ISO/IEC 17025 ASSESSMENT WORKSHEET
with GCLP overlay

Self-assessment

This self assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

4.1 Impartiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
4.1.1	Laboratory activities • shall be undertaken impartially and structured and safeguarded to ensure impartiality	
4.1.2	Laboratory management • shall be committed to impartiality	
4.1.3	Laboratory responsibility • commercial, financial or other pressures must not compromise impartiality with regard to laboratory activities	
4.1.4	Risk identification • the laboratory to undertake this on an on-going basis and include those arising from – its activities – its relationships – relationships of personnel	
4.1.5	Risk mitigation • the laboratory shall demonstrate how risk to impartiality is eliminated or minimised	

Self-assessment

4.2 Confidentiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
4.2.1 **17.1** **17.3**	Laboratory responsibility • through legally enforceable commitments, manage all information obtained or created during the performance of laboratory activities • inform the customer in advance of the information it intends to place in the public domain • maintain all customer information as confidential, except for that information the customer makes public or that agreed to be made public between the laboratory and customer • procedures for the handling of trial materials, collection of data and reporting of results should be designed to maintain subject confidentiality and study blinding/coding arrangements within the requirements of Good Clinical Practice, Declaration of Helsinki and the trial protocol	
4.2.2 **17.2** **17.3**	Release of customer information • must not occur unless – when required by law – authorised by contractual arrangements • customer to be notified of information provided (unless prohibited by law) • procedures should assure that a sponsor's proprietary information is not disclosed to anyone other than authorized individuals	
4.2.3	Customer information from other sources • shall be confidential between the customer and laboratory • the source of this information shall remain confidential to the laboratory	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
4.2.4	Confidentiality obligations of personnel • shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law	

5 STRUCTURAL REQUIREMENTS

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
5.1	Legal status • the laboratory shall be a legal entity, or a defined part of a legal entity	ABN:
5.2 **5.1.1** **5.2.1**	Laboratory management • identify management that has overall responsibility for the laboratory • trial facility management should ensure that the principles of Good Clinical Laboratory Practice as defined in this document are complied • the Analytical Project Manager has the responsibility for the overall conduct of the analyses performed by the trial facility and for its report	
5.3	Scope of laboratory activities • the laboratory to define and document the range of activities which it claims conformity to the Standard – cannot include laboratory activities which are provided externally on an ongoing basis	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
5.4	Conduct of laboratory activities and premises • to be performed to meet the requirements of – the Standard – customer requirements – regulatory authorities – NATA • activities include those conducted at – permanent facilities – sites away from permanent facilities – temporary or mobile facilities – customer premises	
5.5	Structure, personnel and documentation a) define the laboratory's place in any parent organisation, the relationship between management, technical operations and support services b) specify the responsibilities, authorities and interrelationships of those who manage, perform or verify work affecting the results of laboratory activities c) document procedures to the extent necessary to ensure consistent conduct of laboratory activities and the validity of results	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
5.6 **5.1.2 l)** **5.1.2 m)** **5.1.2 n)**	Personnel authorities and resources a) available to implement, maintain and improve the management system b) able to identify deviations in the management system or laboratory activity procedures c) able to initiate actions to prevent or minimise deviations d) report to laboratory management the performance of the management system and needs for improvement e) ensure the effectiveness of laboratory activities l) for each trial, laboratory management must designate an individual with appropriate qualifications, training and experience as the Analytical Project Manager. If it is necessary to replace the Analytical Project Manager during a trial, this should be documented m) laboratory management must ensure there is a quality audit program with designated personnel (independent) n) laboratory Management must ensure that an individual or organisation is identified as having responsibility for the management of the archives used for the retention of trial and facility records (Archivist)	
5.7 **5.1.2**	Laboratory management responsibilities a) ensure communication on the effectiveness of the management system and meeting customers' and other requirements b) ensure integrity of the management system is maintained when changes are planned and implemented c) prior to the initiation of analytical work, lines of communication should be established and documented between the sponsor, or their representative, and the analytical project manager	

Self-assessment

6 RESOURCE REQUIREMENTS

6.1 General

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.1 **5.1.2 a)** **5.1.2 k)**	Available resources • laboratory to have available personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities	

6.2 Personnel

Clause No.	Summary	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.1	Competence and impartiality • all personnel (internal or external) associated with the laboratory that could influence the laboratory activities to be competent and act impartially in accordance with the management system	
6.2.2	Documentation of competency requirements • to include education, qualification, training, technical knowledge, skills and experience for each role which influences the laboratory activities	
6.2.3	Competency • ensure personnel are competent to perform laboratory activities for which they are responsible and to evaluate the significance of deviations	

Clause No.	Summary	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.4 **5.1.2 b)** **5.1.2 c)** **5.2.2** **5.3**	Duties, responsibilities and authorities • ensure these are communicated • job description Analytical Project Managers responsibilities include: a) sign and date the analytical plan b) ensure the procedures specified in the analytical plan are followed, and that authorisation for any modification is obtained and documented together with the reasons for change c) ensure that all results of the analyses are fully documented and recorded d) sign and date the analytical report, if issued, to indicate acceptance of responsibility for the validity of the results and to confirm compliance with Good Clinical Laboratory Practice *(e.g. compliance statement)* e) when analytical results are issued the Analytical Project Manager should ensure that these results are only issued under the dated signature of an authorized signatory *(see also 5.2.2e))* f) ensure that after completion of the analyses, the analytical plan, the analytical report and/or analytical results, raw data and supporting g) documentation are archived and retained Trial Staff responsibilities include: a) all staff working with trial materials should be aware of those guidelines that apply to their work. *(e.g. training in GCLP / GCP)* b) all staff are responsible for recording raw data promptly and accurately and in compliance with these guidelines and are responsible for the quality of their data	

Clause No.	Summary	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	c) all staff are responsible for following the instructions given in the trial protocol, analytical plans and standard operating procedures	
6.2.5 **5.1.2 b)**	Procedures and records a) for the determination of the competence requirements b) for the selection of personnel c) for training d) for supervision e) for authorisations f) for the monitoring of competence	
6.2.6 **5.2.2 e)**	Authorisations to perform specific activities a) develop, modify, verify and validate methods b) analyse results, including statements of conformity or opinions and interpretations c) report, review and authorise results	

Self-assessment

6.3 Facilities and environmental conditions

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.3.1 **6.1.1** **6.1.3** **6.2.1** **6.3.1**	Suitability of facilities and environmental conditions • appropriate and not adversely affect the validity of results • suitable facilities should be available for the preparation of trial supplies in order to ensure accurate preparation of such materials • appropriate space should be provided for the safe and secure archive storage and retrieval of data, reports, samples and specimens • the handling and disposal of wastes generated during the performance of a trial should be carried out in a manner that is consistent with local regulatory requirements	
6.3.2	Document • the requirements for facilities and environmental conditions to perform laboratory activities	
6.3.3	Monitor, control and record • the environmental conditions in accordance with the relevant specifications, methods and procedures or when they influence the validity of results	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.3.4 **6.1.2**	Measures to control facilities • to be implemented, monitored and periodically reviewed, including but not limited to a) access to and use of areas affecting laboratory activities b) prevention of contamination, interference or adverse influences on laboratory activities c) effective separation between areas with incompatible laboratory activities d) adequate degree of separation and security to assure the integrity of trial samples at all times	
6.3.5	Sites outside laboratory's permanent control • ensure facilities and environmental conditions comply with requirements of the Standard	

6.4 Equipment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.4.1 **7.1.1** **7.1.6** **7.2.1**	Availability of equipment • laboratory has access to equipment for correct performance of laboratory activities	
6.4.2	Equipment outside control of laboratory • the requirements of the Standard are met	
6.4.3 **7.1.2** **8.2.1 b)**	Procedure • is available for handling, storage, use and planned maintenance to ensure proper functions and to prevent contamination or deterioration	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.4.4	Verification • ensure equipment conforms to specified requirements before being placed or returned into service	
6.4.5 **7.1.1**	Accuracy and/or measurement uncertainty (MU) • to provide a valid result, equipment must be capable of achieving the required – measurement accuracy; and/or – MU	
6.4.6 **7.1.2**	Calibration • equipment shall be calibrated when – measurement accuracy or MU affects the validity of the results; and/or – the equipment is necessary to establish metrological traceability of the results	
6.4.7 **7.1.3**	Calibration program • shall be establish and reviewed and adjusted as necessary in order to maintain confidence in the status of calibration including the schedule of planned service and calibration activities	
6.4.8 **7.3.1**	Labelling • all equipment which requires calibration or has a defined period of validity shall be labelled, coded or otherwise identified • reagents should be suitably labelled and indicate the identity, concentration, specific storage instructions and stability. Stability information may include the preparation date and expiration date	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.4.9 **7.1.4**	Out-of-service • overloaded, mishandled or poorly functioning equipment shall be isolated and not reused until verified that it performs correctly • the effect of such defective equipment shall be investigated and the management of non-conforming work initiated	
6.4.10 **7.1.2**	Intermediate checks • shall be carried out when necessary to confirm performance of the equipment • in accordance with a procedure	
6.4.11	Correction factors • when calibration and reference material data include reference values or correction factors, these are to be updated and implemented, as appropriate, to meet specified requirements	
6.4.12	Unintended adjustments • practicable measures are taken to prevent these from occurring and invalidating results	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.4.13	Records • shall be retained for equipment which can influence laboratory activities, including: - identity, including software / firmware version - manufacturer's name, type and serial number or other identification - evidence of verification - location - calibration dates and results, results of adjustments, acceptance criteria, due date of next calibration or interval - documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity - maintenance plan and maintenance performed; - details of damage, malfunction, modifications or repair	

6.5 Metrological traceability

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.5.1	Establish metrological traceability • the laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.5.2	Measurement results traceable to SI units • to be established through a) calibration provided by a competent laboratory; or b) certified values of CRMs from a competent producer with stated traceability to SI units; or c) direct realisation of the SI units ensured by comparison with national or international standards	
6.5.3	Traceability to SI not technically possible • where this occurs, metrological traceability to an appropriate reference shall be demonstrated, for example a) certified values of CRMs provided by a competent producer to non SI values b) results of reference measurement procedures, specified methods or consensus standards that are accepted as providing measurement results fit for their intended use and ensured by suitable comparison	

Self-assessment

6.6 Externally provided products and services

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.6.1 **5.1.2 n)**	Use of externally provided products and services • Only suitable products and services are used when a) incorporated into the laboratory's own activities b) provided directly to the customer by the laboratory as received from the external provider c) used to support the operation of the laboratory d) for any work sub-contracted by the trial facility, trial facility management are responsible to the sponsor for its conduct	
6.6.2 **10.2** **10.3**	Procedure and records for a) defining, reviewing and approving the laboratory's requirements for externally provided products and services b) defining criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers c) ensuring that prior to laboratory use or supply to customers, the products and services conform to the laboratory's requirements or where relevant to the Standard d) actions to take arising from evaluations, monitoring or re-evaluations of external providers	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
6.6.3 **10.4**	Communication of requirements to external providers • These include a) the products and services to be provided b) the acceptance criteria c) competence, including any required qualification of personnel d) activities that the laboratory, or its customer, intends to perform at the external provider's premises e) the contract for sub-contracted work (agreement, protocol or analytical plan) should clearly spell out the detail of the analyses and the retention of trial data	

7 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.1.1 **9.1** **9.2** **10.1**	Procedure Shall ensure a) requirements are defined, documented and understood b) laboratory has the capability and resources to meet the requirements c) where external providers are used, the customer is advised and approves; d) appropriate methods or procedures are selected	- a list of records to be retained and their archive location on the completion of the work; - the method of reporting results; - quality audits to be performed. - Trial material should be analysed and reported within a time frame consistent with patient safety issues and trial protocol, analytical plan, standard operating procedure and any contractual requirements.

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.1.1 **9.1** **9.2** **10.1**	e) written analytical plan shall exist prior to initiation of the work and be available to the staff involved in the work *(note the analytical plan may form part of the contractual agreement with the Sponsor or be contained within the trial protocol)* f) the analytical plan shall be approved by dated signature of the Analytical Project Manager and Sponsor, and as appropriate the Investigator g) maintain copies of trial protocols and analytical plans The content of the Analytical Plan includes: - identification of the work (title, nature and purpose, unique identifier); - information concerning the sponsor, Investigator, Trial Facility and Analytical Project Manager; - dates of agreement to the analytical plan and the proposed starting and completion dates; - analytical processes including: - methods of analysis; - preparation/shipment of materials such as sample kits used in the collection of trial materials; - type and number of trial materials to be received; - method and conditions under which trial materials are to be transported; - for blinded or codes trials, the conditions of blinding and the unblinding processes to be followed;	
7.1.2	Inappropriate method requested • customer is informed, including if method is out-of-date	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.1.3	Statement of conformity requested • specification or standard and the decision rule are clearly defined • unless inherent in the specification or standard, the decision rule is agreed with the customer	
7.1.4	Differences between requests and contract • are resolved prior to laboratory activities commencing • contract to be acceptable to both the laboratory and customer • deviations requested do not impact on the laboratory's integrity or the validity of results	
7.1.5	Deviations from the contract • customer is informed	
7.1.6	Amendments to contracts • contract review is repeated after work commences and amendments communicated to all affected personnel	
7.1.7	Cooperation with customers • laboratory to clarify requests and to allow the customer to monitor its performance	
7.1.8	Records of reviews • are retained, including changes to contracts and discussions had with the customer	

Self-assessment

7.2 Selection, verification and validation of methods

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.2.1	**Selection and verification of methods**	
7.2.1.1 8.1.1 8.1.2 g)	Methods and procedures • to be appropriate for all laboratory activities, including where necessary, for evaluation of measurement uncertainty and statistical techniques for data analysis • approved by Trial Facility Management	
7.2.1.2 8.1.4	Currency of methods and procedures • to be kept up-to-date and made available to personnel	
7.2.1.3	Method version • latest valid versions to be used unless it is not appropriate or possible • where necessary, supplemented with additional details for consistent application	
7.2.1.4 12.3.1	Method selection • the laboratory to select an appropriate method and inform the customer when the customer has not specified the method	
7.2.1.5	Method verification • before introducing methods, the laboratory must verify that it can achieve the required performance • records of verification must be kept • verification to be repeated when changes to the methods are made by the issuing body/ies	
7.2.1.6	Method development • as proceeds, periodic review to occur to confirm the needs of the customer are still satisfied • changes to the development plan to be approved and authorised	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.2.1.7 12.3.5	Deviations from methods • shall only occur if the deviation is technically justified, documented, authorised and accepted by the customer • analytical platforms/methods should not be changed during the course of a trial, without prior consultation and agreement with the Sponsor. Such changes must be controlled, documented and appropriately	
7.2.2 Validation of methods		
7.2.2.1 12.3.2 12.3.3	Validation • non-standard methods, laboratory developed methods and standard methods used outside their scope or modified shall be validated	
7.2.2.2 12.3.2	Changes made to validated method • the influence of such changes shall be determined and if they affect the original validation, then the method must be revalidated	
7.2.2.3	Method performance characteristics • satisfy the customers needs and specified requirements	
7.2.2.4 12.3.4	Validation records a) the validation procedure used b) specification of the requirements c) performance characteristics of the method d) results obtained e) a statement on the validity of the method, and its fitness for the intended use	

Self-assessment

7.3 Sampling

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.3.1 **8.2.1 a)** **11.3.1**	Sampling plan and method • method addresses factors to be controlled to ensure validity of subsequent testing or calibration • plan and method available at sampling site • sampling plans based on statistical methods whenever reasonable When a trial facility prepares sample kits or materials used for the collection of trial samples, the systems used for the preparation, distribution, labelling, handling, sample collection, handling, shipment and storage must be documented and the systems and procedures used validated.	
7.3.2	Method • describes a) selection of samples or sites b) sampling plan c) preparation and treatment of samples from a substance, material or product	
7.3.3	Records of sampling data • include a) reference to the sampling method b) date and time of sampling c) data to identify and describe the sample d) identification of the personnel e) identification of the equipment used f) environmental or transport conditions g) diagrams or other means to identify the sampling location when appropriate h) deviations, additions or exclusions from the method or sampling plan	

7.4 Handling of test and calibration items

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.4.1 **8.2.1 d)** **8.1.2 f)** **11.1.1** **11.1.2** **11.3.2** **11.3.3** **11.3.4** **16.2** **16.3** **17.1**	Procedure • ensures the protection of integrity of the item and the interests of the laboratory and customer and covers – transportation – receipt – handling – protection – storage – retention and/or disposal • precautions taken to avoid deterioration, contamination, loss or damage	
7.4.1 (cont) **8.2.1 d)** **8.1.2 f)** **11.1.1** **11.1.2** **11.3.2** **11.3.3** **11.3.4** **16.2** **16.3** **17.1**	• handling instructions provided with the item to be followed • records shall be maintained to allow the reconstruction of the chain of custody of trial material received and to allow retrospective evaluation of material storage • records of disposal of any retained materials shall be maintained	
7.4.2 **11.1.1** **11.2.1**	Identification • system is in place for the unambiguous identification of items, including, if relevant, the subdivision and transfer of items • facilities and procedures should be designed and operated to maintain trial materials identification and traceability at all times	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.4.3 **11.1.2**	Item deviations • upon receipt, deviations from specified conditions are recorded • if there is doubt about suitability of item, or it does not conform to description provided, ensure that the customer is consulted and that the instructions are recorded • when deviation is acknowledged and customer instructs to proceed with testing or calibration, the laboratory is to include a disclaimer in the report indicating that the results may be affected	
7.4.4 **11.2.3**	Storage conditions • to be maintained, monitored and recorded	

7.5 Technical Records

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.5.1 **11.2.2** **12.1.2**	Records • for each laboratory activity include – results – report – factors affecting the results and its measurement uncertainty – date – identify of personnel conducting the laboratory activity and checking data and results • allow repetition of the laboratory activity • original observations, data and calculations to be recorded at the time they made and be identifiable with the specific task	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.5.2 **12.1.3**	Amendments • can be traced to original observations or previous version of records • original and amended data – to be retained – include the date – an indication of the altered aspects – the personnel responsible	

7.6 Evaluation of measurement uncertainty

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.6.1	Contributions of MU • shall be identified • significant contributions taken into account when evaluating MU, including those from sampling	
7.6.2	Calibration • MU for all calibrations performed shall be evaluated	
7.6.3	Testing • where the test method precludes rigorous evaluation, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method	

Self-assessment

7.7 Ensuring the validity of results

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.7.1 **8.1.2 h)** **14.1**	Procedure • for monitoring validity of results is in place • data from monitoring activities are recorded in a manner which allows the detection of trends with statistical methods applied, where possible, for review of the results • monitoring is to be planned and reviewed and include, where appropriate a) use of reference materials or quality control materials b) use of alternative calibrated instrumentation providing traceable results c) functional checks of measuring and testing equipment; d) use of check or working standards with control charts e) intermediate checks on measuring equipment f) replicate tests or calibrations g) retesting or recalibration of retained items h) correlation of results for different characteristics of an item i) review of reported results j) intra-laboratory comparisons k) testing of blind sample(s)	
7.7.2 **14.2**	Comparison of results with other laboratories • shall be used to monitor the laboratory's performance • monitoring shall be planned and reviewed and include participation in either or both a) proficiency testing b) inter-laboratory comparisons	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.7.3	Analysis of monitoring data • used to control and improve, where applicable, laboratory activities • appropriate action is taken to prevent incorrect results from being reported when monitoring data is found to be outside of pre-defined criteria	

7.8 Reporting of results

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.8.1 General		
7.8.1.1 **13.1.4** **13.4.3**	Review and authorisation of results • shall occur prior to release	
7.8.1.2	Reports • results are provided accurately, clearly, unambiguously and objectively • include all the information agreed with the customer and necessary for the interpretation of the results • issued reports are retained as technical records	
7.8.1.3 **13.1.1** **14.4**	Simplified reports • when agreed with the customer • all information not reported to customer and covered by 7.8.2 to 7.8.7 must be readily available Reports may take the format of analytical results. Analytical results shall include: • identification of the analytical work by unique identification number • clinical trial number • sponsor	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
	• identity of the trial facilities and the Investigator to whom the results are directed • name of the Analytical Project Manager • presentation of the results	
7.8.2 Common requirements for reports (test, calibration or sampling)		
7.8.2.1 **13.3**	Report content a) title b) name and address of the laboratory c) location where the laboratory activities were performed d) unique identification that all components are recognised as a portion of a complete report and a clear identification of the end e) name and contact information of the customer f) method used g) a description, unambiguous identification, and if necessary, the condition of the item h) date of receipt of the item or date of sampling of the item where critical to the validity and application of the results i) date(s) of the performance of the laboratory activity j) date of the issue of the report k) reference to the sampling plan and sampling method if relevant to the validity and application of the results l) statement to the effect that results only relate to the item tested, calibrated or sampled m) the results with the units of measurement, where appropriate n) additions, deviations or exclusions from the method o) identification of the person authorising the report	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
	p) clear identification when the results are from external providers q) clinical trial number r) sponsor investigator s) name and address of any trial facilities and any investigator sites involved; including identity of any Investigators t) analytical project manager u) quality audit certificate (QA statement) v) methods and materials used including data manipulation techniques and any statistical methods used w) the location(s) where the analytical plan, any specimens required to be retained, data and the final analytical report are to be stored	
7.8.2.2	Laboratory responsibility • for all information provided in the report except when provided by the customer – customer information to be clearly identified and a disclaimer included when information supplied can affect the validity of results • when customer is responsible for sampling, the report is to state that the results apply to the sample as received (also refer to 7.4.3)	
7.8.3 Specific requirements for test reports		
7.8.3.1	Additional information • for the interpretation of the test results, in addition to 7.8.2, reports to include where necessary a) information on specific test conditions, such as environmental conditions b) where relevant, a statement of conformity with requirements or specifications	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
	c) where applicable, the MU in the same units as the measurand or in a term relative to the measurand when – relevant to the validity or application of the results – customer's instruction – MU affects conformity to a specification limit d) where appropriate, opinions and interpretations; e) additional information which may be required by specific methods, authorities, customers or groups of customers	
7.8.3.2	Sampling • when the laboratory is responsible for sampling, test reports shall meet the requirements of 7.8.5 where necessary	
7.8.4 Specific requirements for calibration certificates		
7.8.4.1	Additional information • in addition to 7.8.2, calibration certificates to include a) the MU of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand b) the conditions under which the calibrations were made that have an influence on the measurement results c) a statement to indicate how the measurements are metrologically traceable d) results before and after any adjustments or repair e) where relevant, a statement of conformity with requirements or specifications f) where appropriate, opinions and interpretation	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.8.4.2	Sampling • when the laboratory is responsible for sampling, calibration certificates shall meet the requirements of 7.8.5 where necessary	
7.8.4.3	Calibration certificates or labels • shall not include any recommendation on calibration intervals, unless agreed with the customer	
7.8.5 Reporting sampling - specific requirements		
7.8.5	Additional information • when the laboratory is responsible for the sampling, in addition to 7.8.2, reports to include a) date of sampling b) unique identification of the item or material sampled c) location of sampling, including any diagrams, sketches or photographs d) reference to the sampling plan and sampling method e) details of any environmental conditions that affect the interpretation of the results f) information required to evaluate MU for subsequent testing or calibration	
7.8.6 Reporting statements of conformity		
7.8.6.1	Decision rule • to be documented and applied, taking into account the associated risk, when a statement of conformity is provided to a customer	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.8.6.2	Statement of conformity • includes a) which results the statement of conformity applies to b) which specifications, standards or parts thereof are met or not met c) the decision rule applied (unless it is inherent in the requested specification or standard)	
7.8.7 Reporting opinions and interpretations		
7.8.7.1	Authorised personnel • opinions and interpretations are only made by authorised personnel and the basis upon which they have been made shall be documented	
7.8.7.2	Based on results • opinions and interpretations are based on the results obtained and clearly identified as such in reports	
7.8.7.3	Direct verbal communication • when opinions and interpretations are verbally communicated to the client, a record is retained	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.8.8 Amendments to reports		
7.8.8.1, **7.8.8.2,** **7.8.8.3** **13.3.1** **13.4.3**	Amendments to reports • are clearly identified • where appropriate, the reason for the change is included in the report • a further report is issued and referenced as amended, is uniquely identified and makes reference to the original report it replaces • corrections or additions to a final analytical report once issued should be in the form of an amendment • amendments should clearly state the reasons for corrections or additions and should be authorized by the dated signature of the Analytical Project Manager	

7.9 Complaints

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.9.1	Documented process • is available for receiving, evaluating and making decisions on complaints	
7.9.2	Availability of documented process and responsibility • is available to any interested party • when a complaint is received, the laboratory is to confirm whether it relates to laboratory activities it is responsible for and action it • laboratory is responsible for all decisions relating to complaints handling	

Self-assessment

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.9.3	Content of complaints process a) a description of the process for receiving, validating, investigating and deciding what actions are to be taken in response to it b) tracking and recording complaints, including actions taken c) ensuring that any appropriate action is taken	
7.9.4	Gathering and verifying information • the laboratory is responsible in order to validate the complaint	
7.9.5	Acknowledging receipt • whenever possible, the laboratory does this and provides the complainant with progress reports and the outcome	
7.9.6	Communication of outcomes • to be made by, or reviewed and approved by, an individual(s) not involved in the original laboratory activities in question.	
7.9.7	Formal notice of end of complaint • whenever possible, the laboratory to advise the complainant	

Self-assessment

7.10 Non-conforming work

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.10.1 **12.4.2** **17.2**	Procedure • is available and implemented when any aspect of the laboratories activities does not conform to its own procedures or the agreed requirements of the customer a) defines the responsibilities and authorisations for the management of non-conforming work b) actions are based upon the risk levels established by the laboratory c) an evaluation is made of the significance of the non-conforming work, including an impact analysis on previous results d) a decision is taken on the acceptability of the non-conforming work e) where necessary, the client is notified and work is recalled f) defines the responsibility for authorising the resumption of work The laboratory shall have documented procedures governing rules for repeat analysis consistent with pharmaceutical industry standards. These may be included within the analytical plan. The Sponsor should be informed of any event, either accidental or arising as a result of an investigation, which may compromise study blinding.	
7.10.2	Records • are retained of non-conforming work and the actions taken	
7.10.3	Implementation of corrective action • shall be taken when the non-conforming work could recur, or there is doubt with the laboratory's operations with its own management system	

Self-assessment

7.11 Control of data and information management

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.11.1	Access to data and information • data and information needed to perform laboratory activities is available	
7.11.2 **12.2.1** **12.2.2**	Laboratory information management system • the system for collecting, processing, recording, reporting, storing and retrieving data is validated, including interfacing with other laboratory systems before being used • changes to the system are authorised, documented and validated before used • computerized systems used to receive, capture, process or report data should be acquired, developed, tested, released, used, maintained and retired according to established guidelines or laws. These may include the OECD Monograph "The application of GLP Principles to computerized systems" the FDA 21CFR Part 11: Electronic Records, Electronic Signatures, Rule and the FDA Guideline for the use of computer systems in the conduct of clinical trials	

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
7.11.3 **12.2.2** **12.2.3** **12.2.4**	Protection, safeguard and maintenance • the information system a) is protected from unauthorised access b) is safeguarded against tampering and loss c) is operated in an environment that complies with supplier or laboratory specifications or, for non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription d) is maintained in a manner which ensures the integrity of the data and information e) includes the recording of system failures and the appropriate immediate and corrective actions Procedures that address the security and operation of the computer systems should exist. These should include the maintenance of a data audit trail, the date/time and individual responsible for the collection of the data, system change control procedures, maintenance and system security procedures that ensure the integrity of trial data.	
7.11.4	Off-site systems • laboratory ensures that the provider or operator complies with all applicable requirements of the Standard	
7.11.5	Instructions, manuals and reference data • are readily available to personnel	
7.11.6	Calculations and data transfers • are checked in an appropriate and systematic manner	

Self-assessment

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

Clause No.	General Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.1.1 General		
8.1.1	Management system • supports and demonstrates the consistent achievement of the requirements of the Standard • assures the quality of the laboratory results • allows the requirements of clauses 4 to 7 to be met • is in accordance with either Option A or Option B	

On the following sections, only complete either Option A or Option B.

Option A

The laboratory must address clauses 8.2 to 8.9.

8.2 Management system documentation

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.2.1 **8.2.1**	Policies and objectives • are established, documented for the fulfilment of the Standard • are acknowledged and implemented at all levels of the laboratory SOPs must be available for: • *record keeping, reporting, storage, and retrieval* including coding of trials, data collection, preparation of reports, indexing systems, handling of data, the use of computerized data systems and the operation of the archive • preparation of trial packs	

Self-assessment

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.2.2	Competence, impartiality consistent operations • are addressed by the polices and objectives	
8.2.3	Laboratory management • provides evidence of commitment to the development of the management system • continually improves the management system's effectiveness	
8.2.4	Reference to the management system • of all documentation, processes, systems and records	
8.2.5	Access to parts of the management system • is available to personnel	

8.3 Control of management system documents

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.3.1 **8.1.3**	Control of documents • both internal and external documents relating to the fulfilment t of the requirements of the Standard A list of current standard operating procedures which includes the version number should be maintained current and up to date.	

Self-assessment

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.3.2 **8.1.1** **8.1.2** **8.1.4** **12.3.2**	Document control process a) documents are approved by authorised personnel prior to issue b) documents are periodically reviewed and updated as necessary c) changes and current revision status of documents are identified d) relevant versions of documents are available and their distribution controlled as necessary e) documents are uniquely identified f) unintended use of obsolete documents is prevented	

Self-assessment

8.4 Control of records

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.4.1 **13.1.6** **16.1**	Records retention • to demonstrate fulfilment of the requirements of the Standard • including analytical plan, data, analytical results, analytical report, internal audit records, qualifications, training, experience, job descriptions, equipment records, historical file of SOPs, QC records	
8.4.2 **12.2.5**	Controls • are implemented for – identification – storage – protection – back-up – archive – retrieval – retention times – disposal • are established for – retention periods to satisfy contractual obligations – confidentiality commitments – access and availability If data is retained electronically, means should exist to ensure the data held can always be retrieved.	

Self-assessment

8.5 Actions to address risks and opportunities

Note: There is no requirement for formal methods for risk management or a documented risk management process

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.5.1	Risks and opportunities are considered a) to assure the management system achieves its intended goals b) to achieve the laboratory objectives c) to prevent (or minimise) undesired impacts and potential failures d) to achieve improvement	
8.5.2 **11.2.3**	Plan a) actions to address risks and opportunities b) how to – implement actions into the management system – evaluate the effectiveness of actions Contingency plans that define the actions to be taken in the case of failure of equipment used to store and monitor trial materials shall be in place. Such plans should ensure the integrity of the stored trial materials.	
8.5.3	Actions to address risks and opportunities • are proportional to the potential impact on the validity of the laboratory results	

Self-assessment

8.6 Improvement

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.6.1	Opportunities • are identified and any necessary action implemented	
8.6.2	Customer feedback • both positive and negative are sought, analysed and used to improve the management system, laboratory activities and customer service	

8.7 Corrective actions

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.7.1	Nonconformities • when occur, the laboratory shall a) react and, as applicable, take action, correct the issue and address the consequences b) evaluate the need for action to eliminate the cause so that it does not recur c) implement any action necessary d) review the effectiveness of any corrective action e) update any risk and opportunities f) makes any necessary changes to the management system	
8.7.2	Corrective action taken • is appropriate to the effects of the nonconformity	
8.7.3	Records retained a) of the nature of the nonconformity, cause(s) and any action(s) taken b) of the outcomes of corrective action	

Self-assessment

8.8 Internal audits

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.8.1 **8.1.2 i)** **15.1** **15.2**	Conducted at planned intervals • to establish whether the management system a) conforms to – the laboratory's requirements, including laboratory activities – the requirements of the Standard b) is effectively implemented and maintained Quality audit procedures must be documented and include operation of quality audit personnel in performing and reporting trial audits, inspections, and analytical report reviews.	

Self-assessment

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.8.2 **15.2** **15.3** **15.4** **15.5** **15.6** **15.7**	Audit requirements a) is planned and implemented, including frequency, defined responsibilities and reporting, taking into account – the importance of the laboratory activities concerned – changes affecting the laboratory – the results of previous audits b) audit criteria and the scope of each audit are defined c) audit results are reported to relevant management d) corrective actions, where necessary, are implemented promptly e) records of the audit program, including outcomes, are retained f) audits should be conducted by a competent person(s) designated by trial facility management. This person(s) should be independent of the work being audited. Independent audits by external experts may also be utilized g) on the satisfactory completion of an audit, an audit certificate should be produced, which identifies the activities audited, and an indication of the compliance of those activities with GCLP	

Self-assessment

8.9 Management reviews

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.9.1	Review of management system • is conducted at planned intervals by laboratory management to ensure – continued suitability, adequacy and effectiveness – covers the stated policies and objectives related to the fulfilment of the Standard	
8.9.2	Records of inputs • including information related to a) changes in internal and external issues b) fulfilment of objectives c) suitability of policies and procedures d) status of actions from previous reviews e) outcomes of recent internal audits f) corrective actions g) assessment by external bodies h) changes in volume, type and range of laboratory activities i) customer and personnel feedback j) complaints k) effectiveness of any implemented improvements l) adequacy of resources m) results of risk identification n) outcomes of the assurance of validity of results o) any other relevant factors	

Self-assessment

Clause No.	Management System Requirements	Evidence (outcome of discussions with staff; observations; records; procedures & documentation reviewed)
8.9.3	Records of outputs • include all decisions and actions relating to a) effectiveness of the management system b) improvement of the laboratory activities relating to satisfying the requirements of the Standard c) provision of required resources d) any need for change(s)	

Self-assessment

Option B

Where 1) to 5) below are confirmed, a document review of the laboratory's management system does not need to be formally performed. The Lead Assessor is still, however, to be familiar with the management system documentation and hence a copy of the documentation is to be provided by the laboratory.

A limited review of records at assessment is to be performed to specifically confirm 6) e.g. management review, an internal audit, example of corrective action etc.

The required extent of assessment will be dependent on the evidence provided in 3) and 4) below.

Where nonconformities are identified, these are to be raised against clause 8.1.3.

Where 1) to 5) cannot be confirmed, then assessment of the laboratory's management system shall be against Option A requirements.

If the laboratory has adopted Option B	Evidence
1) evidence the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA). 2) evidence that the CB's accreditation covers ISO/IEC 17021-3 i.e. the CB can certify management systems to ISO 9001. 3) copies of the most recent certification audit report(s) issued by the CB covering the laboratory's management system in full. 4) confirmation from the CB of the close out of any non-conformities raised during certification audits. 5) evidence the certification of the management system covers the laboratory activities covered by its NATA scope of accreditation. 6) supports the facility fulfilling consistently the requirements of ISO/IEC 17025 to assure the quality of results.	