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Quality Management System – Policy and Programme Support Section					
WRITING A PROCEDURE OR WORKING INSTRUCTION					

1. PURPOSE

To describe the content and the layout of a procedure or working instruction documentation.

2. SCOPE

This procedure applies to all procedures (managerial or technical), working instructions and supporting documents, which are part of the quality management system documentation.

3. RESPONSIBILITIES

Section Head (Technical Manager of the Testing Laboratory)

- to check the compliance of the content of a procedure with the policy and practices of the Agency.

Unit Head (Deputy Technical Manager of the Testing Laboratory)/Service Group Leaders:






- to check the compliance of the content of a procedure or working instruction with applicable technical standards.

Quality Manager:

- to check the compliance of the content of a procedure or working instruction with the applied quality standard.

Author:

- to comply with the rules for content and layout described in this procedure.

	Function	Name	Signature and Date
Authorized	Section Head	K. Mrabit	 2006-12-13
Approved	Unit Head	Pascal Deboodt	 2006.11.21
Approved	Service Group Leader	R. Cruz-Suarez	 2006.11.20
Approved	Service Group Leader	Pascal Deboodt (acting)	 2006.11.20
Registered	Quality Manager	J. Zeger	 17 November 2006

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4. ADDITIONAL INFORMATION

Quality Manual

PR-01-OP “Document control”

5. DESCRIPTION

Every member of staff may write a document to be incorporated into the quality documentation. The content of this document may be a set of rules, a procedure or a set of relevant data on which work is based.

The layout of a procedure or working instruction shall follow the example given by the structure of this document.

5.1 Procedures and working instructions shall include, as needed:

- title of the procedure or working instruction
- code and revision number according to the numbering system given in 4.4.2
- purpose, describing which goal shall be reached by applying the procedure
- scope, describing where, on what items or at which locations the procedure shall be applied
- responsibilities within the application of the procedure, using functions only (e.g.: Section Head/Technical Manager, Unit Head/Deputy Technical Manager, Service Group Leader, Staff, Quality Manager)
- a list of any additional sources of information for the procedure like internal and external standards, technical publications or other external documents issued by international organizations, compilations of data, etc.
- a flowchart (compulsory for technical procedures, optional for managerial ones; for symbols to be used see Annex I at the end of this procedure) of the method/procedure/process that depicts the sequences of actions and decisions, inputs, outputs and interfaces with other methods/procedures,
- paragraphs describing the actions and decisions required according to the flow chart, if one exists and any precautions needed to prevent incident, accident, error, problems, etc. (preventive actions).
- a list of records that will result of applying the procedure and the designated record keeper (function, not name)

5.2 Technical procedures require additionally :

- information, conditions (inputs, approvals), equipment needed to perform each activity, layout of the laboratory where the task has to be performed (can be generalized into an extra, stand-alone document) and calculations used to arrive at the correct results;
- exit conditions for ending the process or task, in term of the outputs and approvals to be satisfied for successful completion of the process;

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- ways of recording and/or reporting the output from the method/procedure;
- control actions, acceptance values (reference values) and actions to be taken if the results of the control is not acceptable.

5.3 Working instructions requirements:

Working Instructions generally follow the same principles that are applied for technical procedures. With additional paragraphs on Equipment and Supplies, whenever needed.

5.4 , Lists, Checklists, Forms (Templates for reports)

These documents are free of form, but they have to follow the numbering code issued by the quality manager.

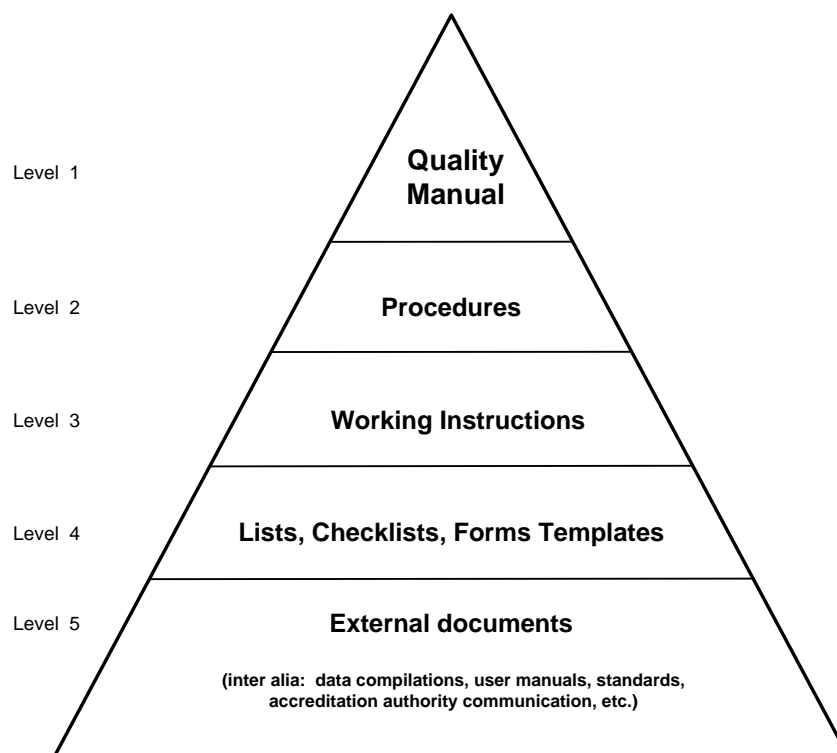
5.5 Assigning code to the documents

The quality manager will distribute codes for all documents (procedures, working instructions, lists, tables, checklists, forms, reports, etc.) that are produced as separate documentation.

For this he will follow the system described in the following.

5.5.1 Hierarchy of documents

The documents related to the QMS are structured into hierarchical levels according to the following figure:



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Code system

The general format of the document code is:

<document type> - *<procedure number>* - - *<given number>*.

For the quality manual, the *<procedure number>*, *<area of application>* and the *<given number>* do not apply.

For the procedures, the *<given number>* does not apply.

Level	Code	Document type	Comment
1	QM	Quality Manual	The Quality Manual comprises statements on quality policy, quality objectives, organizational structures, and an overview of the quality management system
2	PR-x-A	Procedure	Procedures specify the way to carry out an activity
3	WI-x-A-y	Working instruction	Work instructions provide detailed information on how to perform specific duties
4	CL-x-A-y FO-x-A-y LI-x-A-y	Checklists, Forms, Lists	These documents are to be referenced in the respective PR or WI.
5	None	External documents	Standards, technical publications, data compilations, regulatory requirements, accreditation authority information, etc.

Examples:

PR-11-OP Procedure applicable for the whole testing laboratory

CL-11-OP-01 Checklist attached to the above procedure

WI-33-IC-01 Working Instruction in the area of Instrument Checking

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5.5.2 The abbreviations for <document types> are:

QM Quality Manual

PR Procedure

WI Working instruction

CL Checklist

FO Form (for reports)

5.5.3 The abbreviations for <area of application> are:

OP Occupational Radiation Protection at PPSS

IM Individual monitoring

ED External dosimetry

ID Internal dosimetry

UA Urine analysis

WB Whole body counting

WM Workplace monitoring

WH Waste handling

IC Instrument check and maintenance

VS Ventilation system checks

6. RECORDS

None

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DOCUMENT CONTROL ANNEX I				

Flowchart symbols

