



Forensic Quality Services-International

General Requirements for Accreditation
(GRA)

REVISION LOG

Version	Issued	Changes
May 2004	May 2004	Initial document with FQS-I references
2006/1	12-30-2005	Incorporate changes to standards from ISO/IEC 17025:2005; revise sections 1-3 to update ISO references and clarify procedures.
2006/2	2-9-2006	Corrected mis-numbering in the standards
2006/3	June 29, 2006	Revise definition of non-conformances and concerns; clarification of program development; section on relationship between AB and laboratory changed to "responsibilities of FQS-I and the Laboratory" to bring document into conformance with requirements of ISO 17011; expand application section-add requirement to provide completed ISO checklist prior to the on-site assessment with preference for electronic documents on CD; add specific requirements for minimum number of test records to be available during the assessment; remove detailed standards in sections 4 and 5 and replace them with a reference to ISO 17025:2005.
2006/4	October 27, 2006	Revise section 2.6.1 to allow for flexibility in accreditation cycle up to 5 years; add section 2.7.4 to describe more stringent surveillance requirements if the accreditation cycle is greater than 24 months; revise section 2.8 to acknowledge the potential for different surveillance schedules.
2007/1	November 17, 2007	Substitute "agency" for "laboratory"; broaden definition of agencies accredited by FQS-I; limit applicability of FRA-1 to those agencies performing testing for criminal investigations; clarify that FRA-2 applies only to laboratories performing forensic DNA casework and databasing with possible CODIS application; add section describing FQS-I supplemental documents (1.2.4); clarify the basis for objecting to the appointment of an FQS-I lead assessor (2.3.3); add section regarding accreditation when corrective actions are incomplete (2.5.3); add section regarding appeal of assessment non-conformities (2.4.3); add section clarifying what is required to substantiate agency "belief in conformance" with standards prior to submitting application for accreditation (2.1.3.1); clarification of language regarding cycle of accreditation; add section (2.3.10) to discuss issues surrounding the postponement of an assessment.
2008/1	January 24, 2008	Delete FQS-I address and phone numbers from cover sheet.
2008/2	May 31, 2008	Move fee discussion to Section 1.2.2; add information in 1.2.3 regarding consideration of

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		<p>requirements of regulators when expanding programs; expand scope discussion to reference conformance with the ILAC MRA; remove “FRA-2” designation from the FBI DNA QAS audit document, add a separate section for discussion of this standards document; change application process for new applicants to include document review prior to setting dates for on-site assessment; add requirement to correlate DNA QAS findings to an ISO 17025 or FRA-1 requirement and its effect on the assessment reports; add requirement for an opening meeting during on-site assessment; clarify surveillance types and when each will be used</p>

1. GENERAL INFORMATION

1.1 Forensic Quality Services - International (FQS-I)

Forensic Quality Services is an independent, not-for-profit corporation established in October 2003 by the National Forensic Science Technology Center (NFSTC) and incorporated in Florida. FQS provides a range of services and training to support management systems development and service delivery in organizations, including those working in the area of forensic science. FQS-I is a separate business unit within FQS whose sole purpose is accreditation of testing agencies to ISO 17025. FQS-I's accreditation program history dates back to 1998 as part of the quality support provided to forensic science by the NFSTC, but the NFSTC no longer provides services in this area.

1.2 The FQS-I Accreditation Programs

1.2.1 Scope of programs offered

In order to identify competent and reliable testing and calibration agencies, FQS-I:

- a. offers accreditation programs to agencies which conduct testing in areas in which the results may have legal (criminal, civil) or regulatory implications;
- b. develops programs for testing applications where FQS-I is satisfied that there is a need for the program and that the program can be operated to national or international standards as determined by ISO/IEC 17025:2005;
- c. provides documentation that can be used in the development and implementation of the agency's management system; and
- d. Operates its programs in conformance with ISO/IEC 17011:2004 and the additional supplementary requirements of the ILAC Mutual Recognition Arrangement

1.2.2 Basic program requirements

Granting and maintenance of accreditation requires:

- a. assessment of an agency's technical qualifications and competence for conducting specific testing activities within the scope of ISO/IEC 17025;
- b. demonstration that an agency meets all of the requirements of ISO/IEC 17025:2005, including any relevant field specific standards included in amplification documents which are also part of the program;
- c. demonstration that an agency can maintain its impartiality and integrity;
- d. continued conformance of an agency with the standards as described in its certificate of accreditation and demonstrated by an agreed system of surveillance; and
- e. payment of all accreditation fees. The FQS-I fees for accreditation are described in the "FQS-I ISO Accreditation Pricing Guidelines."

1.2.3 Program development

An agency which meets the requirements of paragraph 1.2.1a and performs testing in an area or areas for which FQS-I does not have an accreditation program may submit a written request to FQS-I to develop a program. FQS-I may also determine, independent of a request from an agency, that it is desirable to develop an accreditation program in a particular testing area.

Depending on the complexity of the proposed testing or calibration area, FQS-I may establish a relevant and impartial Technical Advisory Committee (TAC) made up one or more members of FQS-I staff and one or more persons possessing the necessary technical competence to consider the request. The TAC will work with the requestor to consider whether an amplification document and/or any additional field specific standards are needed to cover interpretation of the requirements of ISO/IEC 17025 for the specific test or testing activity(s). The TAC makes its recommendations to the FQS-I Manager of Accreditations, who includes the information in any FQS-I Forensic Requirements for Accreditation (FRA)-series document that is developed.

When the Manager of Accreditations decides that there is no need to set up a TAC, an amplification document can be developed by the Manager of Accreditations in consultation with the requesting agency.

In all cases, FQS-I will consider whether requirements of regulators/other authorities exist for the testing area being considered for the new accreditation program. Where such requirements exist, FQS-I will determine if the requirements must be incorporated into the accreditation program and, if so, the best way to do so. This may involve contacting representative(s) of the regulator/authority.

1.2.4 Supplemental FQS-I Requirements and Policies

FQS-I supplemental requirements, policies, and guidance are available from the FQS web site and/or by contacting FQS-I.

1.2.4.1 Forensic Requirements for Accreditation (FRA) series documents. The FRA documents provide interpretation and additional requirements for agencies when used in conjunction with ISO/IEC 17025.

- a) **FRA-1:** General forensic supplemental requirements that apply to all applicants for accreditation that conduct forensic testing in criminal investigations. The FRA-1 document is derived from the International Laboratory Accreditation Cooperation (ILAC) Guide 19, *Guidelines for Forensic Science Laboratories*.
- b) **FRA-3:** Supplemental requirements that apply to laboratories performing drug testing related to animal racing. They are derived from ILAC G7, an international guidance/standards document published by ILAC.
- c) **FRA 4:** Supplemental standards document that applies to agencies seeking accreditation in latent print testing. It was developed by a Technical Advisory Committee (TAC) convened by FQS-I.
- d) **FRA-5:** Supplemental standards/guidance document that applies to agencies seeking accreditation in the area of crime scene processing. It is a product of an FQS-I TAC.

- e) **FRA-6:** Supplemental standards/guidance document that applies to agencies seeking accreditation in the area of digital and multimedia evidence examination. The document was developed by an FQS-I TAC

1.2.4.2 Other Supplemental Requirements

- a) **FBI DNA Quality Assurance Audit Document.** As part of the FQS-I accreditation program's recognition by the National DNA Index System (NDIS), assessments of laboratories seeking accreditation in forensic DNA analysis for casework or offender databasing must incorporate an audit using the FBI DNA QAS audit document (in addition to the ISO/IEC 17025 and FRA-1 standards). **Note:** An FBI DNA QAS audit is not required for assessment of DNA laboratories whose testing is unrelated to forensic casework or databasing intended for inclusion in CODIS (Combined DNA Index System), e.g., relationship testing agencies.

“FRA-2” was formerly used by FQS-I to designate the FBI's DNA Quality Assurance Standards audit document. While FQS-I continues to conduct DNA audits using the FBI DNA QAS as part of its full assessments, the audit document no longer carries an FQS-I “FRA” designation.

1.2.4.3 Forensic Requirements for Accreditation Policy (FRAP) series documents. FQS-I has developed a number of policies in areas where (a) clarification of standards was needed ; or (b) there were requirements for FQS-I accreditation program operation that needed to be addressed; or (c) to add additional program requirements in areas for which it would not have been appropriate to add to existing FRA documents or create new FRA documents.

- a) **FRAP-1:** Control of records
- b) **FRAP-2:** Proficiency testing
- c) **FRAP-3:** Uncertainty of Measurement
- d) **FRAP-4:** Traceability
- e) **FRAP-5:** Use of Accreditation Symbols
- f) **FRAP-6:** Suspension, Withdrawal, Complaints, Appeals, and Extension of the Term of Accreditation
- g) **FRAP-7:** Safety
- h) **FRAP-8:** FQS-I Policy on Cross-Frontier Accreditation

1.2.4.4 Forensic Requirements for Accreditation Guidance (FRAG) series documents. These guidance documents provide information on a variety of subjects not specifically tied to ISO/IEC 17025 requirements.

- a) **FRAG-1:** Guidance Document for Lead Assessors.
- b) **FRAG-2:** Guidance Document for Technical Assessors
- c) **FRAG-3:** Guidance document on scopes of accreditation
- d) **FRAG-4:** Provides correlation between the DNA standards of FRA-2 and the general accreditation standards ISO 17025/FRA-1

FRAG-1 and FRAG-2 lay out performance expectations for FQS-I lead assessors and technical assessors/experts, respectively, and do not have specific application to agencies seeking accreditation.

1.2.5 References and Definitions

1.2.5.1 References

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.

ISO/IEC 17011:2004, General requirements for bodies providing assessment and accreditation of conformity assessment bodies

ILAC G19:2002, Guidelines for Forensic Science Laboratories

FBI DNA Quality Assurance Audit Document, Issue date July 1, 2004.

1.2.5.2 Definitions

The relevant definitions contained in *ISO/IEC 17011:2004*, *ISO/IEC 17025:2005*, and sources cited therein are applicable for the purposes of this document.

2 OPERATION OF THE ACCREDITATION PROGRAM

2.1 Applying for accreditation

2.1.1 Any agency performing testing in applications covered by an FQS-I program may apply for accreditation. The procedures under which FQS-I operates are administered in a non-discriminatory manner.

2.1.2. An agency seeking accreditation by FQS-I must have an official copy of *ISO/IEC 17025:2005* (or subsequent revisions as applicable).

2.1.2.1 The agency must be familiar with the FQS-I General Requirements for Accreditation (GRA), any applicable Field Specific requirements (FRA series) and the FQS-I accreditation policies (FRAP series).

2.1.2.2 Agencies are encouraged to use the guidance documents available through ISO and ILAC (the International Laboratory Accreditation Cooperation, www.ilac.org) for assistance in developing their management systems.

2.1.3 When an agency believes itself to be conformance with the requirements of the relevant standards and wishes to seek accreditation by FQS-I, an "Application for Accreditation by FQS-I" form must be completed and returned to FQS-I.

2.1.3.1. Belief in conformance with standards must be based upon objective evidence. This shall include completion of a self-assessment against all applicable accreditation standards, and corrective action to remediate non-conformities that were identified during this process.

2.1.3.2. The results of the self-assessment shall be recorded on an FQS-I Assessor Checklist for ISO 17025 and applicable supplemental requirements.

- a. The FQS-I ISO/IEC 17025 Assessor Checklist can be obtained from FQS-I by submitting a “Request for FQS-I Assessor Checklists” form to FQS-I. The form contains a section where the agency attests that it has an official copy of ISO/IEC 17025.
- b. A clause graded as “yes” must reference the agency’s objective evidence for conformance (e.g., a specific written procedure or applicable records); a clause rated as “no” shall contain a comment regarding how the agency plans to come into conformance; and a clause rated as “N/A” shall contain a comment regarding why the agency believes the standard does not apply.

2.1.4 The Application for Accreditation by FQS-I must be accompanied by the non-refundable application fee stated on the application form. The Manager of Accreditations may waive this requirement if presented with sufficient justification from the applicant agency as to why payment of the fee cannot be made at the time of application for accreditation. An agency which applies for accreditation without paying the fee will be liable for payment of the application fee if it withdraws from the accreditation process prior to the on-site assessment

2.3 Processing the Application

2.3.1 Upon receipt of an application, the Manager of Accreditations will review the information.

2.3.1.1 Applications for Initial Accreditation

- a. The Manager of Accreditations will clarify the proposed scope of accreditation with the applicant.
- b. The services of a lead assessor will be obtained. The name of the lead assessor will be provided to the applicant in order to give them the opportunity to identify potential conflicts of interest. Objections to the selection of a proposed lead assessor must have an objective basis. e.g., conflict of interest or past performance problems. Any objection must be made **in writing** to FQS-I and must describe the basis for the objection. Personal dislikes or hearsay are not sufficient grounds for an objection. The Manager of Accreditations will determine whether the agency has a reasonable basis for objecting to a particular lead assessor and will either appoint another lead assessor or retain the original lead assessor. The agency may appeal (FRAP-6) the decision made by the Manager of Accreditations
- c. On-site assessment will be significantly less effective if the agency’s management system, as documented in their quality manual and supporting documents, contains many conformance “gaps” with the requirements of ISO 17025 and applicable supplemental requirements. Therefore, before an on-site assessment will be scheduled, a pre-assessment document review must be conducted by the lead assessor.
- d. The applicant must provide the lead assessor with a copy of their completed self-assessment checklist, quality manual, and supporting management system documents.

- e. The lead assessor will evaluate the sufficiency of the documents against the Standards. The applicant will be provided with a report that identifies non-conformities with accreditation requirements.
- f. The applicant must correct the non-conformities and provide objective evidence to the lead assessor. When the lead assessor notifies the Manager of Accreditations that all non-conformities have been remediated, the Manager of Accreditations will work with the applicant and the lead assessor to establish mutually agreeable dates for the on-site assessment.
- g. Prospective technical assessors/experts will be selected, and the names forwarded to the applicant. The parameters for objecting to the selection of any technical assessor/expert is the same as for the lead assessor.
- h. The lead assessor arranges for the members of the assessment team to receive the management system documents and records they will need to review prior to the on-site assessment. The team should have the documents no later than one month prior to the on-site assessment.

The required documentation includes, but is not necessarily limited to:

1. A completed copy of the assessment checklist for ISO 17025 and applicable supplemental requirements. A clause graded as “yes” shall reference the agency’s objective evidence for conformance (e.g., a specific written procedure or applicable records); a clause rated as “no” shall contain a comment regarding how the agency plans to come into conformance; and a clause rated as “N/A” shall contain a comment regarding why the agency believes the standard does not apply;
2. A copy of the agency’s quality manual and relevant associated policies and procedures; and
3. Verification that the agency has met the pre-accreditation proficiency test requirements of FQS-I.

It is preferable to receive the above listed documentation in electronic form on a CD so that the references to objective evidence in the checklist can be hyperlinked, where applicable, to the appropriate locations in the quality manual or other management system documents or records. This format makes the document review process much more efficient. Paper copies will be accepted if the agency is unable to provide documents in electronic format.

2.3.1.2 Applications for Reaccreditation and Extension of Scope of Accreditation

- a. The Manager of Accreditations will clarify the proposed scope of accreditation with the applicant. Proposed dates for the on-site assessment will be selected.
- b. The services of a prospective lead assessor and/or technical assessors/experts will be obtained. The names will be provided to the applicant in order to give them the

opportunity to identify potential conflicts of interest. Objections to the selection of any assessor must have an objective basis. e.g., conflict of interest or past performance problems. Any objection must be made **in writing** to FQS-I and must describe the basis for the objection. Personal dislikes or hearsay are not sufficient grounds for an objection. The Manager of Accreditations will determine whether the agency has a reasonable basis for objecting to a particular assessor and will either appoint another assessor or retain the original assessor. The agency may appeal (FRAP-6) the decision made by the Manager of Accreditations.

- c. The lead assessor arranges for the members of the assessment team to receive the management system documents and records they will need to review prior to the on-site assessment. The team should have the documents no later than one month prior to the on-site assessment.

The required documentation includes, but is not necessarily limited to:

1. A completed copy of the assessment checklist for ISO 17025 and applicable supplemental requirements. A clause graded as “yes” shall reference the agency’s objective evidence for conformance (e.g., a specific written procedure or applicable records); a clause rated as “no” shall contain a comment regarding how the agency plans to come into conformance; and a clause rated as “N/A” shall contain a comment regarding why the agency believes the standard does not apply;
2. A copy of the agency’s quality manual and relevant associated policies and procedures; and
3. Verification that the agency has met the pre-accreditation proficiency test requirements of FQS-I.

It is preferable to receive the above listed documentation in electronic form on a CD so that the references to objective evidence in the checklist can be hyperlinked, where applicable, to the appropriate locations in the quality manual or other management system documents or records. This format makes the document review process much more efficient. Paper copies will be accepted if the agency is unable to provide documents in electronic format.

2.4 Assessment

2.4.1 Assessments are conducted against the current version of ISO/IEC 17025; additional Field Specific Requirements (FRA’s) as required by the scope of the particular accreditation, and by Forensic Requirements for Accreditation Policy (FRAP) documents. Requirements, assessments, and decisions on accreditation are made only on matters specifically related to the scope of the accreditation being considered.

2.4.2 The mandate given to the assessment team is clearly defined and made known to the applicant agency.

2.4.3 **Agencies seeking accreditation must have sufficient and appropriate test records and samples available for review by the assessment team.** Samples must have been tested in accordance

with the policies and procedures established by the agency for the scope of testing for which accreditation is being sought.

- a. The minimum requirement is the equivalent of five (5) “case” records per major sub-category of testing. These cases should cover a range of sample types that might be encountered by the agency.
- b. Agencies seeking accreditation in databasing applications must provide test data (and other records as appropriate) for a minimum of fifty (50) samples, and objective evidence that they can deal effectively with a high-volume throughput operation.
- c. Agencies that must become accredited prior to providing services in the categories or sub-categories of testing for which they are seeking accreditation must find other ways of meeting the requirements listed in “a” and “b” above. The analysis of simulated database samples, mock cases, and/or proficiency tests are examples of approaches that might be taken.
 - 1) **The agency must notify FQS-I when it begins receiving samples from customers.** FQS-I may require an on-site surveillance visit to verify the agency’s continued conformance with accreditation requirements.

2.4.4 An on-site assessment begins with an opening meeting between the assessment team and the representatives of the applicant agency. The lead assessor outlines the schedule for the assessment and confirms the proposed scope of accreditation with the applicant agency.

2.4.5 Assessments of agencies seeking accreditation in DNA testing for forensic casework or offender databasing will include a DNA audit conducted with the FBI DNA Quality Assurance Standards audit document. Non-conformities identified as a result of that audit will be correlated to a clause in ISO 17025 and/or FRA-1.

2.4.6 A scheduled assessment may be postponed for a variety of reasons, including:

- a. The applicant laboratory does not supply the required documentation to the assessment team in a timely manner prior to the assessment,
- b. The number and seriousness of nonconformities identified during the pre-assessment document review (for an agency applying for reaccreditation) leads FQS-I to believe that the agency is not ready for accreditation and that an on-site assessment would not be productive. In such cases the non-conformities will be reported in writing to the applicant agency;
- c. FQS-I is notified that critical personnel will not be available for the scheduled assessment.

FQS-I will work with the applicant agency to reschedule the on-site assessment. **The applicant agency is responsible for any additional costs incurred by a postponement, e.g., assessor air travel cancellation penalties, when the postponement is due to actions of the applicant agency.**

2.5 Assessment Closeout and the Assessment Reports

2.5.1 A closing meeting takes place between the lead assessor or assessment team and the agency representative(s) prior to the assessment team’s departure from the agency. At this meeting the agency is provided with draft written or oral report(s) on the conformance of the applicant agency with the accreditation requirements.

2.5.2 Agencies with a proposed scope of accreditation that contains “DNA typing for forensic casework” and/or “DNA typing in offender databasing” will receive two draft reports, the FQS-I “ISO” report and the completed FBI DNA audit document.

2.5.3 The lead assessor provides the written draft report(s) to the Manager of Accreditations for review. The Manager of Accreditations will consult with the lead assessor and/or assessment team and revisions will be made if needed. The written report(s) is (are) finalized and submitted to the agency by the Manager of Accreditations. The “ISO” report will identify:

- a. **Non-conformities:** Non-conformities are areas where an agency does not conform to the requirements of accreditation standards, FQS-I policies, or the agency’s own policies and procedures. A non-conformity must be supported by objective evidence identified by the assessment team. Non-conformities that cause profound concern about a agency’s ability to issue valid test results could result in suspension of accreditation for those agencies that are undergoing their reaccreditation assessment. Non-conformities identified during a DNA audit using the FBI DNA QAS will be correlated to an applicable “ISO” clause and included in the “ISO” report.
- b. **Concerns:** A concern is a practice that may have a potential detrimental effect on the agency’s operational effectiveness or the quality of its test results, but is not supported by objective evidence of non-conformance.
- c. **Comment:** Identification of practices of the agency that are commendable , or that may present opportunities for improvement.

2.5.4 An agency that disagrees with one or more of the non-conformities cited in the “ISO” report (and, by extension, in a DNA audit document, if applicable) may appeal the non-conformity(ies) through the FQS-I appeals process (FRAP-6). Non-conformities that are overturned as a result of the appeals process shall be removed from the assessment report, and a revised report issued to the applicant agency.

2.5.5 After all reports are in final form and provided to the agency, FQS-I will take no further action with regard to the FBI DNA QAS audit document. All remediation activity will be taken with regard to the findings listed on the FQS-I “ISO” report.

2.5.6 The agency will be directed to work with the lead assessor to coordinate their responses to the non-conformities and concerns in the “ISO” report. The lead assessor will evaluate the actions of the agency for sufficiency and effectiveness, and may request assistance from other members of the assessment team.

2.6 Decision-making and granting accreditation

2.6.1 The decision whether to grant accreditation to a agency is made by the Manager of Accreditations of FQS-I. The decision is based on information gathered during the on-site assessment and the follow-up to the assessment.

2.6.2 Prior to any decision to grant accreditation the lead assessor must inform FQS-I that the applicant agency conforms to all accreditation standards (as per ISO/IEC 17025 4.1.2). This means that the agency has:

- a. provided evidence of successful implementation of appropriate corrective action to resolve *non-conformities* identified during the on-site assessment;. And
- b. provided a response to all *concerns* noted in the assessment report. (An agency may complete corrective actions on concerns; however, they are not required to do so. What they must show is that they have considered the concerns and what their response to the concerns will be.)

2.6.3 Under the following limited circumstances accreditation may be granted when corrective actions have not yet been completed for all non-conformities:

- a. The agency chooses to withdraw or delay its request for accreditation in a specific portion of the proposed scope.
- b. Exigent circumstances exist in which a delay in granting accreditation would cause an undue hardship on the agency AND the unresolved non-conformities within the proposed scope of accreditation are not likely to affect the quality of the test results.
 1. The agency must provide the lead assessor with a corrective action plan for each unresolved non-conformity. The lead assessor must approve the plans and the time frames for their full implementation, and recommend that FQS-I grant accreditation.
 2. Agencies which do not complete their corrective action plans as agreed upon as a condition of accreditation are subject to reduction, suspension, or withdrawal of accreditation.

2.6.4 FQS-I is solely responsible for granting, maintaining, extending, suspending, or withdrawing accreditation.

2.6.5 FQS-I provides each accredited agency with an accreditation certificate signed by an officer who has been assigned such responsibility (usually the Manager of Accreditations) The certificate contains:

- a. the name and address of the agency that has been accredited;
- b. identification of FQS-I as the accreditation body, along with the FQS-I logo;
- c. the unique accreditation certificate number for the agency;
- d. the effective date of accreditation and the expiry date;
- e. a statement of conformity with listed accreditation standards
- f. reference to the scope of the accreditation.

The Scope of Accreditation is supplied as a supplement to the accreditation certificate. (See the FQS-I guidance document for scopes of accreditation, FRAG-3.)

2.7 Duration of accreditation

2.7.1 The recommended duration of accreditation is two years; however a different cycle of up to five years may be established depending on the needs of the agency and with consideration of the maturity and stability of the agency's management system. In all cases there must be sufficiently rigorous surveillance to ensure that conformance to standards is maintained.

2.7.2 An accredited agency may make a written request to FQS-I for an extension of the accreditation certificate expiration date. Extensions may be granted where deemed appropriate by the Manager of Accreditations. Extensions are usually 3 months or less; however, in rare situations extensions of up to 6 months may be granted at the discretion of the Manager of Accreditations.

2.8 Surveillance of accredited agencies

2.8.1 Continued conformance with accreditation standards will be monitored annually after accreditation is granted, on-or-near the agency's "accreditation anniversary date". There are two types of surveillance, (1) office surveillance and (2) on-site surveillance.

2.8.2 Accreditation cycles of more than two years require one or more on-site surveillance audits. The period of time between on-site assessment or surveillance may not exceed approximately two years.

2.8.3 Office surveillance is permissible in situations where assessment indicates that the accredited agency has a mature and effective management system and therefore does not require an annual site visit. Agencies that are eligible for "office review" will be sent reminders by FQS-I. Office surveillance is conducted through review at the FQS-I office of an agency's "Surveillance Report" records which includes, but is not limited to, the agency's proficiency test results, internal and external audit reports, and reports of management review. The records are to be submitted within +/- 30 days of the accreditation anniversary date, and encompass the pertinent activities that were conducted in the period of time subsequent to the date of the last on-site assessment or surveillance. The information will be reviewed at the FQS-I office. A written report will be sent to the accredited agency. The agency will be expected to remediate any non-conformities identified in the report.

2.8.4 An on-site surveillance visit may be required annually if FQS-I believes that an "office surveillance" is insufficient to verify an agency's continuing conformance to the applicable accreditation standards.

2.8.5 FQS-I may also require an on-site assessment in response to extraordinary circumstances such as complaints about the agency or significant changes at the agency, e.g., change in facility, changes in key personnel.

2.8.6 For agencies conducting forensic casework or database DNA analysis and for which the agreed cycle of accreditation is more than two years, maintenance of accreditation is conditional on agency demonstration of external DNA audits that meet the requirements of the FBI DNA QAS.

2.8.7 Agencies that fail to conform to the surveillance requirements of FQS-I are subject to suspension or withdrawal of accreditation.

2.9 Reassessment of accredited agencies

2.9.1 Reassessments of accredited agencies are conducted near the end of the agency's accreditation cycle. Ideally, reassessment will occur at least 60-90 days prior to the accreditation expiration date.

2.9.2 The procedure for an on-site reassessment is the same as that for an initial assessment. Information from the previous assessment and surveillance activities will be available to the team conducting the reassessment visit.

2.10 Extension of scope of accreditation

2.10.1 An accredited agency may request FQS-I in writing to extend the agency's scope of accreditation to a method or methods whose principles of measurement are not covered by its original scope. The decision by the Manager of Accreditations on such a request must be supported by objective evidence. The complexity of the proposed extension of scope will determine what activities are needed to obtain the objective evidence. Options include, for example, an off-site review of validation documentation by FQS-I, a technical expert, or a TAC; or a limited-scope on-site assessment.

2.11 Proficiency Testing

2.11.1 Agencies are required by FQS-I to participate in proficiency testing or other interagency comparisons.

2.11.2 Proficiency testing or other interagency comparisons may be organized by FQS-I itself or by any other body judged competent. Where possible, proficiency testing should be consistent with the provisions contained in ISO/IEC Guide 43 or its successor documents.

2.11.3 All agencies are required to participate in a minimum of one proficiency test or interagency comparison per category of testing prior to the on-site accreditation assessment.

2.11.4 See **FRAP-2** for the minimum proficiency testing activity required to maintain accreditation.

2.11.5 FQS-I will expect formal corrective action for any unsatisfactory results reported by the operator of the proficiency test program. The corrective action shall be conducted in accordance with section 4.9, Control of Nonconforming work, and 4.11, Corrective Action, using the agency's own policies and procedures. The corrective action shall contain objective evidence that the problem has been resolved.

2.11.6 When the results of a PT are deficient, the agency shall participate at their earliest opportunity in another PT for the same type of testing in order to confirm that they have corrected the problem.

2.11.7 In the event that an agency consistently has unsatisfactory results in PT programs or fails to take appropriate corrective action in a timely manner, FQS-I may choose to do an on-site evaluation, or to exercise the procedure for suspension or withdrawal of accreditation for that test or types of tests.

2.11.8 The agency shall maintain records of participation in PT programs, including pertinent corrective actions taken for at least one full FQS-I cycle of accreditation. These records shall be available for review by FQS-I assessors during on-site assessments. FQS-I shall forward pertinent information on agency performance during PT to assessors prior to an on-site assessment.

2.12 Withdrawal, Suspension, or Reduction of Scope of Accreditation

2.12.1 A agency may voluntarily request the suspension, withdrawal, or reduction in scope of its accreditation due to changes in its circumstances.

2.12.2 In the event that FQS-I initiates the withdrawal, suspension, or reduction in the scope of accreditation for cause, the agency shall be notified of the reasons for such actions. The agency shall be given the opportunity to provide evidence that the reasons for withdrawal, suspension, or reduction are not warranted. If FQS-I upholds its action and the agency disagrees with the decision, the agency may

appeal to the Manager of Accreditations of FQS-I, who will initiate the Appeals Procedure as defined in **FRAP 6**. Appeal actions must be initiated within 30 days of the notification to withdraw, suspend, or reduce the scope of accreditation.

2.12.3 If the accreditation is withdrawn or suspended, the agency shall cease using the FQS-I accreditation symbol in any way.

2.12.4 When the scope of accreditation has been reduced, the agency shall not make any statements that infer accreditation for activities that have been removed from its scope of accreditation

2.12.5 A agency which has been denied accreditation or had their accreditation suspended or withdrawn may re-apply for and be granted accreditation if the following requirements are met:

- a. The agency management system is in full compliance with ISO/IEC 17025 and all supplemental requirements; and
- b. The agency can prove its technical competence in the tests or types of tests for which accreditation is sought.

2.12.6 The procedure for “extension of scope of accreditation” shall be used when an agency seeks to restore a method to its scope of accreditation.

3. RESPONSIBILITIES OF FQS-I AND THE AGENCY

3.1 Obligations of the agency

3.1.1 FQS-I requires that the agency agree to the following:

- a. Commit to fulfill continually the requirements for accreditation set by FQS-I for the areas where accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation;
- b. When requested, afford such accommodation and cooperation as is necessary to enable FQS-I to verify conformance with the requirements for accreditation at all premises where the accreditation assessments take place;
- c. Make provision for examination information, documents, and records as needed for the assessment and maintenance of the accreditation;
- d. Claim accreditation only with respect to the scope of services for which it has been granted accreditation;
- e. Provide access to documents that provide insight into the level of independence and impartiality of the agency from its related bodies, where applicable;
- f. Do not use its accreditation in such a manner as to bring FQS-I into disrepute;
- g. Pay fees as determined by FQS-I; and

h. Arrange the witnessing of agency services when requested by FQS-I.

3.1.2 An accredited agency must inform FQS-I without delay of significant changes relevant to its accreditation in any aspect of the agency's status or operation relating to:

- a. Its legal, commercial, ownership, or organizational status;
- b. The organization, top management, and key personnel;
- c. Main policies;
- d. Resources and premises;
- e. Scope of accreditation; and
- f. Other such matters that may affect the ability of the agency to fulfill requirements for accreditation.

Any changes in the legal status (e.g. ownership) of the agency must be reviewed by the Manager of Accreditations. The Manager of Accreditations will instruct the agency on the action to be taken relating to the transfer of accreditation.

3.2 Obligations of FQS-I

3.2.1 FQS-I will publish a directory on its web site (www.forquality.org) that contains information about the current status of the accreditations that it has granted to agencies. The directory includes at least the following information:

- a. The name and address of each accredited agency;
- b. The expiration date of the agency's accreditation;
- c. A copy of the agency's certificate of accreditation;
- d. A copy of the agency's scope of accreditation; and
- e. Lists of agencies whose accreditation has been suspended or withdrawn, or who have voluntarily requested the withdrawal of their accreditation.

3.2.2 FQS-I shall provide agencies with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided.

3.2.3 FQS-I shall, where applicable, provide information to agencies about international arrangements in which it is involved.

3.2.4 FQS-I may be required to make changes to its accreditation requirements (both standards and FQS-I policies) from time to time. Many changes occur because of revisions to International standards that must be adopted by FQS-I. Other changes occur as a result of the work of TACs.

The Manager of Accreditations will consider information obtained or requested from various sources (e.g., accredited agencies, assessors, FQS senior management, TACs, other accreditation bodies, etc.) before making a decision as to the form and effective date of substantive changes to requirements for accreditation.

Changes to accreditation requirements and transition plans, if applicable, will be posted on the FQS-I web site. FQS-I may also provide the information separately to accredited agencies and FQS-I assessors via e-mail or similar communication.

FQS-I welcomes input from accredited agencies, assessors, and others with respect to suggestions for improvements to the accreditation process.

3.3 Appeals and Complaints

3.3.1 Appeals, complaints, or disputes regarding an accreditation decision or the accreditation process shall be made in writing to the Manager of Accreditations. The matter shall be dealt with as described in **FRAP 6**.

GENERAL REQUIREMENTS FOR ACCREDITATION

The FQS-I General Requirements for Accreditation (GRA) require conformance with ISO/IEC 17025:2005.

Sections 4 and 5 of ISO/IEC 17025:2005 address the Management and Technical requirements, respectively, that must be met in order to satisfy FQS-I's General Requirements for Accreditation.

FQS-I's Forensic Requirements for Accreditation (FRA) provide interpretation and additional requirements for testing agencies when used in conjunction with the GRA. Individual accreditation programs may also have additional Field Specific Criteria that provide interpretation and/or include additional requirements.

SECTION 4 MANAGEMENT REQUIREMENTS

See ISO/IEC 17025:2005 Section 4

SECTION 5 TECHNICAL REQUIREMENTS

See ISO/IEC 17025:2005 Section 5