue Date: __/ __ . _____		PIC: __/ __/ __ _____			
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Distributed to:	Name of recipient:	Original date	Rev. 1. date	Rev. 2. date	Rev. 3. date
KTL Kuopio					
University of Wageningen					
GSF Oberschleissheim					
ECN Petten					
University of Kuopio					
University of Helsinki					

PREPARATION OF STANDARD OPERATING PROCEDURES (SOPs)

1.0 Purpose and Applicability

The purpose of SOPs in general is to ensure that

- * each task is carefully planned and tested,
- * the task is performed by each individual each time in the same way, and with the same equipment calibrated in the same way,
- * each data record can be tracked back as for how the task was performed step by step, and what if any irregularities were encountered or performed in the process.

The purpose of this SOP is to develop/establish a uniform format for the preparation of Standard Operating Procedures (SOPs) for the Exposure and Risk Assessment for Fine and Ultrafine Particles in Ambient Air (ULTRA) European multicenter project consortia. Use of these protocols ensures consistent implementation of project tasks, documents the preparation and implementation of the procedures used, describes quality control measures and the limits of the procedure.

2.0 Definitions

pSOP: Preliminary SOP, which can be copied, distributed and edited freely within the ULTRA project consortia until the date when a real SOP is established. After that date remaining copies of the respective SOP should be destroyed.

SOP: Standard Operating Procedure, which must be prepared, revised, distributed and applied with full SOP formalities

PIC: Principal Investigators' Committee (Steering Committee)

3.0 References

The development of this SOP is based on

- * SOP Expolis/KTL-G-1.0 (December 1996) developed for the Expolis project at KTL Division of Environmental Health in Kuopio, Finland
- * SOP # UA-G-1 (July 1994) developed in University of Arizona for the U.S. EPA NHEXAS project
- * SOP HA1 (17.5.1994) developed for GLP at KTL Division of Environmental Health in Kuopio, Finland

4.0 Discussion

The purpose of each SOP is to facilitate efficient design and training of work procedure and to ensure comparability and reliability of results. SOP:s may contain references to textbooks, articles or other SOPs. SOPs need to contain all appropriate and relevant information for valid completion of the task. Preparation of SOPs using the format defined in this procedure ensures that major sections of different SOPs are consistently labeled and easily identified.

5.0 Responsibilities

5.1 The Coordinator is responsible for the contents of this SOP, and he is responsible for final review and approval of each SOP applied in ULTRA-project.

5.2 Members of the project-team with first-hand knowledge of the procedure will prepare the SOP as assigned by the Coordinator and Principal Investigators' Committee in the format outlined in this procedure. PIC will inspect and approve each SOP to ensure that it meets the relevant OECD and FDA requirements.

5.3 Any person who changes a procedure is responsible for ensuring that the change has been properly documented, the SOP changed, reviewed and approved by the local principal investigator(s).

5.4 Occasional deviations in application of SOPs need to be properly documented (who; when, begin... end...; what changes, why, possible impact), and approved by the local principal investigator.

6.0 Equipment and Materials

SOPs can be written and edited using any word processor, but they must be saved for distribution in MS-Word 6.0 format, which can be easily read by most MS Windows compatible word processors.

7.0 Procedure

7.1 Procedure Identification

7.1.1 Assign each procedure a unique identification code of two sets of letters and one set of numbers as follows:

In the beginning the project name, ULTRA is stated. After this The first set of letters indicates the Applicable Consortium Member:

KTL	National Public Health Institute, Kuopio and Helsinki
ECN	Netherlands Energy Research Foundation
GSF	Forschungszentrum für Umwelt und Gesundheit
UoH	University of Helsinki
UoK	University of Kuopio
UoT	University of Tartu
UoW	University of Wageningen
YTV	Helsinki Metropolitan Area Council

The second set of letters indicates the Project Area of Applicability:

G -	general,
T -	training of personnel,
I -	interview and instruction,
F -	field packet preparation and field application,
L -	laboratory methods and equipment calibration,
C -	custody of samples and data,

- D - data management and transfer,
- A - statistical data analysis,
- M - other miscellaneous as needed

Numbers following each Project Area designation will be in consecutive order with the decimal place indicating the revision of the SOP. Note that for original issues of the SOPs, the decimal is "n.0".

EXAMPLE: SOP ULTRA / KTL-G-1.0 where:

- ULTRA: the name of the project
- KTL: National Public Health Institute
- G: General procedure
- 1.: The first issued SOP in the General procedure category
- 0: Indicates that this is the original issue of the SOP

7.1.2 Assign every procedure a descriptive and unique title.

7.1.3 Include in the heading of each page: Unique SOP ID number, original/revision number and date (month, day, year) of the procedure.

7.1.4 Paginate every page of the SOP "Page X of Y. "

7.2 Title Page

Each SOP will include a title page (Figure 1) which will serve as a record of the SOP from its original issue date through any revisions. The Title Page shall include at a minimum the following information:

- * Issuer/Project/Title of project and contract agreement number (KTL/ULTRA/EU Environment and Climate contract No ENV4-CT97-0568)
- * SOP identification code,
- * Dated signatures of coordinator and local principal investigator, and PIC,
- * Issue date,
- * Brief description of revisions and affected pages,
- * Indication of the centers and principal investigators (dates) to which this SOP original/revision has been distributed.

7.3 Format of Text (title number in SOP)

The recommended format of the body of the SOP will be as outlined below. This is meant as a guide. The writer has the latitude to alter the format to meet the needs of the protocol development. Modify each heading as needed to make clear what is happening in the SOP. Do not leave any title (number and text) away, but use the word "none" or "N/A" for any subject heading not required in the SOP. Adjust tab spacing as seems appropriate, but keep it consistent within a given SOP.

7.3.1 (1.0) Purpose and Applicability

Describe the purpose and scope of the procedure. Define when and where the procedure

should be used.

7.3.2 (2.0) Definitions

Define words and phrases having a specified meaning or application within the SOP. Definitions will be alphabetized.

7.3.3 (3.0) References

Cite other sources of work as applicable. Alphabetize by author and year. Use a bibliographic reference style of your choice. Cite relevant SOPs necessary to carry out the work, but omit the version number. After first SOP citation mark in place of revision number “(*)”, and add the following text after the reference list: “(*) This statement refers to the latest SOP revision available. Make sure that you know and have it”.

7.3.4 (4.0) Discussion

Include background or contextual information as applicable to make SOP more understandable. Refer to material listed in references including other SOPs (revision No: !) or figures or appendices in other SOPs as necessary.

7.3.5 (5.0) Responsibilities

Identify the organizational positions and responsibilities of the people who are charged with implementing the procedure.

7.3.6 (6.0) Equipment and Materials

All equipment and materials needed to complete the described task need to be listed here.

- a) Equipment: Itemize equipment (e.g. pump, sampler, valve) and major instrumentation (e.g. calibrator, computer, software) needed to perform SOP. Identify supplier or manufacturer of any non-stock item.
- b) Paper materials: Itemize all questionnaires, information texts, data sheets needed in this procedure.
- c) Materials: Itemize materials (e.g. gases, filters, tubing) needed to perform SOP. Identify supplier or manufacturer of any non-stock item.

7.3.7 (7.0) Procedure

Identify, list and label specific tasks in a step-by-step sequence. Be specific in context and scope, using short, declarative statements. The following is a suggested format: (see outline Figure 2)

- a) Preparation (Before field/Contacts/Lab preparations)
- b) Steps followed (Field Procedures/Lab Analyses/Data Procedures)
- c) Calculations, input values, data tables
- d) Quality Controls

7.3.8 (8.0) Data Records

- a) Define clearly and concisely what data need to be recorded, what recording method used.
- b) Define where data are to be recorded. Attach forms or tables as appropriate.
- c) Define where completed data forms/logbooks will be archived, and for how long.

7.3.9 (9.0) Sample Archiving

- a) Define clearly and concisely what samples need to be stored, what for and how protected.
- b) Define where samples will be stored, and for how long.

7.3.10 (10) Implementation and Application

Describe here any details needed to properly implement and apply the particular SOP under work, and which is not already covered in this SOP ULTRA/KTL-G-1.

7.3.11 (11) Attachments

Revision of a SOP may only change a figure or an appendix. Also in such cases the whole SOP must be revised.

Figures include all tables, forms, charts or graphs that are referenced in the SOP. They will follow the text of the SOP, one figure in each page, and numbered sequentially.

Appendices referenced in the SOP will follow figures and be labeled and paginated independently of each other and the SOP.

NOTE: If the same figures and appendices are referenced in a different SOP, the figure or appendix label must include the SOP #, e. g. "SOP ULTRA/KTL-G-1; Figure 1."

English versions of the diaries and questionnaires used in ULTRA are added as attachments to the relevant SOPs. The domestic language translated versions are also attached to local SOP copies, but the SOPs are not revised when/if this translation is edited, as long as the domestic text is still a translation of the same original English text. Such text editions are not recorded as local changes or temporal deviations of SOPs. However, it is essential that the local principal investigator approves the domestic text change and that the new edited text is then attached to all affected local SOP copies.

7.4 Quality Control

See following chapters 8.0 ... 10.3

8.0 Data Records

During the study a complete set and list of all original signed and dated ULTRA SOPs and SOP revisions will be kept by the coordinating ULTRA office of KTL in both computerized and paper form. The same office will also keep a dated list of all centers to which each SOP and each revision has been distributed. All local SOP changes, deviations and attachments, such as all versions of domestic language questionnaires will also be listed and archived at KTL ULTRA Office in Finland.

SOPs including any and all revisions shall be archived and retained for no less than 10 years unless otherwise specified by the project coordinator. All original SOPs and revisions as well as all records of deviation and changes will be archived in the KTL Division of Environmental Health archive in Kuopio after the field work.

9.0 Sample Archiving

N.A.

10.0 Implementation and application

10.1 Distribution

ULTRA SOPs will be distributed by KTL ULTRA office to all ULTRA centers by mail or fax. Reception of a new SOP or revision will always be confirmed back to KTL ULTRA office using the SOP confirmation sheet (Figure 4.).

Each individual performing any ULTRA task for which a SOP has been written, must have the latest SOP version in hand. He/she should also know and understand the SOP, the physical and chemical principles behind the SOP and the fundamental reasons why SOPs are prepared and applied as part of modern Quality Assurance. Distribution of signed and dated copies of the new SOPs/revisions is the task of the local principal investigator, who is also responsible for recovering and destroying any unnecessary or outdated SOPs/revisions. Final versions of a particular SOP may be freely copied for ULTRA team workers with consent from local principal investigator. Also, SOPs can be copied for any interested persons upon their request. However, local PI should keep up-to-date records of the SOPs copied in order to avoid confusion and uncertainty as for what SOP/revision is applied in a particular task.

Explaining personal texts, illustrations and comments may be added by handwriting to the SOPs used by each individual. However, this text may in no way contradict the original SOP text, it does not replace or change any of the SOP context, and this practice cannot be used as an alternative to formal local SOP deviation, change or revision, see 10.2 and 10.3.

10.2 Deviation from SOP in One Location for a Limited Period of Time

In the case that a specific SOP cannot be followed for a limited number of tasks (e.g. in one center for a period while repairing an instrument), but there is no intention to change or revise the SOP, this deviation will be reported to and approved (in emergencies after the fact) by the local principal investigator and recorded in a special form (Figure 3.), which will be archived locally and sent to ULTRA coordinator. For the time that this deviation is in effect, copies of that form must be attached to each copy of the original SOP used in that center. After that time these forms will be collected back to the local principal investigator.

10.3 Changing SOP in One Location

In the case that a specific SOP needs to be changed in one or a few centers and this change will remain in effect in those centers, but there is no intention to revise the SOP, this change will be recorded in a special form (Figure 3.) and reported to and approved by the local principal investigator(s) who will also report the change to ULTRA Coordinator. Copies of that form must be attached to each copy of the original SOP used in the respective center(s).

11.0 ATTACHMENTS

- Figure 1. The SOP title page.
- Figure 2. An outline of the SOP format.
- Figure 3. Local and temporal deviation from or local change of a SOP.
- Figure 4. SOP Confirmation Sheet

Figure 2. An outline of the SOP format. The headings of each SOP needs to include but is not limited to these headings.

TITLE OF THE SOP

1.0 Purpose and Applicability

2.0 Definitions

3.0 References

4.0 Discussion

5.0 Responsibilities

6.0 Equipment and Materials

7.0 Procedure

7.1 Preparation (Before field/Contacts/Lab preparations)

7.2 Steps Followed (Field Procedures/Lab Analyses/Data Procedures)

7.3 Calculations, Input Values, Data Tables

7.4 Quality Controls

8.0 Data Records

9.0 Sample Archiving

10.0 Implementation and Application

11.0 Attachments

Figures

Appendices

Figure 4.

SOP CONFIRMATION SHEET

This SOP has been received by Principal Investigator of

Research center _____ Date ____ / ____ / _____

Signature of PI: _____

INSTRUCTIONS :

0) **Keep this sheet attached to the original copy of the corresponding SOP**

- 1) When copying the SOP, mark the date of copying for each copy, number each copy
- 2) When delivering the SOP copy, take the signature and mark the date
- 3) When delivering a new revision to this SOP, collect previous SOP copies away and confirm with signature and mark the date
- 4) After each change fax this sheet to coordinator

Copy	Date of the copy	Delivered to Signature	Date of delivery	Received back PI signature	Received back Date
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Coordinator fax : + 358 - 17 - 201 265