

Standards D, E, F and G

Finding the evidence

Already covered or straight forward

D 1.2	Procurement and management of equipment	Procedures	
D 1.3	Procurement and management of equipment	List	
D 2.2	Management of data and information	Procedures	
D 2.3	Management of data and information	Regulations	
D 3.2	Management of materials	Procedures	
E 2.1	Request form	List	
E 3.1	Specimen collection and handling	Procedures	
E 3.2	Specimen collection and handling	Start v end	
E 3.3	Specimen collection and handling	Start v end	Regional Assessor Talk
E 4.1	Specimen transportation	Procedures	Regional Assessor Talk
E 4.2	Specimen transportation	Regulations	Regional Assessor Talk
E 5.1	Specimen reception	Procedures	
E 5.2	Specimen reception	Procedures	
E 5.3	Specimen reception	Systematic review	
E 6.1	Referral to other laboratories	Procedures	
F 1.1	Selection and validation of examination procedures	Validation & Verification	David's Talk
F 1.2	Selection and validation of examination procedures	Validation & Verification	David's Talk
F 2.1	Examination procedures	Procedures	
F 2.2	Examination procedures	Procedures	
F 3.1	Assuring the quality of examinations	FRAMEWORK	
F 3.2	Assuring the quality of examinations	Procedures	
F 3.3	Assuring the quality of examinations	Uncertainty	Covered 2009
F 3.4	Assuring the quality of examinations	Traceability	Covered 2009
G 1.1	Reporting results	Procedures	
G 3.1	The telephoned report	Procedures	
G 4.1	The amended report	Procedures	

Remaining Standards

D 1.1	Procurement and management of equipment	Resource availability
D 2.1	Management of data and information	Resource availability
D 3.1	Management of materials	Resource availability
E 1.1	Information for users & patients	Interaction with users
E 1.2	Information for users & patients	Interaction with users
E 1.3	Information for users & patients	Interaction with users
E 1.4	Information for users & patients	Interaction with users
E 2.2	Request form	Interaction with users
E 2.3	Request form	Interaction with users
F 1.3	Selection and validation of examination procedures	Interaction with users
G 1.2	Reporting results	Interaction with users
G 2.1	The report	Interaction with users
G 2.2	The report	Interaction with users
G 2.3	The report	Interaction with users
G 2.4	The report	Interaction with users
G 2.5	The report	Interaction with users
G 5.1	Clinical advice and interpretation	Interaction with users
G 5.2	Clinical advice and interpretation	Interaction with users
G 5.3	Clinical advice and interpretation	Interaction with users
G 5.4	Clinical advice and interpretation	Interaction with users
F 3.5	Assuring the quality of examinations	Comparability
D 3.3	Management of materials	Materials management

The essence of this clause

The service offered must meet the needs and requirements of their users.

Equipment must be appropriate and sufficient to fulfil the requirements of the service offered.

The essence of this clause

The data and information provided by the laboratory must meet the needs and requirements of their users.

All data and information must be available to whoever may legitimately require it.

The essence of this clause

The service offered must meet the needs and requirements of their users.

All necessary materials required for service provision are available at all times and are appropriately managed.

The essence of these clauses

The information for users must be fit for purpose and must be produced in consultation with users of the laboratory service(s).

The information provided must clearly describe what services are available and how to use these services.

The essence of these clauses

The information for patients must be fit for purpose and must be produced in consultation with patients or patient representative groups.

The information provided must clearly describe instructions for preparation for the procedure and an explanation of any clinical procedure to be performed.

The essence of these clauses

The request form must allow for the unequivocal identification of the patient and allow the inclusion of relevant clinical information/diagnosis of the patient.

It must allow for the inclusion of tests requested (within an appropriate) timeframe by the requestor.

The essence of this clause

The patient is safe because the results will not be misinterpreted as users are kept up to date of any changes.

The essence of this clause

The laboratory produce the results of examinations in reports. The reports are accurate, timely, unambiguous and clinically relevant. Users must be involved in agreeing turn around times relevant to clinical need.

There must be a mechanism for monitoring turn around times, recording non conformities and taking remedial and corrective action where necessary.

The essence of this clause

This is a clause that can be subjective.

The report is the method by which the laboratory communicates the results of examinations. We need to ensure that the requesters are satisfied with the report. That they are satisfied with the level of information provided to make an interpretation. That interpretation is readily available if they need it.

The essence of this clause

The design has just been discussed. If it is to fit with local medical records then these needs should also be met. The peer assessors tend to look at this clause.

The essence of this clause

This should be less subjective as there is a list of items to be included.

The essence of this clause

This is to ensure that if a laboratory uses another laboratory to help with the examination that it is identified to the user. This is to ensure that the user is not misled and would know where to go for a contact for further information if required. There may also be an issue that the referral laboratory is not an accredited lab and that the laboratory reports these results on a report format claiming accreditation.

Interaction With Users

G2.5

The essence of this clause

Simply confidentiality of the patient.

Interaction With Users

G5.1 G5.2 G5.3

The essence of these clauses

This is the essence of the diagnostic medical laboratory as opposed to testing, results only or research laboratory.

It will be variable between disciplines. The amount of advice required by users will also vary but the essential aspect that sets medical labs apart is that it is available as part of the routine service and not as an add on if required. It is essential that competent personnel are engaged and links in with other standards in the personnel section B.

The essence of this clause

That the lab personnel are not working in isolation from their clinical users. There is a system in place for ongoing communication. The word systematic could be replaced by “formal and regular ongoing”. There will be an element of subjectivity regarding the use of this word in the clause but it is lifted directly from 15189. However, there is no definition.

The essence of this clause

This provides continuity for the user and patient safety if more than one method is used. Users must be aware of any differences in results.

The essence of this clause

Materials must be properly and appropriately managed.