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1. PURPOSE AND SCOPE

This procedure defines the rules for drafting and document management of SOAC's quality management system (Quality manual, procedures, work instructions, guides, forms, etc.). It also deals with the management of documents of external origin.

2. REFERENCES

- ISO/IEC 17011, Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies.

3. DISTRIBUTION LIST

All services concerned.

4. EFFECTIVE DATE AND REVIEW

This document is applicable from the date mentioned on the cover page. It will be updated as necessary.

5. SUMMARY OF CHANGES

Version 00: creation.
Version 01: strengthening conservation provisions
Version 02: revision to some sections and update of the table of modifications.

6. TERMS AND DEFINITIONS

Conformity assessment body (CAB): Body that carries out the conformity assessment activities (testing, calibration, inspection, certification, organization of proficiency testing, reference material production, validation/verification) and that can be the subject of accreditation.

QMS: Quality Management System
QTSO: Quality & Technical Senior Officer
JAO: Junior Accreditation Officer
AFO: Administrative & Financial Officer
EEWG: External Expert /External Working Group
DG: Director-General

7. PROCESS DESCRIPTION

7.1 Writing, verification, approval, and issue

Responsibilities for drafting, verifying, approving, and issuing quality documents are defined below:

Documents	Writing	Verification	Approval	Issue
Contract documents	DG, QTSO, EEWG	QTSO, DG	DG	QTSO
Quality manual	DG QTSO,	QTSO, DG	DG	QTSO
Procedures	DG, QTSO, JAO, AFO, EEWG	QTSO, DG	DG	QTSO
Guidelines	QTSO, JAO, EEWG	QTSO	DG	QTSO

Work instruction	QTSO, JAO, AFO, EEWG	QTSO	DG	QTSO
Forms	QTSO, JAO, AFO, EEWG	QTSO	DG	QTSO

7.2 Layout
Each page has a header. The first page includes a footer for verifications and approvals.

7.3 Header
The Header is as follows:

	Document type	Code :
	Document title	Version :

The contract documents, quality policy, quality manual, some forms, and work instructions have no header.

7.4 Version
The version begins with 00 and is incremented by one with every amendment or updating of the document.

7.5 Pagination
The pagination of the document type X with Y
X = sequence number of the page starting with 1 for the cover sheet
Y = total number of pages of the document

7.6 Lower cartridge
The lower cartridge cover page is as follows:

Written by: Date:	Verify by: Date:	Approved by : Date:

The quality policy and forms have no footer.

The contractual documents and some work instructions have a particular lower cartridge. It is as follows:

Approval		Effective date
Date		

7.7 Structure of procedures, guidelines, and instructions

Procedures, guidelines, and instructions are structured as follows:

1 Purpose and scope
2 References
3 Distribution list
4 Effective date and review
5 Summary of Changes
6 Terms and Definitions
7 Process description
8 Related documents
9 Table of modifications

NB: There is no fixed structure type for the forms and some general documents of the QMS.

7.8 Structure of contract documents

The contract documents have a common structure type and specific one depending on the content of the document. The common structure type is presented as follows:

1 Purpose and scope
2 References
3 Effective date and review
4 Summary of Changes
5 Terms and Definitions

7.9 Documents coding

Apart from work instructions and forms, QMS documents are coded as follows:

- a series of letters indicating the type of document
- a serial number
- where appropriate, the code of the specific scope of accreditation body of SOAC which the document emanates.

The order numbers are double digits. They start with 01 and are assigned by document type.
Instructions and forms are coded as follows:

- the letter **I** for instructions and **F** for forms
- a serial number
- the code for the procedure to which the instructions or form is attached.

The code and version can be written in abbreviated form by uniting with a period (.).

The document type codes, areas of accreditation, and SOAC organs are specified in the table below:

Types of documents	Indicative	Areas of accreditation and Bodies	Indicative
Contract documents	C	Medical Laboratories	BM
Quality Manual	MQ	Testing laboratories	ES
Procedure	P	Calibration laboratories	ET
Instruction	I	Inspection bodies	IN
Forms	F	Bodies certifying products, processes, and services	CE
Technical Guide	G	Bodies providing audit and certification of management systems	CS
Assessment report	RE	Bodies operating certification of persons	CP
Report	CR		

Examples

P01: 1st QMS procedure

P01.00: 1st procedure of the QMS at its creation.

I01P05: 1st instruction of the procedure P05

I01P05.02: 1st instruction of the P05 procedure to its 2nd revision.

F02P03BM: 2nd form attached to the P03 procedure. It is only usable in medical laboratories.

F01I02P03: 1st form attached to the instruction 02 which is attached to the procedure P03

The provisions relating to the coding of requests, accreditation agreements, and certificates are defined in instruction *(see I01P01- Coding of accreditation applications)*. This statement also addresses the coding of assessment reports of accredited organizations or candidates.

7.10 Date format

The date formats adopted in SOAC's QMS documents (footer on contractual documents, procedures, forms, guidelines, and instructions, etc…) is written in British format: day-month-year (dd-mm-yyyy) same as the French format: jour-mois-année (jj-mm-aaaa);

for example 14 March 2019 or 14/03/19 or March 2019 as presented by the table below:

Format	**British** **dd-mm-yyyy** Day-Month-Year / **mm-yyy** Month-Year	**French** **jj-mm-aaaa** Jour-Mois-Année / **mm-aaa** Mois-Année
A	14 March 2019	14 mars 2019

B	14/03/19	14/03/19
C	March 2019	mars 2019
D	03/19	03/19

7.11 Document Management

Document management is ensured by the Quality & Technical Senior Officer under the conditions below.

7.12 Issue

The QTSO issues documents preferably by electronic means and ensures their follow-up (Example: Email with acknowledgment of receipt, etc.).

All procedures, regulations, work instructions, publications, and quality manual will be as PDF files.

All forms that can be filled in electronically will be kept as an editable document (Word, Excel ...).

Each recipient service shall take appropriate measures to ensure easy access to documents to appropriate personnel.

The authoritative documents are those in the website or the intranet.
The use of any documents from other sources than this means is prohibited.
Any copy (hard or soft) outside this source will be considered as an uncontrolled copy.

The authoritative documents between two versions: French and English, are those in French.

7.13 Effective Date
Unless otherwise specified, the document takes effect from the date of approval.

7.14 List of current documents
The quality officer maintains a list of the documents in force with an indication of the corresponding versions *(see F02P01- Current QMS Control list)*.

7.15 Changes
Anyone may contact the QTSO to seek a modification of a document *(see F03P01- Document Improvement Request)*. The relevance of the request is analyzed before initiating any change.
A modification of a document requires:

- a change in the version number

- new verification and approval
- a new issuing.

The latest changes in the updated document are summarized in section **"summary of changes"** and/or in the **table of modifications** at the end of some documents.
The modification of the recording media is managed by the list of documents of the current F02P01-Current QMS Control list.

7.16 Conservation
The QTSO ensures that all documents in use remain legible and easily identifiable.
QMS Original documents in force are kept by the QTSO. When a document requires confidential handling, it is managed as such and kept so as to preserve its confidentiality.

7.17 Application
The QTSO is responsible for ensuring that the provisions of the QMS are applied.

7.18 Management of obsolete documents
The QSTO ensures the removal and disposal of obsolete documents so as to avoid unintended use.
The original outdated versions of the QMS documents are kept for at least **01 year** with the indication "EXPIRED".

7.19 Documents on electronic media
The provisions for the control of computerized documents are defined in the procedure P02**.**

7.20 Documents of external origin
The documents of external origin are those that are not produced by SOAC.
These standards, documents of international accreditation organizations, regional or national regulations, etc.
Each service maintains its documents and has the responsibility to ensure the use of updated documents.
When a document is used by several services, the QTSO or the DG defines the responsibility for its management.

The list of documents of external origin is maintained by the QTSO (see *F04P01-list of documents of external origin*)

7.21 Monitoring of documents of external origin
These are mainly the standards, regulations, policies, and guides of regional and international accreditation organizations. Documents of external origin are reviewed at least every 02 years.

8. RELATED DOCUMENTS

Refer to F02P01-Current QMS Control list

9. TABLE OF MODIFICATIONS

No.	Source	Modification in brief (Relevant changes)
P01.00- 13 March 2019		
Creation		
P01.01- 22 July 2019		
Strengthening conservation provisions		
P01.02- 12 October 2019		
1	§ 1	Update to take into account the management of documents of external origin
2	§ 2	The reference has been revised in line with the wording of the standards
3	§ 6 & 7	AG changed to JAO: Junior Accreditation Officer Number 6 & 7 modified — The words “Abbreviations and Definitions” and “Related forms” have been respectively replaced by “Terms and Definitions” and “Related documents”
4	§ 7.3	Update of the section
5	§ 7.6	Update of the section
6	§ 7.8	Update of the structure of contract documents
7	§ 7.9	Update and clarification of the codes of accreditation fields
8	§ 7.10 to § 7.19	Update of the chapters' alignment and content with the insertion of two new chapters: 7.10. Date format and 7.11. to be addressed before and after dealing with 7.12. document management. (from 7.10 to .7.21); cancelation of signature requirement
9	§ 7.13	Review of issuing documents provisions
10	§ 7.16	This section has been revised to specify the dispositions for changes to documents
11	§ 7.19	This section has been revised with the addition of the text "expired"
12	§ 7.21	Creation of the list of documents of external origin
13	§ 7.22	Addition of chapter 7.22 Monitoring of documents of external origin
14	§ 8	This section has been revised : the words “related forms” (title) have been replaced by “related documents” (title)