



EUROPEAN  
FEDERATION FOR  
IMMUNOGENETICS

**PROCEDURE MANUAL**  
Standards and Quality Assurance  
Committee

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# The Standards and Quality Assurance Committee

## *Introduction*

The first EFI Standards and Quality Assurance Committee (SQC) was formed in 1994 to modify the ASHI Standards to a more acceptable and appropriate format for use within Europe, and to provide the basis for launching the accreditation program in European laboratories. The SQC is closely linked to other EFI committees, especially to the Accreditation Committee and the Committee for External Proficiency Testing.

## *Mission, Purpose, Aims and Goals*

The mission of the EFI SQC is to promote high quality practice standardization and traceability in Histocompatibility and Immunogenetics (H&I) through up to date standards.

The purpose of the SQC is to provide EFI laboratories with standards for quality practice in immunogenetics laboratory procedures, use of official nomenclature and also in personal qualification.

The goals of the SQC are:

- to provide standards for H&I laboratories
- to maintain relevance in the standards
- to introduce new methods into the standards
- to represent new developments in the standards
- to ensure minimum requirements without preventing development
- to avoid ambiguity in the standards
- to raise quality within H&I laboratories
- to promote patient safety

## ***Committee Structure***

The committee is composed of the following: Chair, Co-Chair and 9 members.

## **Chairperson**

### **Appointment and Term**

- is proposed by the SQC or by the EFI Executive Committee (EC)
- is approved and appointed by the EFI EC
- the term of office is 3 years, with a reappointment for a second and third term contingent on approval of the EFI EC

### **Qualifications**

- is a member of EFI
- must belong to an EFI accredited laboratory

### **Responsibilities**

- has the overall authority for the writing process of the standards
- to organise, and chair the SQC meetings
- to be a point of contact for EFI members who have queries or suggestions for consideration by the Standards Committee
- to write reports for the newsletter, as necessary – a minimum requirement would be after the meeting at Congress and after the Autumn meeting in October/November
- to publish all proposed changes on the EFI website, and to inform the EFI membership in writing in the EFI Newsletter, and by email
- to set a deadline for the consultation process with the membership on proposed changes
- to collate all responses from the consultation and to circulate to members of the SQC prior to discussion at the next meeting
- to revise the Standards as agreed by members of the SQC
- to send revised versions of the Standards to the Chair of the Accreditation Committee for comments before circulating to the EFI Executive Committee.

- to prepare a Tracking Document of all agreed changes to the current version of the EFI Standards to be published alongside the new version of the EFI Standards on the EFI website
- to liaise with the EFI Webmaster to ensure that the downloadable documents are up to date
- to circulate revised documents to the EFI Accreditation Committee Chair and Manager of EFI Accreditation Office to enable necessary changes to accreditation documentation and checklist
- to liaise with the Chairs of the Accreditation Committee and EPT Committees prior to the EFI EC and Co-ordinators meeting to avoid any conflicts with other committees
- to organize voting for SQC membership
- to assist EFI EC in coordination of QA programs with other organisations

### **Duties during the EFI Annual Congress**

- to attend the Commissioners meeting before the Annual Congress to focus on problems with Standards raised during the current year's inspections
- to chair the SQC Meeting
- to present the main revisions to the Standards during the annual Inspectors' Workshop
- to attend other EFI Meetings where the Chair's presence is requested
- to prepare the report for the EFI Executive Committee, briefly summarising any changes to the Standards and outlining future plans
- to prepare the report for presentation at the EFI General Assembly, again briefly summarising any changes to the Standards and outlining future plans. Slides are handed over to the EFI Secretary after the meeting

## **Co-Chairperson**

### **Appointment and Term**

- is proposed by the Chairperson of the SQC with the approval of the SQC
- is approved and appointed by the EFI EC

- the term of office is 3 years, with a reappointment for a second and third term contingent on approval of the EFI EC

### **Qualifications**

- is a member of EFI
- must belong to an EFI accredited laboratory

### **Responsibilities**

- takes the responsibilities of the Chairperson in his/her absence
- undertakes duties as deemed appropriate by the Chairperson or by the SQC
- keeps proper records of meetings
- keeps records of members' contact details

## *Members*

### **Appointment and Term**

- can be proposed by any member of the SQC
- are approved and appointed by the EFI EC
- the term of office is 3 years, with reappointment for a second and third term contingent on approval of the EFI EC with a rotation approximately 2 members annually

### **Qualifications**

- is a member of EFI
- have specialist knowledge about standards or belong to an EFI or ASHI accredited laboratory

### **Responsibilities**

- follows the developments of H&I
- participates in SQC meetings
- proposes changes to current standards
- proposes new standards

### **Members' recruitment and records**

The SQC keeps a record of the vacant positions. The SQC also keeps a record of the skill mix of current members. Preference will be given to applicants with skills required by the committee. Vacancies will be advertised on the EFI website and in the

newsletter. Any EFI member wishing to participate in a committee should complete the following [application form](#) (PDF File). Applications are sent to EFI secretary. For committee vacancies please click [here](#). New members are elected from the list of nominations by secret vote.

## ***Process for standards revision***

### **Information**

EFI members or other EFI Committees can send queries or suggestions to the SQC using the electronic form available on the EFI website or the form included in the accreditation packet.

### **Meetings**

The SQC meets at least annually. Typically a one day meeting is held in the autumn and a half day meeting during the EFI annual conference. Meetings held outside the annual EFI conference require budgetary approval from the Executive Committee. Revisions to the current version of the EFI Standards are discussed and addressed at the meeting. This is followed by a consultation process whereby proposed changes are circulated to members, and comments invited. Comments received are discussed and addressed at the SQC meeting.

### **Revision cycle**

The standards are reviewed annually and new versions are introduced depending on need which is usually every two to three years. Standards are revised by communication between the committee members and all changes are presented during the SQC meetings. A revised version of the standards will be published when changes have been introduced. Standards will become effective after Executive Committee approval.

### **Major and minor changes**

Major changes in standards gives a new version number (version 7.0 changes to version 8.0. Minor changes in standards will keep the same main version number, but will only change the suffix (version 7.0 will change to 7.1)

Criteria to call revisions major changes in the standards may include:

- Re-organization of standards.
- Addition of new category of testing.
- Changes in nomenclature.
- Addition or removal of standard affecting of good laboratory practice.
- Addition or removal of standards on techniques or clinical services.
- Addition or removal of standard affecting quality assurance activities.

Criteria to call revisions minor changes in the standards might include:

- Rephrasing a standard without changing the mandatory essential.
- Changes from a mandatory standard to a recommendation.

## **Valid version of EFI Standards**

After approval by the EC, Standards will be published on the EFI website and submitted to the Accreditation Committee for incorporation into the accreditation process.

## **Review process**

### **Before the meeting**

1. Public comments on the standards will be gathered prior the meetings
2. Potential conflicts of interest or matters of relevance to the Accreditation Committee and EPT Committees will be discussed by the Chairs prior the meeting
3. The public comments and suggestions will be circulated to SQC members prior to the meeting

### **During the meeting**

4. Comments will be considered by the SQC and all modifications to standards will be recorded
5. The committee will cross check the revised standards to ensure that each standard is consistent with the entire document
6. The developments will be presented at the Co-ordinators meeting

### **After the meeting**

7. Proposed changes to the EFI Standards will be circulated to the SQC for review and confirmation of changes.
8. The EFI Executive Committee will be notified about the proposed changes
9. The proposed changes will be published on the EFI Website and membership informed by email and/or in the EFI Newsletter
10. Following the consultation, comments to proposed standards will be collated

### **Approval**

11. The Standards and Tracking Document will be updated with changes accepted by the SQC
12. The developments will be presented to the EFI Executive Committee, briefly summarising any changes to the Standards and outlining future plans
13. The revised standards will be submitted to the Executive Committee for approval a month before EFI annual meeting
14. Revised standards may either be approved or returned to the SQC for further revision
15. An article will be submitted for publication on the EFI Website and members will be informed via the EFI Newsletter and by email
16. Revised documents will be circulated to the EFI Accreditation Committee Chair and Manager of EFI Accreditation Office to enable the changes to the accreditation documentation

## **Documents sent to the members prior meeting**

Prior the autumn meeting or annual congress the following documents will be sent to the committee members:

- Agenda
- Members' Contact Details
- Rotation of Committee Members
- Applications for membership
- Comments received from Members, Accreditation Committee, Commissioners and Inspectors
- Drafted standard/Proposed changes
- Procedure Manual of the Standards Committee

## **Interaction with other EFI committees**

In order to update the EFI standards, the SQC will work in collaboration with other EFI committees (Accreditation Committee, External Proficiency Testing Committee, Education Committee, Web Committee). The Chairperson will act as a liaison-officer between all parties.

## **Interaction with ASHI**

In order to maintain relations and to ensure alignment of EFI and ASHI standards a representative of the EFI SQC will participate in appropriate ASHI QAS teleconferences. On a biennial basis a representative will attend the ASHI QAS held during the ASHI annual conference. Also a representative of ASHI QAS is invited on a biennial basis to the EFI SQC meeting held during EFI annual meeting.

## ***Update of the procedure manual***

The procedure manual will be updated when necessary and in order to document that the manual has been revised, the version index will be increased (for example version 2.3→2.4); major changes in the manual will lead to an increase of the version number (for example 2.3 ->3.0). The new effective date will be set as the date of approval by the EFI Executive Committee.