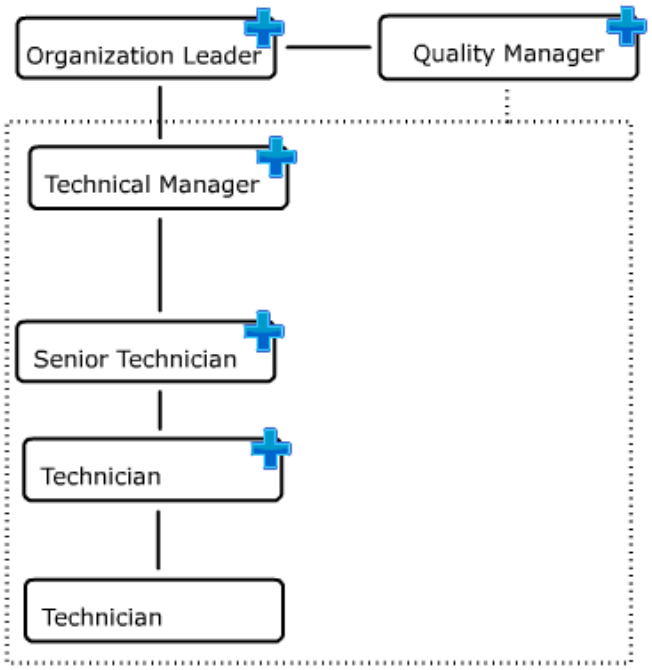
4 SECTION 4: TEMPLATES OF QUALITY DOCUMENTATION

This section is aimed to assist you in the creation of your Quality Documentation. A set of templates has been created using general formulations that you shall adapt to the specifics of your organization.

The documentation has been coded as DT.0nn (DT is the type of document: OP-Operational Procedure, OR-Operational Record, F-Form). The acronym XRFG serves to declare that documentation belongs to XRF Group QMS. If you are an independent organization you may remove XRFG from the coding.

4.1 SCHEME OF RESPONSIBILITIES FOR QM

The documentation has been created assuming the following list of specific and general responsibilities in regard to Quality Management in a laboratory composed by a Head (H), a Technical Manager (TM), a Quality Manager (QM) and some technicians:



All the members of the staff are responsible for:

- maintaining the services at the highest possible quality level
- keeping the functioning of the instrumentation in conditions that ensure the traceability of the measurements and calibration results
- implementing the operational procedures and instructions, as well as to contribute to the preparation of new ones whenever it might be needed
- different technicians shall be appointed to keep records and operation of stocks, instrumentation control, outsourcing, among other specific activities

ONE OF THE TECHNICIANS OF EACH SERVICE GROUP MUST ASSUME THE RESPONSIBILITIES OF THE GROUP SENIOR TECHNICIAN IN CASE OF ABSENCE.

4.2 About organizational structure

- Your organization has been coded as X RAY FLUORESCENCE GROUP (XRFG), belonging to an ORGANIZATION. The names, positions and denominations of such organization are HIGHLIGHTED IN YELLOW (with the exempt of XRFG). Wouldn't be the case, remove these texts and rephrase the writing as appropriate.

- Your organization might be subordinated to a PARENT ORGANIZATION. Texts regarding the parent organization are HIGHLIGHTED IN BLUE. Please, introduce the specific denominations regarding such parent organization. Wouldn't be the case, remove these texts and rephrase the writing as appropriate.

- Your organization might have less or more personnel. In that case you shall redefine the responsibilities in regard to QM. If so, notice that cross references are made among the different documents. Whenever you change a specific position or responsibility, proper changes shall be made in the rest of linked documentation.

4.3 Hints for adapting the documentation

- Be aware that the provided templates have been prepared for a system aimed to a scope covering the tasks of your XRF laboratory. Please, adjust the texts HIGHLIGHTED IN GREY to fit to your activities and related procedures.

- You might have advanced tools for electronic records (specialized software). Otherwise, you must use at least hard copy records. Notice that texts related to these type of records are HIGHLIGHTED IN GREY. Please, make proper changes to reflect your real scenario.

- Some texts describe the type of customers you work for. These texts are HIGHLIGHTED IN GREEN. Please, elaborate the proper descriptions of your customers.

4.4 LIST OF AVAILABLE DOCUMENTS

Code	Title	Purpose
DCH	History on documentation changes	To record the modifications made in the quality documentation.
QM.001	Quality Manual	To define the scope of the QMS, to declare the quality policy, objectives and commitment. To relate the procedures established, the interactions among them and the responsibilities.
OPERATIONAL PROCEDURES		
OP.001	Working flow for analytical services.	To establish a working flow for the performance of analytical services that ensures the quality system requirements.
OP.002	Sample reception, classification and storage.	To define the procedures and responsibilities for sample reception, classification, conservation, manipulation, distribution and storage in the laboratory.
OP.003	Sample Preparation for XRF analysis: Preparation of sample pellets for the analysis with SPECTRO X-Lab 2000 spectrometer.	To define the set of procedures and responsibilities undertaken for the preparation of samples for XRF analysis with SPECTRO X-Lab 2000 spectrometer.
OP.004	Reception, conservation and use of reference materials and certified reference materials.	To define the set of procedures and responsibilities undertaken by the laboratory for the continuous monitoring of operation and the results of measurements in order to decide whether the obtained results are reliable enough to be released.
OP.005	Realization of internal quality control.	To define the set of procedures and responsibilities undertaken by the laboratory for the proper conservation and use of reference materials, in order to ensure the quality of the analytical results.
OP.006	Estimation of uncertainty in XRF analysis.	To define the set of procedures for the estimation of the uncertainty of the results obtained by X-ray fluorescence spectroscopic methods and to give a step by step practical example for a specific application.

OP.007	Operation of X-ray tube and generators.	To define the set of procedures for the operation of X-ray tubes and generators.
OP.008	Method validation in the determination of elemental mass fractions by EDXRF.	The purpose of this procedure is to assure that test methods used for element mass fraction determination by EDXRF are properly validated before being applied; and to provide documented evidence that the selected method fulfils the requirements set for a specific analysis.

4.5 LIST OF AVAILABLE RECORDS/FORMS

Code	Title	Forms/Software tools
OR.001	Requests for Analysis.	F.001
OR.002	Work flow of analytical services.	F.002
OR.003	Work assignment information forms.	F.003
OR.004	Reports of results of analysis.	F.004
OR.005	Results of Internal Quality Control	F.005
OR.006	Inventories. Certified Reference Materials and certificates. Reference Materials and specifications sheets.	F.006
OR.007	Inventories. Chemical reagents. Consumable supplies.	F.007
OR.008	Instrumentation User's Manuals. Service Manuals.	
OR.009	Calibrations / verifications of Instrumentation.	F.009
OR.010	Results of participation in proficiency tests and inter-comparison exercises.	F.010
OR.011	Curriculum Vitae of the staff/Certificates of training	
OR.012	Customer's opinions and suggestions	F.012
OR.013	Results of Management Reviews	F.013
OR.014	Results of Internal Audits	
OR.015	Complaints, nonconformities and corrective actions report	

OR.016	Method validation plan and report.	
OR.017	Request for electronic services.	
OR.018	Request for PC-service.	
OR.019	List of Requests and Goods Received.	Received Request & shipping lists
OR.020	Periodic maintenance/servicing of SPECTRO X-Lab 2000 spectrometer	
OR.021	Control of radioactive reference materials and sources.	F.014

4.6 GOOD LUCK IN YOUR WORK!

This ICT module has been developed in collaboration with the Nuclear Spectrometry and Applications Laboratory (NSAL), Physics Section, from IAEA NAPC. The NSAL and the team of authors hopes that our work has been useful to you.

We would highly appreciate if you send some comments on the course. Your information is of outmost value for further development of this course or other similar modules!

Please, send your comments to Official.Mail@iaea.org