DOCUMENT CONTROL

1 PURPOSE

To define rules governing the preparation, review, change and approval of documents.

2 SCOPE

This procedure applies to all quality documents — e.g. procedures, working instructions, checklists, forms, reports and external documents— that are used to define an action within the testing laboratory operated by the Radiation Safety and Monitoring Section (RSM). It does not apply to other documents (i.e. documents coming from Agency sources outside the Section).

3 RESPONSIBILITIES

Technical Manager of the Testing Laboratory

- To authorize documents.
- To seek the authorization of any document by higher management whenever necessary.
- To determine the date on which procedures enter into force.

	Function	Name	Signature and Date
Authorized	Technical Manager	R. Czarwinski	Czarwinski 01/04/09
Approved	Deputy Technical Manager	P. Deboodt	2009-03-27
Approved	Individual Monitoring Service Group Leader	R. Cruz-Suarez	2009-03.19.
Approved	Operational Service Group Leader	J. Hunt	John Hunt 2009-03-27
Registered	Quality Manager	J. Zeger	2009-03-17

Deputy Technical Manager of the Testing Laboratory

- To approve procedures.
- To authorize working instructions.
- To determine the date on which working instructions enter into force.
- To perform a review of the technical documentation status every second year.

Service Group Leader

- To approve procedures and working instructions.
- To supervise the preparation of quality documents for use within the Service Group.
- To authorize forms and templates for result reports within the Service Group.
- To authorize external technical documents for use within the Service Group.
- To inform the quality manager about any external documents used within the Service Group.
- To place any external standards into the common folder assigned for standards.
- To initiate updates of documents for use within the Service Group as necessary.

Quality Manager

- To keep the documentation in compliance with applicable standards.
- To update the list of documents in force.
- To post authorized versions of documents (in read-only form) on a disk drive accessible to all staff of the section.
- To archive one copy of all distributed versions of documents.
- To perform a review of the managerial documentation status every two years.
- To keep a list of external documents or organizations, who should be monitored for their publications, together with the responsible persons.

Staff

- To observe improvement possibilities in all working and managerial activities.
- To initiate changes by proposing improvements.

4 ADDITIONAL INFORMATION

PR-18 Writing a procedure or working instruction

5 DESCRIPTION

All staff members are obliged to look for improvement possibilities within the tasks they are performing and shall draft quality documents to describe either new techniques or improvements to existing ones.

All documents shall be formatted and codified in accordance with PR-18.

The final authorized version of any quality document (an electronic equivalent to the signed and dated master copy) shall be posted by the quality manager in read-only format in the folder *"s:\quality management\quality management documentation"* and thematic subfolders on the internal network system of the NSRW-Division, which is read-only accessible to all staff members of the Section.

At the same time, the Quality Manager shall make the new version of any document available to the staff members of the testing laboratory working in the SERA laboratory by transferring the files to the special folder reserved for QM-documentation on the Safeguards public (P:\) drive, which is also open for reading to all SERA staff members.

To enter into force all documents have to be approved and authorized according to the following matrix.

Level	Type of document	Contents	Approved by	Authorized by
1	Quality Manual	General description of the QM-system.	Technical Manager	Director
2	General Procedure (managerial or technical)	Description of processes relevant for all members of the testing laboratory.	Deputy Technical Manager and both Service Group Leaders	Technical Manager

DOCUMENT CONTROL

Level	Type of document	Contents	Approved by	Authorized by
2	Special Technical Procedure	Description of technical processes relevant for only one of the Service Groups.	Deputy Technical Manager and Service Group Leader	Technical Manager
3	Working Instruction (WI)	Detailed description on how the measurement methods have to be performed.	Responsible Service Group Leader	Deputy Technical Manager
4	Check List	Support to decision finding. Is connected to a procedure or WI.	Either (WI) or both (PR) Service Group Leaders	Deputy Technical Manager
4	Report form	Template to be used for specified result reports to the customer.	Service Group Leader	Service Group Leader
4	List	Compiled information collected by the quality manager.	Quality Manager	Quality Manager
5	External documents	Standards, accreditation authority documents, instrument manuals, calibration procedures, technical specifications, tables, drawings, etc.	Deputy Technical Manager or responsible Service Group Leader or Quality Manager	

The Technical Manager is responsible for seeking the authorization of any other document by higher management of the Agency, whenever necessary.

It is the duty of the Quality Manager to ensure compliance of issued internal documents with applicable management standards (e.g. ISO/IEC17025) and other

requirements and to keep a copy of all issued documents of the testing laboratory to document the historical development and improvement of quality documentation. The Quality Manager is also responsible for reviewing all managerial documentation (procedures, working instructions, checklists, forms, etc.) before they come into force within the testing laboratory and afterwards every two years in order to ensure continuing compliance of the installed quality management system with the applicable international standards and the suitability to provide the services to the customer in the desired quality.

The Quality Manager shall register all issued documents within the testing laboratory into a list showing their code, revision number and date of entry into force and, therefore, shall be kept informed by the Technical Manager, the Deputy Technical Manager and Service Group Leaders of any new document.

Changes to a document may be proposed — preferably in written form — by any staff member. These proposals shall be addressed to the respective Service Group Leader, who will start the procedure of evaluation as for a new document. A change in a document shall be supervised and authorized through the same procedure, but, if necessary, by different persons, as for the original version. Any handwritten change or comment on a document can only be for private use to create a proposal for changing the document. Handwritten changes may never enter into force.

If a proposed change within a document is authorized, the document shall get the next version number and a new date of entry into force. Changes, when significant to warrant attention, within this newly posted document have to be marked with a yellow background for easier reading. The Quality Manager has to archive the electronic copy which is replaced and post an electronic copy of the new version with an increased version number in the file name. The printed “history” copy has to be clearly marked on the first page (containing the signatures) as no longer valid and only this page must also be archived in a special folder by the Quality Manager.

Documents issued by external sources, such as, inter alia, technical standards, instrument manuals, calibration procedures, technical specifications, tables and drawings, are excluded from the above mentioned rules. They only have to be authorized by the respective Service Group Leader, with signature and date of entry into force. Their title and enforcement date must be relayed to the quality manager to be entered into the documentation list.

The Service Group Leaders have to inform the Quality Manager about necessary external documents from other international organizations, which they need to render the services and to regularly check these every half year (international standards, publications of methods, physical data, etc.) to keep them up to date and to have the possibility of working with the most recent edition.

6 RECORDS

List of all documents in force within the testing laboratory to be kept by the Quality Manager.