



Following the introduction of Version 2.00 (Sept 2007) a document revision exercise has taken place. A number of changes have been considered and those changes agreed are noted below. Version 2.01 (March 2009) is now the current document.

General

Company registration number has been revised to read **Registered in England and Wales**

3 Terms and definitions

Addition of 3.38 verification to read as follows;

3.38 verification

confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

[ISO 9000:2000]

NOTE 1

The term “verified” is used to designate the corresponding status.

NOTE 2

Confirmation can comprise activities such as

- performing alternative calculations,
- comparing a new design specification with a similar proven design specification,
- undertaking tests and demonstrations, and
- reviewing documents prior to issue.

4 The Standards

Additional text as follows;

4 The standards

The standards are presented in eight sections (see diagram below):

Diagram added

A8 Document control

Change A 8.3 to read as follows;

A 8.3) Laboratory management shall determine, with regard to current regulations and guidelines, the appropriate retention times for documents removed from current use.

B3 Personnel management

Change B 3.1 notes to read as follows;

B 3.1 NOTES

1 If the laboratory is part of a parent organisation, reference should be made in the procedure for personnel management to those procedures undertaken by management in the parent organisation.

B5 Job descriptions and contracts

Change B 5.2 to read as follows;

B 5.2 All staff shall have contracts of employment that provide clear terms and conditions of service.

B6 Staff records

Change B 6.1 to read as follows;

B 6.1 Laboratory management shall ensure confidentiality of staff records.

C5 Health and safety

Change C 5 NOTES to read as follows;

NOTES

1 A copy of the latest Health & Safety Executive inspector report should be available to assessors.

D1 Procurement and management of equipment

Change D 1.4 to read as follows;

D1.4 The programmes for preventive maintenance, calibration and monitoring of function shall be documented and at a minimum, follow manufacturer's recommendations.

F1 Selection and validation of examination procedures

Change F 1.1 to read as follows;

F 1.1 Examination procedures, including those for sampling, shall meet the needs and requirements of users and shall be validated by the manufacturer/method developer for their intended use

Change F 1.2 to read as follows;

F 1.2 Manufacturer/method developer's performance claims shall be verified prior to introduction and records kept of the methods used and results obtained.

F2 Examination procedures

Change F 2 NOTES to read as follows;

NOTES

1 The laboratory may utilise the instructions for use written by the manufacturer, if they are in accordance with the criteria set out in F2.1. Any deviations shall be validated, reviewed and documented.