INAB guidance on assessment planning GD04

INAB is required to assess all elements of relevant accreditation standards in terms of policies, procedures and records.

This document is a useful guide for Conformity Assessment Bodies (CABs) and assessors to indicate the general format that INAB teams plan and assess during initial, surveillance, extension to scope and re-assessment visits.

CABs should not consider this document as mandatory as the INAB assessment teams will deviate/amend/extend the plan as necessary to ensure effective and robust assessments.

Reassessment visits are normally longer than the annual surveillance but shorter than the initial assessment.

This document covers the accreditation standards only and there are clearly other mandatory, guidance and policy documents applicable – See INAB DC1.

This document is to be taken as a guide only.
It is an extract from INAB internal procedure IP11.

Appendix 2: ISO 17025:2017 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Impartiality	X					4.1 Impartiality
4.2 Confidentiality		X				4.2 Confidentiality
5.0 Structural requirements			X			5.0 Structural requirements
6.1, 6.2 Personnel				X	X	6.1, 6.2 Personnel
6.3 Facilities and Environmental conditions	X				X	6.3 Facilities and Environmental conditions
6.4 Equipment		X			X	6.4 Equipment
6.5 Metrological traceability			X		X	6.5 Metrological traceability
6.6 Externally provided products and services.				X		6.6 Externally provided products and services.
7.1 Review of requests, tenders and contracts	X					7.1 Review of requests, tenders and contracts
7.2 Selection, verification and validation of methods		X			X	7.2 Selection, verification and validation of methods
7.3 Sampling			X			7.3 Sampling
7.4 Handling of test or calibration items				X	X	7.4 Handling of test or calibration items
7.5 Technical records	X					7.5 Technical records
7.6 Evaluation of measurement uncertainty		X			X	7.6 Evaluation of measurement uncertainty
7.7 Ensuring the validity of results	X	X	X	X	X	7.7 Ensuring the validity of results
7.8 Reporting of results				X	X	7.8 Reporting of results
7.9 Complaints	X	X	X	X		7.9 Complaints
7.10 Non-conforming work	X	X	X	X		7.10 Non-conforming work
7.11 Control of data and information management	X					7.11 Control of data and information management
8.1 Management system requirements, Option A or B	X	X	X	X		8 Management system requirements, Option A or B
8.2 Management system documentation		X				8.2 Management system documentation
8.3 Control of Management system documents			X			8.3 Control of Management system documents
8.4 Control of records				X		8.4 Control of records
8.5 Actions to address risks and opportunities	X					8.5 Actions to address risks and opportunities
8.6 Improvement		X				8.6 Improvement
8.7 Corrective action			X			8.7 Corrective action
8.8 Internal audits	X	X	X	X	X	8.8 Internal audits
8.9 Management review	X	X	X	X		8.9 Management review
Flexible Scope	X	X	X	X	X	Flexible Scope
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 3: ISO 15189:2012 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Organisation and management responsibility	X					4.1 Organisation and management responsibility
4.2 Quality management system		X				4.2 Quality management system
4.3 Document control			X			4.3 Document control
4.4 Service agreements				X	X	4.4 Service agreements
4.5 Examination by referral laboratories	X		X			4.5 Examination by referral laboratories
4.6 External services and supplies		X				4.6 External services and supplies
4.7 Advisory services	X	X	X	X	X	4.7 Advisory services
4.8 Resolution of complaints	X	X	X	X		4.8 Resolution of complaints
4.9 Identification and control of nonconformities	X	X	X	X		4.9 Identification and control of nonconformities
4.10 Corrective action			X			4.10 Corrective action
4.11 Preventive action				X		4.11 Preventive action
4.12 Continual improvement	X					4.12 Continual improvement
4.13 Control of records		X				4.13 Control of records
4.14.1 General			X			4.14.1 General
4.14.2 Periodic review of requests etc.				X		4.14.2 Periodic review of requests etc.
4.14.3 Assessment of user feedback	X	X	X	X		4.14.3 Assessment of user feedback
4.14.4 Staff suggestions	X					4.14.4 Staff suggestions
4.14.5 Internal audit	X	X	X	X	X	4.14.5 Internal audit
4.14.6 Risk management		X		X	X	4.14.6 Risk management
4.14.7 Quality indicators	X	X	X	X		4.14.7 Quality indicators
4.14.8 Reviews by external organisations			X			4.14.8 Reviews by external organisations
4.15 Management review	X	X	X	X		4.15 Management review
5.1 Personnel	X	X	X	X	X	5.1 Personnel
5.2 Accommodation & environmental conditions			X		X	5.2 Accommodation & environmental conditions
5.3 Lab equipment, reagents & consumables				X	X	5.3 Lab equipment, reagents & consumables
5.4 Pre-examination processes	X				X	5.4 Pre-examination processes
5.5 Examination processes		X			X	5.5 Examination processes
5.6 Ensuring quality of examination results	X	X	X	X	X	5.6 Ensuring quality of examination results
5.7 Post-examination process			X		X	5.7 Post-examination process
5.8 Reporting of results				X	X	5.8 Reporting of results
5.9 Release of results	X				X	5.9 Release of results
5.10 Lab information management		X			X	5.10 Lab information management
Flexible Scope	X	X	X	X	X	Flexible Scope
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 3b: ISO 22870:2016 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Organisation and management responsibility	X					4.1 Organisation and management responsibility
4.2 Quality management system		X				4.2 Quality management system
4.3 Document control			X			4.3 Document control
4.4 Service agreements				X	X	4.4 Service agreements
4.5 Examination by referral laboratories	X		X			4.5 Examination by referral laboratories
4.6 External services and supplies		X				4.6 External services and supplies
4.7 Advisory services	X	X	X	X	X	4.7 Advisory services
4.8 Resolution of complaints	X	X	X	X		4.8 Resolution of complaints
4.9 Identification and control of nonconformities	X	X	X	X		4.9 Identification and control of nonconformities
4.10 Corrective action			X			4.10 Corrective action
4.11 Preventive action				X		4.11 Preventive action
4.12 Continual improvement	X					4.12 Continual improvement
4.13 Control of records		X				4.13 Control of records
4.14.1 General			X			4.14.1 General
4.14.2 Periodic review of requests etc.				X		4.14.2 Periodic review of requests etc.
4.14.3 Assessment of user feedback	X	X	X	X		4.14.3 Assessment of user feedback
4.14.4 Staff suggestions	X					4.14.4 Staff suggestions
4.14.5 Internal audit	X	X	X	X	X	4.14.5 Internal audit
4.14.6 Risk management		X		X	X	4.14.6 Risk management
4.14.7 Quality indicators	X	X	X	X		4.14.7 Quality indicators
4.14.8 Reviews by external organisations			X			4.14.8 Reviews by external organisations
4.15 Management review	X	X	X	X		4.15 Management review
5.1 Personnel	X	X	X	X	X	5.1 Personnel
5.2 Accommodation & environmental conditions			X		X	5.2 Accommodation & environmental conditions
5.3 Lab equipment, reagents & consumables				X	X	5.3 Lab equipment, reagents & consumables
5.4 Pre-examination processes	X				X	5.4 Pre-examination processes
5.5 Examination processes		X			X	5.5 Examination processes
5.6 Ensuring quality of examination results	X	X	X	X	X	5.6 Ensuring quality of examination results
5.7 Post-examination process			X		X	5.7 Post-examination process
5.8 Reporting of results				X	X	5.8 Reporting of results
5.9 Release of results	X				X	5.9 Release of results
5.10 Lab information management		X			X	5.10 Lab information management
Flexible Scope	X	X	X	X	X	Flexible Scope
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 3c: ISO 15189:2022 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Impartiality	X					4.1 Impartiality
4.2 Confidentiality		X				4.2 Confidentiality
4.3 Requirements regarding patients	X	X	X	X	X	4.3 Requirements regarding patients
5.1 Legal entity	X		X			5.1 Legal entity
5.2 Laboratory director		X				5.2 Laboratory director
5.3 Laboratory activities			X			5.3 Laboratory activities
5.4 Structure and authority				X		5.4 Structure and authority
5.5 Objectives and policies	X					5.5 Objectives and policies
5.6 Risk management		X			X	5.6 Risk management
6.1, 6.2 Personnel				X	X	6.1, 6.2 Personnel
6.3 Facilities and Environmental conditions	X				X	6.3 Facilities and Environmental conditions
6.4 Equipment		X			X	6.4 Equipment
6.5 Equipment calibration and metrological traceability			X		X	6.5 Equipment calibration and metrological traceability
6.6 Reagents and consumables				X	X	6.6 Reagents and consumables
6.7 Service agreements			X			6.7 Service agreements
6.8 Externally provided products and services				X		6.8 Externally provided products and services
7.1 General	X					7.1 General
7.2 Pre-examination processes		X			X	7.2 Pre-examination processes
7.3 Examination processes			X			7.3 Examination processes
7.4 Post-examination processes				X	X	7.4 Post-examination processes
7.5 Nonconforming work	X	X	X	X	X	7.5 Nonconforming work
7.6 Control of data and information management			X		X	7.6 Control of data and information management
7.7 Complaints	X	X	X	X	X	7.7 Complaints
7.8 Continuity and emergency preparedness planning				X		7.8 Continuity and emergency preparedness planning
8.1 General requirements				X		8.1 General requirements
8.2 Management system documentation		X				8.2 Management system documentation
8.3 Control of Management system documents			X			8.3 Control of Management system documents
8.4 Control of records				X		8.4 Control of records
8.5 Actions to address risks and opportunities for improvement	X					8.5 Actions to address risks and opportunities for improvement
8.6 Improvement		X				8.6 Improvement
8.7 Nonconformities and corrective actions	X	X	X	X		8.7 Nonconformities and corrective actions
8.8 Evaluations	X	X	X	X	X	8.8 Evaluations
8.9 Management reviews	X	X	X	X		8.9 Management reviews
Flexible Scope	X	X	X	X	X	Flexible Scope
Review of sites & activities	X	X	X	X	X	Review of sites & activities
Annex A Additional requirements for Point-of-Care Testing (POCT)	X	X	X	X	X	Annex A Additional requirements for Point-of-Care Testing (POCT)

Appendix 4: ISO 17020:2012 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Impartiality & Independence	X	X	X	X	X	4.1 Impartiality & Independence
4.2 Confidentiality		X				4.2 Confidentiality
5.1 Administration Requirements			X			5.1 Administration Requirements
5.2 Organization and management				X		5.2 Organization and management
6.1 Personnel	X	X	X	X	X	6.1 Personnel
6.2 Facilities and equipment	X				X	6.2 Facilities and equipment
6.3 Subcontracting	X	X	X	X		6.3 Subcontracting
7.1 Inspection methods and procedures			X			7.1 Inspection methods and procedures
7.2 Handling inspection items and sampling				X	X	7.2 Handling inspection items and sampling
7.3 Inspection records	X				X	7.3 Inspection records
7.4 Inspection reports and certificates		X			X	7.4 Inspection reports and certificates
7.5 Complaints & appeals	X	X	X	X		7.5 Complaints & appeals
7.6 Complaints & appeals process			X			7.6 Complaints & appeals process
8. Management System				X		8. Management System
8.1 Option B (see 8.2-8.8)						8.1 Option B (see 8.2-8.8)
8.2 Documentation (Option A)	X					8.2 Documentation (Option A)
8.3 Control of documents		X				8.3 Control of documents
8.4 Control of records			X			8.4 Control of records
8.5 Management review	X	X	X	X		8.5 Management review
8.6 Internal audits	X	X	X	X	X	8.6 Internal audits
8.7 Corrective action				X		8.7 Corrective action
8.8 Preventive action	X					8.8 Preventive action
Annex A – Independence requirements		X			X	Annex A – Independence requirements
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 5: ISO 17065:2012 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Legal and contractual matters	X					4.1 Legal and contractual matters
4.2 Management of impartiality	X	X	X	X	X	4.2 Management of impartiality
4.3 Liability and financing	X	X	X	X		4.3 Liability and financing
4.4 Non-discriminatory conditions			X			4.4 Non-discriminatory conditions
4.5 Confidentiality				X		4.5 Confidentiality
4.6 Publically available information	X					4.6 Publically available information
5.1 Organization and top management		X				5.1 Organization and top management
5.2 Mechanism for safeguarding impartiality	X	X	X	X	X	5.2 Mechanism for safeguarding impartiality
6.1 Certification body personnel	X	X	X	X	X	6.1 Certification body personnel
6.2 Resources for evaluation	X	X	X	X		6.2 Resources for evaluation
7.1 Process requirements – General		X			X	7.1 Process requirements – General
7.2 Application / 7.3 App review			X		X	7.2 Application / 7.3 App review
7.4 Evaluation / 7.5 Review				X		7.4 Evaluation / 7.5 Review
7.6 Certification Decision	X				X	7.6 Certification Decision
7.7 Certification documentation		X			X	7.7 Certification documentation
7.8 Directory of certified products			X		X	7.8 Directory of certified products
7.9 Surveillance				X	X	7.9 Surveillance
7.10 Changes affecting certification	X				X	7.10 Changes affecting certification
7.11 Termination, reduction, suspension or withdrawal of certification		X			X	7.11 Termination, reduction, suspension or withdrawal of certification
7.12 Records			X			7.12 Records
7.13 Complaints and appeals	X	X	X	X		7.13 Complaints and appeals
8.1.3 Option B (see 8.2-8.8)	X	X	X	X		8.1.3 Option B (see 8.2-8.8)
8.2 General management system doc (Option A)				X		8.2 General management system doc (Option A)
8.3 Control of documents	X					8.3 Control of documents
8.4 Control of records		X				8.4 Control of records
8.5 Management review	X	X	X	X		8.5 Management review
8.6 Internal audits	X	X	X	X	X	8.6 Internal audits
8.7 CA / 8.8 PA			X			8.7 CA / 8.8 PA
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 6: ISO 17021-1:2015 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
5.1 Legal and contractual matters	X					5.1 Legal and contractual matters
5.2 Management of impartiality	X	X	X	X	X	5.2 Management of impartiality
5.3 Liability and financing	X	X	X	X		5.3 Liability and financing
6.1 Organisational structure and top management.			X			6.1 Organisational structure and top management.
6.2 Operational control				X		6.2 Operational control
7.1 Competence of personnel	X	X	X	X	X	7.1 Competence of personnel
7.2 Personnel involved in cert. activities	X				X	7.2 Personnel involved in cert. activities
7.3 Use of individual auditors and ext. tech experts		X			X	7.3 Use of individual auditors and ext. tech experts
7.4 Personnel records			X		X	7.4 Personnel records
7.5 Outsourcing	X	X	X	X	X	7.5 Outsourcing
8.1 Public information / 8.2 Certification documents / 8.3 Reference to certification and use of marks	X		X		X	8.1 Public information / 8.2 Certification documents / 8.3 Reference to certification and use of marks
8.4 Confidentiality		X			X	8.4 Confidentiality
8.5 Information exchange between CB and its clients			X		X	8.5 Information exchange between CB and its clients
9.1 Pre-certification activities	X				X	9.1 Pre-certification activities
9.2 Planning audits		X			X	9.2 Planning audits
9.3 Initial certification			X		X	9.3 Initial certification
9.4 Conducting audits				X		9.4 Conducting audits
9.5 Certification decision	X					9.5 Certification decision
9.6 Maintaining certification		X				9.6 Maintaining certification
9.7 Appeals			X			9.7 Appeals
9.8 Complaints	X	X	X	X		9.8 Complaints
9.9 Client records	X				X	9.9 Client records
10.1 Options		X				10.1 Options
10.2.1 General				X		10.3.1 General
10.2.2 Management system manual	X					10.3.2 Management system manual
10.2.3 Control of documents		X				10.3.3 Control of documents
10.2.4 Control of records			X			10.3.4 Control of records
10.2.5 Management review	X	X	X	X		10.3.5 Management review
10.2.6 Internal Audits	X	X	X	X	X	10.3.6 Internal Audits
10.2.7 Corrective actions				X		10.3.7 Corrective actions
10.3 Option B (sampling as 10.2.1-10.2.7)	X	X	X	X	X	10.3 Option B (sampling as 10.2.1-10.2.7)
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 7: ISO 17034:2016 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4	X	
4.1 Contractual matters	X				X	4.1 Contractual matters
4.2 Impartiality		X		X		4.2 Impartiality
4.3 Confidentiality		X		X		4.3 Confidentiality
5 Structural requirements	X		X			5 Structural requirements
6.1 Personnel	X	X	X	X		6.1 Personnel
6.2 Subcontracting		X		X		6.2 Subcontracting
6.3 Provision of equipment, services and supplies			X		X	6.3 Provision of equipment, services and supplies
6.4 Facilities and environmental conditions	X				X	6.4 Facilities and environmental conditions
7.1 General technical and production requirements	X				X	7.1 General technical and production requirements
7.2 Production planning	X				X	7.2 Production planning
7.3 Production control	X				X	7.3 Production control
7.4 Material handling and storage			X		X	7.4 Material handling and storage
7.5 Material processing			X		X	7.5 Material processing
7.6 Measurement procedures		X		X	X	7.6 Measurement procedures
7.7 Measuring equipment		X		X	X	7.7 Measuring equipment
7.8 Data integrity and evaluation		X			X	7.8 Data integrity and evaluation
7.9 Metrological traceability	X	X	X	X	X	7.9 Metrological traceability
7.10 Assessment of homogeneity	X		X		X	7.10 Assessment of homogeneity
7.11 Assessment and monitoring of stability	X		X		X	7.11 Assessment and monitoring of stability
7.12 Characterisation		X		X	X	7.12 Characterisation
7.13 Assignment of property values and their uncertainties		X		X	X	7.13 Assignment of property values and their uncertainties
7.14 RM documents and labels	X	X	X	X	X	7.14 RM documents and labels
7.15 Distribution services		X		X	X	7.15 Distribution services
7.16 Control of quality and technical records			X			7.16 Control of quality and technical records
7.17 Management of non-conforming work	X	X	X	X	X	7.17 Management of non-conforming work
7.18 Complaints	X		X			7.18 Complaints
8.1 Management system options (A or B)		X				8.1 Management system options (A or B)
8.2 Quality policy (Option A)			X			8.2 Quality policy (Option A)
8.3 Management system documentation (Option A)				X		8.3 Management system documentation (Option A)
8.4 Control of management documents (Option A)				X		8.4 Control of management documents (Option A)
8.5 Control of records (Option A)			X			8.5 Control of records (Option A)
8.6 Management review (Option A)	X	X	X	X		8.6 Management review (Option A)
8.7 Internal audit (Option A)	X	X	X	X	X	8.7 Internal audit (Option A)
8.8 Actions to address risks and opportunities (Option A)	X					8.8 Actions to address risks and opportunities (Option A)
8.9 Corrective actions (Option A)	X	X	X	X		8.9 Corrective actions (Option A)
8.10 Improvement (Option A)			X			8.10 Improvement (Option A)
8.11 Feedback from customers (Option A)		X				8.11 Feedback from customers (Option A)
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 8: ISO 17024:2012 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 Legal matters	X					4.1 Legal matters
4.2 Responsibility for decision on certification		X			X	4.2 Responsibility for decision on certification
4.3 Management of impartiality	X	X	X	X	X	4.3 Management of impartiality
4.4 Finance and liability	X	X	X	X		4.4 Finance and liability
5.1 Management and organization structure				X		5.1 Management and organization structure
5.2 Structure of CB in relation to training	X					5.2 Structure of CB in relation to training
6.1 General personnel requirements		X				6.1 General personnel requirements
6.2 Personnel involved in the certification activities	X	X	X	X	X	6.2 Personnel involved in the certification activities
6.3 Outsourcing	X	X	X	X	X	6.3 Outsourcing
6.4 Other resources				X	X	6.4 Other resources
7.1 Records of applicants, candidates and certified persons	X				X	7.1 Records of applicants, candidates and certified persons
7.2 Public information		X			X	7.2 Public information
7.3 Confidentiality			X		X	7.3 Confidentiality
7.4 Security				X	X	7.4 Security
8 Certification schemes	X				X	8 Certification schemes
9.1 Application process		X			X	9.1 Application process
9.2 Assessment process			X		X	9.2 Assessment process
9.3 Examination process				X	X	9.3 Examination process
9.4 Decision on certification	X				X	9.4 Decision on certification
9.5 Suspending, withdrawing or reducing the scope of certification		X			X	9.5 Suspending, withdrawing or reducing the scope of certification
9.6 Recertification process			X		X	9.6 Recertification process
9.7 Use of certificates, logos and marks				X	X	9.7 Use of certificates, logos and marks
9.8 Appeals against decisions on certification	X				X	9.8 Appeals against decisions on certification
9.9 Complaints	X	X	X	X		9.9 Complaints
10.1 Option B (see 10.2.1-10.2.8)	X	X	X	X		10.1 Option B (see 10.2.1-10.2.8)
10.2.1 General requirements (Option A)		X				10.2.1 General requirements (Option A)
10.2.2 Management system documentation			X			10.2.2 Management system documentation
10.2.3 Control of documents				X		10.2.3 Control of documents
10.2.4 Control of records	X					10.2.4 Control of records
10.2.5 Management review	X	X	X	X		10.2.5 Management review
10.2.6 Internal audits	X	X	X	X	X	10.2.6 Internal audits
10.2.7 Corrective actions		X				10.2.7 Corrective actions
10.2.8 Preventive actions			X			10.2.8 Preventive actions
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 9: ISO/IEC 17029:2019 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
5.1 Legal matters	X					5.1 Legal matters
5.2 Responsibility validation/verification statements		X			X	5.2 Responsibility validation/verification statements
5.3 Management of impartiality	X	X	X	X	X	5.3 Management of impartiality
5.4 Liability	X	X	X	X		5.4 Liability
6.1 Organizational structure and top management				X		6.1 Organizational structure and top management
6.2 Operational control	X					6.2 Operational control
7.1 Resource requirements - General		X				7.1 Resource requirements - General
7.2 Personnel	X	X	X	X	X	7.2 Personnel
7.3 Management process for the competence of personnel			X		X	7.3 Management process for the competence of personnel
7.4 Outsourcing	X	X	X	X	X	7.4 Outsourcing
8 Validation/verification programme	X				X	8 Validation/verification programme
9.1 Process requirements - General		X			X	9.1 Process requirements - General
9.2 Pre-engagement			X		X	9.2 Pre-engagement
9.3 Engagement				X	X	9.3 Engagement
9.4 Planning	X				X	9.4 Planning
9.5 Validation/verification execution		X			X	9.5 Validation/verification execution
9.6 Review			X		X	9.6 Review
9.7 Decision and issue of the validation/verification statement				X	X	9.7 Decision and issue of the validation/verification statement
9.8 Facts discovered after the issue of the validation/verification statement	X				X	9.8 Facts discovered after the issue of the validation/verification statement
9.9 Handling of appeals		X				9.9 Handling of appeals
9.10 Handling of complaints			X			9.10 Handling of complaints
9.11 Records				X		9.11 Records
10.1 Publicly available information	X				X	10.1 Publicly available information
10.2 Other information to be available		X			X	10.2 Other information to be available
10.3 Reference to validation/verification and use of marks			X			10.3 Reference to validation/verification and use of marks
10.4 Confidentiality				X		10.4 Confidentiality
11.1 Management system requirements - General	X					11.1 Management system requirements - General
11.2 Management review	X	X	X	X		11.2 Management review
11.3 Internal audits	X	X	X	X	X	11.3 Internal audits
11.4 Corrective action		X				11.4 Corrective action
11.5 Actions to address risks and opportunities			X			11.5 Actions to address risks and opportunities
11.6 Documented information				X		11.6 Documented information
Review of sites & activities	X	X	X	X	X	Review of sites & activities

Appendix 10: ISO 20387:2018 Requirements Matrix

Initial Assessment	Surveillance				Extension	Reassessment
	1	2	3	4		
4.1 General requirements	X					4.1 General requirements
4.2 Impartiality		X				4.2 Impartiality
4.3 Confidentiality			X			4.3 Confidentiality
5 Structural requirements				X		5 Structural requirements
6.1 Resource requirements – General	X				X	6.1 Resource requirements – General
6.2 Personnel		X			X	6.2 Personnel
6.3 Facilities / dedicated areas and environmental conditions			X		X	6.3 Facilities / dedicated areas and environmental conditions
6.4 Externally provided processes, products and services				X	X	6.4 Externally provided processes, products and services
6.5 Equipment	X				X	6.5 Equipment
7.1 Process requirements – General		X				7.1 Process requirements – General
7.2 Collection of biological material and associated data (BMaD)	X	X	X	X	X	7.2 Collection of biological material and associated data (BMaD)
7.3 Reception and distribution of BMaD			X		X	7.3 Reception and distribution of BMaD
7.4 Transport of BMaD			X		X	7.4 Transport of BMaD
7.5 Traceability of BMaD	X	X	X	X	X	7.5 Traceability of BMaD
7.6 Preparation and preservation of biological material	X				X	7.6 Preparation and preservation of biological material
7.7 Storage of biological material		X			X	7.7 Storage of biological material
7.8 Quality control of BMaD			X		X	7.8 Quality control of BMaD
7.9 Validation and verification of methods				X	X	7.9 Validation and verification of methods
7.10 Management of information and data	X				X	7.10 Management of information and data
7.11 Nonconforming output	X	X	X	X	X	7.11 Nonconforming output
7.12 Report requirements		X				7.12 Report requirements
7.13 Complaints	X	X	X	X		7.13 Complaints
8.1 Quality management system options-A or B	X	X	X	X		8.1 Quality management system options-A or B
8.2 Documented information for the QMS (Option A)			X			8.2 Documented information for the QMS
8.3 Control of QMS documents				X		8.3 Control of QMS documents
8.4 Control of records	X					8.4 Control of records
8.5 Actions to address risks and opportunities (Option A)		X				8.5 Actions to address risks and opportunities (Option A)
8.6 Improvement(Option A)			X			8.6 Improvement(Option A)
8.7 Corrective action for nonconforming output (OptionA)				X		8.7 Corrective action for nonconforming output (OptionA)
8.8 Internal audits (Option A)	X	X	X	X	X	8.8 Internal audits (Option A)
8.9 Quality management reviews (OptionA)	X	X	X	X		8.9 Quality management reviews (OptionA)
Verification of Annex A documentation requirements in the relevant sections as per visit plan.	X	X	X	X	X	Verification of Annex A documentation requirements in the relevant sections as per visit plan.
Review of sites & activities	X	X	X	X	X	Review of sites & activities