



Forensic Requirements for Accreditation
FRAG-4: Guidance Document on Correlation
between FRA 2 and GRA/FRA-1

REVISION LOG.

Version	Issued	Changes
2006/1	March 16, 2006	
2008/1	January 24, 2008	Delete FQS-I address and phone number from cover sheet

I. Purpose of Document

This document provides guidance to internal auditors and/or technical assessors of forensic DNA testing laboratories where conformance to FRA 2 standards must be achieved in addition to the GRA and FRA-1. A chart lists suggested correlations between the FQS GRA and FRA-1 standards and those in FRA 2 (FBI DNA quality assurance standards).

II. Guidance for the Use of the Chart

- **To ensure that all standards are evaluated, the ISO standards should be assessed independently of the FRA 2, both in relation to DNA testing and biological screening (where applicable, and because biological screening is not addressed by FRA 2). This is because some of the GRA and FRA-1 Section 5 Technical Requirements have no counterpart in the FRA 2 or correspond only in part.**
- The correlations are suggested as an appropriate “fit”, but it is the responsibility of the auditor/assessor to determine whether a correlation is accurate given the objective evidence in a specific situation.
- When ISO clauses are listed that apply to an entire section, an auditor/assessor should look at the sub points of the clauses (in both the GRA and FRA-1) to pick the most appropriate standard for the correlation.
- When an FRA 2 requirement is more prescriptive in its requirements than a corresponding ISO standard, an auditor/assessor may assume that conformance with the FRA 2 equates to conformance to the ISO standard.
- It is possible to have multiple non-conformities (e.g., non-conformity in both the ISO standards and FRA 2) that can be addressed by a single corrective action.
- **Suggested approach to Biology/DNA laboratory audit/assessment :**
 - Step 1 Complete the FRA 2
 - Step 2 Go through the GRA/FRA-1 checklist and complete where possible on the basis of evidence gathered during Step 1
 - Step 3 Identify the “gaps” on the GRA/FRA-1 checklist and gather evidence to address those standards

III. Correlation Chart

FRA 2 (FBI DNA Audit Doc)	ISO 17025:2005 (GRA) and FRA-1
Standard 3-Quality Assurance Program	<p>4.2.1 (primary, with 4.2.5 as an alternate for requirements on including or referencing procedures if it seems more appropriate) 4.2.2 for goals and objectives (QAS 3.1.1.a) 4.15 (management review—correlation to QAS discussion under 3.1)</p>
Standard 4-Organization and Management	<p>4.1.5 subpoints 5.2.4 as a possible alternate for requirements about job descriptions (QAS 4.1.c)</p>
Standard 5-Personnel	<p>5.2 (General requirement for competence = 5.1; Job descriptions = 5.2.4; training = 5.2.2; records = 5.2.5) 4.1.5 (h, and maybe f) for QAS standards addressing the technical leader</p>
Standard 6-Facilities	<p>5.3 (especially 5.3.3 and 5.3.4) 5.8.4</p>
Standard 7-Evidence or Sample Control	<p>5.8 (except subpoint 5.8.3)</p>
Standard 8-Validation	<p>5.4.5.2 (primary) 5.2.1 would correlate to QAS requirement for a qualifying test (QAS 8.1.3.3) 5.4.2 would correlate to QAS standard on non-specified methods (QAS 8.1.4)</p>
Standard 9-Analytical Procedures	<p>5.4 (mostly 5.4.1 and 5.4.2) 4.6.2 would correlate to QAS standards on reagents (9.2 and subpoints) 5.9.1 would correlate to QAS QC standards (subpoints of 9.4 and 9.5) 4.3.2.1 relates to procedures approved by management (QAS 9.1)</p>
Standard 10-Equipment Calibration and Maintenance	<p>5.5 5.6.2.2 (with reference to 5.6.2.1)</p>
Standard 11-Reports	<p>4.13 (especially 4.13.1.1 and 4.13.2.1) for laboratory case records and documentation of database samples 5.10 (but see FRA-1 discussion under 5.10.2) for content of reports (QAS 11.1.2)</p>
Standard 12-Review	<p>FRA-1 4.12.2.1.h for review of case records (QAS 12.1) FRA-1 5.9.1.c for testimony monitoring (QAS 12.2)</p>

Standard 13-Proficiency Testing	5.9.1.b FRAP 2 (FQS policy on Proficiency testing)
FRA 2 (FBI DNA Audit Doc)	ISO 17025:2005 (GRA) and FRA-1
Standard 14-Corrective Action	4.9.1 for casework and PT discrepancies (QAS 14.1) 4.11.3 and/or 4.13.1.1 for records retention (QAS 14.1.1)
Standard 15-Audits	4.14 (but note that ISO audits must be to confirm conformance with the requirements of the International Standard; whereas QAS requires use of the DNA audit document)
Standard 16-Safety	No correlation
Standard 17-Subcontractors	4.5.1 for competence of subcontractors (QAS 17.1)—but ISO definition of competence is conformance with International Standards rather than conformance with the DNA QAS; no correlation with QAS 17.1.1 subpoints