Draft FAO Laboratory Internal Audit Tool for Testing Laboratories compliant with ISO/IEC 17025:2005 *Version 1.3 September 2015*

Objective

The objective of this auditing tool is to enable organisations to assess their Quality Assurance performance against the requirements of operating an appropriate Quality Management System and the requirements of an appropriate international quality standard, such as EN ISO 9001:2015 or ISO/IEC 17025:2005

Scope

The auditing tool covers the requirements of operating an appropriate Quality Management System and the requirements of an appropriate international quality standard, such as EN ISO 9001:2015 or ISO/IEC 17025:2005. It does not cover the requirements of Environmental Management or Occupational Health and Safety Management (such as ISO 14001:2015 or BS OHSAS 18001:2007).

For which laboratories

The auditing tool is applicable to every size and type of organisation which provide a laboratory testing service. Although aimed at feed analysis laboratories the principle would apply to any type of testing and/or calibration laboratory. It may also be useful for laboratories seeking accreditation to ISO 15189:2012 (Medical Laboratories – Requirements for quality and competence).

Who should perform the auditing

It should be completed by those familiar with the requirements of a Quality Management System and the appropriate standard.

Further information on the implementation of a Quality Management System is available in FAO Document 14 (http://www.fao.org/docrep/014/i2441e/i2441e00.pdf) and FAO Document 15 (http://www.fao.org/3/i3535e.pdf).

What information does it provide

The auditing tool will provide an assessment of how well an organisation has its procedures under control and identify those operations which would benefit from improvement and review.

Structure of the tool

The auditing tool consists of four parts (1A – Laboratory Infrastructure, 1B – Technical Performance, 1C - Organisation and Quality Assurance Requirements and 2 – Requirements of ISO/IEC 17025:2005), each of which includes a series of questions which produce a numerical score. The parts should be attempted in order and a total score reviewed once each part is complete. Each part may be repeated as many times as is appropriate. Only when a suitable score is attained should the organisation move onto completing the next part.

Unless indicated as 'N/A' (not applicable), scores of zero or less indicate opportunities for improvement. These should be addressed by identifying appropriate Corrective and Preventive Actions (CAPA).

Where a question has a number in the 'score weight' column, the score that you give should be multiplied by this figure to achieve the total score (e.g. a score of '1' with a score weight of '3' = 1 x 3). Some score weighs may be negative numbers and therefore produce negative scores. The total score for each part is achieved by adding all weighted scores together for that part of the audit.

The laboratory should calculate its total score for each part (the total score, including items that are regarded as N/A as indicated in the fourth column). However the laboratory should be careful identifying issues as N/A, especially in part 2 sections 4.2 – 4.15 and part 2 sections 5.1 – 5.10.

The questions in Part 1A are general questions relating to the infrastructure of the laboratory and its support facilities.

Part 1B refers to the technical requirements of the laboratory.
Part 1C refers to organisational requirements.
Part 2 refers to the specific requirements of ISO/IEC 17025:2005.

Key: N/A – not applicable N/K – not known Shaded areas are to be ignored (or no score weight to be applied; in other words the score weight is 1).

Definitions

Quality Policy/Statement and Quality Manual
Source: ISO/IEC 17025:2005 4.2.2
The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:
a) the laboratory management's commitment to good professional practice and to the quality of its testing provided to its customers;
b) the management's statement of the laboratory's standard of service;
c) the purpose of the management system related to quality;
d) a requirement that all personnel concerned with testing within the laboratory familiarise themselves with the quality documentation and implement the policies and procedures in their work;
and
e) the laboratory management's commitment to comply with ISO/IEC 17025:2005 and to continually improve the effectiveness of the management system.

Document Control
Source: ISO/IEC 17025:2005 4.3.1

The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as

regulations, standards, other normative documents, test methods, as well as drawings, software, specifications, instructions and manuals.

In this context 'document' could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans etc. These may be on various media, whether hard copy or electronic, and may be digital, analog, photographic or written.

Part 1A Laboratory infrastructure

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Building & Location							
Is the laboratory isolated from residential areas and in its own private site with limited access?							
Is there restricted access to the laboratory with appropriate security in place to prevent unauthorised access to hazardous areas and confidential material?						2	
Is there good access to transport links and easy access for clients and suppliers (e.g. public transport links nearby and good road/highway access)?						2	
Is the laboratory financially secure with guaranteed funding?						2	
Is there a constant, stable electrical supply guaranteed?						3	
Is there a backup system for electrical supply?						3	
Is there a constant supply of clean water?						3	
If required, is there an adequate supply of purified/distilled/deionised water available?						3	
Is there reliable communication links (e.g. telephone line)?						2	
Is there a reliable internet/broadband connection?						2	
To keep up competency, is there access to appropriate current scientific journals and references for scientific personnel?							
Design, facilities & safety							
Is there sufficient space within the laboratory facility to perform functions safely and without the risk of contamination? (e.g. separating procedures that may pose a risk of contamination or interference with one another. This separation may be physical or by performing the procedures at different times, with suitable decontamination between).						2	
Is the building well maintained, clean, safe and in a good state of repair?						2	
Is there an adequate storage facilities at the laboratory (e.g. cold stores, separation of clean and contaminated material, sufficient consumables)?						2	
Is there adequate heating or cooling in the laboratory to maintain a suitable working environment for both testing and laboratory personnel?						2	
Are there suitable rest areas for personnel within the laboratory building or adjacent?						2	
Are there changing areas/showers/toilets in the laboratory?						2	
Is there suitable lighting in the laboratory?						2	
Is there suitable ventilation in the laboratory?						3	
Are there first aid kits and trained first aid personnel at the laboratory?						3	
Are there fire extinguishers and a fire alarm at the laboratory?						3	
Is there adequate waste disposal facilities?						3	

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Is hazardous waste disposed of appropriately (i.e. biohazard waste sterilised before release and chemicals disposed of in compliance with legislation)?						3	
Is the reliability of critical equipment ensured by servicing/maintenance plans?							
Are any hazardous chemicals or reagents stored appropriately? (e.g. in locked cabinets with Material Safety Data Sheet (MSDS) available).						3	
Are any vehicles used by the laboratory in good working order, reliable and serviced?							
Is there an evacuation plan in case of emergency?						3	
Is there a direct connection (e.g. telephone link and suitable contact person) to the local authorities and emergency services?						3	
Is the laboratory cleaned/disinfected at the end of the working day and before procedures?						2	
Total (Possible score 66)							

The total possible (maximum) score for Part 1A is 66. The score for Part 1A is …….(*laboratory to complete)*

To demonstrate that the laboratory is competent to conduct analytical work, a score of at least 85% (56) should be achieved. After achieving the minimum requirement for Part 1A, the laboratory may progress onto Part 1B.

Part 1B Technical performance

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Personnel							
Are there sufficient staff to perform the analysis?							
Are the staff engaged in analysis suitable trained, experienced and qualified?						3	
Equipment							
Is sufficient equipment available to perform the methods according to an international standard (e.g. ISO/IEC 17025:2005 or ISO 9001:2015)?						3	
Is all the equipment required by the laboratory available and fit for purpose?						3	
Is equipment located at a suitable place without negative interference (e.g. fridges located away from excessive heat sources or balances away from excessive vibration)?						2	
Are procedures available to control and maintain the functioning of critical laboratory equipment (e.g. daily monitoring of temperatures of temperature sensitive equipment, balance check weights for balances etc)?						3	
Are maintenance/calibration records available and up to date for all critical equipment?						4	

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Methods							
Are procedures and methodologies clearly described and available for laboratory staff?						3	
Are methods based on international accepted guidelines? (It is a requirement of ISO standards that methods must be based on internationally accepted guidelines or recognised methods. If this is not the case the method used must be suitably validated).						4	
Is the performance of the methods sufficiently validated?						2	
Is the measurement uncertainty calculated? (further information on Measurement Uncertainty can be found in Eurachem/CITAC guide or on the UKAS website).							
Do methods include quality controls (e.g. confirmation that the procedure is working as required by using reference material/blanks as positive and negative controls)?						2	
Is an inter-lab comparison of the results from other laboratories performed?							
Chemicals & consumables							
Do chemicals and reagents have a specific purity required to conduct the test, and if so are chemicals and reagents which meet this requirement available?						5	
Are solutions appropriately labelled and stored (e.g. expiry, hazard information etc)?						3	
Are calibration solutions traceable (e.g. buffers traceable to a known standard or purity)?							
Are consumables stored as required by the manufacturer?						4	
Are consumables all in date?						4	
Operational quality control & registration							
Is all raw data recorded?						3	
Is a control sample or known standard utilised to ensure the performance of the analytical work meets the agreed requirements (i.e. the first line of control)?						5	
Are the results of control samples or standards reviewed by a technically competent person for consistency between operators and test runs, and to monitor any ‘drift’? If possible consistency between laboratories may also be checked.						3	
Are the results of control samples or standards recorded and periodically evaluated to identify any requirements for further validation or competency training?						2	
Are blind samples analysed by the laboratory?							
Does the laboratory participate in collaborative studies? (e.g. a study involving more than one laboratory but using identical methods and which forms part of a large research project or clinical trial).							
Are results reviewed by a competent person before reporting? (e.g. a member of staff who is trained, competent and conversant with the methods used and the significance of the results obtained).						3	
Are results discarded if there is a batch QC failure of any reagents used in analysis?						3	
Are results discarded if there is a QA failure within a batch of tests?						4	

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Does the laboratory participate in any External Quality Assurance (EQA)/Ring Trial scheme? (e.g. External Proficiency Scheme).						4	
Total (Possible score 78)							

The total possible score for Part 1B is 78. The score for Part 1B is …….(*laboratory to complete).*

To demonstrate that the laboratory is capable of performing accurate and traceable analytical work, a minimum score of 80% is required (i.e. 62).A laboratory which is accredited to ISO 17025:2005, or is working towards accreditation, should aim to achieve a score of 95% (i.e. 74).

After achieving the minimum requirement for Part 1B the laboratory may progress onto Part 1C.

Part 1C Organisational and Quality Assurance (QA) requirements

Requirement	Yes (1)	No (0)	N/A (0)	N/K (0)	Comment	Score weight	Total score
Organisation							
Is there an organisation chart demonstrating line management and responsibilities?						2	
Does the laboratory have an independent position within the organisation to avoid improper influence?						5	
Does the laboratory have a clear legislated form which is recorded as an official business?						3	
Is there commitment for the top management to support the quality system?						4	
Is the organisational chart up to date?						2	
Are the correct job titles used?						2	
Do all staff have a current job description; demonstrating line management and duties?						3	
Are there nominated deputies for all senior positions (e.g. Laboratory Manager, Quality Assurance Manager, Health & Safety Manager etc)?						3	
Is there evidence that staff have read the Quality Manual (e.g. a 'read and understand' log or signatures on the document)?						3	
Is there evidence that staff have read the appropriate SOPs pertaining to their area (e.g. a 'read and understand' log or signatures on the SOPs)?						5	
Quality assurance (QA)							
Is there an independent QA officer or a section/team within the organisation?						5	
Are QA officers sufficient trained? (e.g. trained auditors to ISO/IEC 17025:2005 or ISO 9001:2015, registered with IRCA or members/fellows of CQI)						3	

Requirement	**Yes (1)**	**No (0)**	**N/A (0)**	**N/K (0)**	**Comment**	**Score weight**	**Total score**
Is an overview of SOPs available? (e.g. a list of all SOPs with a brief description of their purpose and scope. This could be included in the Quality Manual)						2	
Are all SOPs current (i.e. no out of date or obsolete SOPs)?						5	
Are there any uncontrolled copies of SOPs in use? (e.g. copies of SOPs or official documents rather than those issued (and recorded as issued) by the Quality Manager or Laboratory Management).						- 5	
Are all SOPs available at their point of use?						3	
Is there a record of issue of controlled copies of SOPs?						3	
Are appropriate review dates assigned to controlled documents? (A suitable review date should be assigned to all controlled documents. This can be between one and three years based on guidance from appropriate technically competent staff).						2	
Is all work done 'in house' (i.e. not subcontracted)?						1	
If subcontractors are used for some work, do they operate to a similar QA standard as the laboratory?						3	
If subcontractors are used are customers made aware of this?						3	
If subcontractors are used is there a current list of approved subcontractors?						3	
Are there maintenance contracts in place for critical equipment (e.g. autoclaves, microscopes, analysers, centrifuges etc)?						3	
Is there a current list of approved service providers/agents? (e.g. suitably trained/ certified providers of service, repair and/or calibration for laboratory equipment)						3	
Are internal laboratory procedures controlled during audits? (i.e. procedures in support of testing or calibration processes conducted by the laboratory e.g. training, method validation, document control etc).						4	
Is a customer satisfaction survey performed regularly (e.g. annual survey, post project questionnaire or repeat business)?						3	
Have there been any valid customer complaints?						- 5	
If there have been complaints, has the laboratory failed any EQA or IQA (Ring Trial) distributions in the past year?						- 5	
If there have been any failures, is there an effective procedure to deal with these (e.g. internal anomalies procedure identifying appropriate Corrective and Preventive Actions (CAPA))?						3	
Are laboratory records maintained (i.e. workbooks/worksheets/laboratory logs)?						4	
Are laboratory records legible and written in permanent ink?						3	
Is there an audit trail on records to identify all the operators that have been involved?						3	
Do laboratory records contain any uncontrolled corrections (e.g. correction fluid, scribbled out or obliterated notes)?						- 4	
Are laboratory records held securely and confidentially (e.g. locked in secure cabinets or rooms and not accessible to the public)?						3	
Are laboratory records disposed of in a secure and confidential manner (e.g. shredded						3	

before disposal)?							
Requirement	**Yes (1)**	**No (0)**	**N/A (0)**	**N/K (0)**	**Comment**	**Score weight**	**Total score**
Do laboratory reports clearly indicate the testing performed?						4	
In laboratory reports are the customer details displayed correctly?						2	
Are laboratory reports authorised before issue?						2	
If any subcontracted testing has been performed, is this highlighted?						3	
If the laboratory report exceeds one page are pages paginated (i.e. 'page 2 of 3')?						2	
Does the laboratory have an internal audit schedule?						5	
Does the internal audit schedule cover all aspects of testing?						5	
Is the internal audit schedule up to date?						5	
Are any non-conformances, identified during internal audits, recorded appropriately?						5	
If there have been non-conformances noted from internal audits, have these had appropriate corrective and preventive actions (CAPA) assigned and actioned?						5	
If there has been non-conformances noted from internal audits, has an impact assessment been conducted to identify if any testing was affected previously?						5	
If yes to the above have any results been retested or traceability evaluated?						5	
If results are subject to repeated testing, are the results obtained consistent between test runs?						1	
If results have changed significantly since reporting, have customers been notified and results recalled?						5	
Does the laboratory conduct regular internal QC on all reagents (e.g. periodic checking that reagents are/remain fit for purpose by use of positive/negative controls)?						4	
Does the laboratory conduct internal QA on every procedure (e.g. periodic checking that the procedure is fit for purpose by use of external proficiency schemes or ring trials)?						4	
Does the laboratory monitor ongoing staff competence?						4	
If staff competence is monitored, is there a procedure to address failures?						4	
Is there a staff training matrix? (i.e. a schedule of competencies to be achieved, or evaluated, to confirm a member of staff is competent to perform testing unsupervised).						3	
Total (Possible score 170)							

The total possible score for Part 1A is 170*.* The score for Part 1A is …….(*laboratory to complete).*

To demonstrate that the laboratory has the basic requirement to set up a Quality System compliant with ISO/IEC 17025:2005, a score of at least 70% (i.e. 119) should be achieved, but only if corrective and preventive actions are implemented and documented to address any scores of <1.

*The maximum possible score may be less than 170 if the laboratory has answered a questions as 'N/A'.

After achieving the minimum requirement for Part 1C, the laboratory may progress onto Part 2.

Part 2

The following questions may be answered in order and correspond to the sections of ISO/IEC 17025:2005. Each question should be scored accordingly and multiplied by the 'score weight' if appropriate to achieve the final score.
In part 2 the questions are divided into two groups. Some questions may be answered with yes (to obtain the full score) or with no (no score) (third column). In some questions the score is dependent on the level of development and implementation, and is scored on a scale of 0 – 5 (fourth column). In such question the box which is required to be completed is blank.

For this purpose, the following scale should be used:

0	No procedure currently available
1	Draft version procedure available
2	Authorised version of procedure available
3	Procedure implemented and operational
4	Evaluation of procedure is available (by audit)
5	The procedure is fully implemented and meets the requirements of the Quality Management System and ISO/IEC 17025:2005

Note: No input is required for the shaded cells.

The total score is obtained by multiplying by the score weight. For example, a score of 3 and a score weight of 4 leads to a total score of 12.

For each question the required scoring is indicated in the table.

Each set of questions may be completed separately, or as a whole to cover all aspects of the standard, and need not be done in the order they appear.

Section 1 of ISO/IEC 17025:2005 refers to the Scope of the standard and therefore there are no questions for this section.

Section 2 of ISO/IEC 17025:2005 refers to the Normative References of the standard and therefore there are no questions for this section.

Section 3 of ISO/IEC 17025:2005 refers to the Terms and Definitions of the standard and therefore there are no questions for this section.

Section 4 of ISO/IEC 17025:2005 refers to **Management Requirements**

To demonstrate compliance a laboratory should aim to achieve a minimum score of 60% for each part of section 4. Proceeding to the next part of section 4 should only be attempted once corrective and preventive actions are implemented and documented to address any scores of <3.

4.1 Organisation

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.1.1	Is the laboratory a legally identifiable entity?						20	
4.1.2	Would the laboratory be confident that its testing would meet the requirements of ISO/IEC 17025:2005 and is it prepared to allow customers and regulators to perform audits of its facilities and procedures to confirm this?						10	
4.1.3	Does the management system cover all the operating locations at which testing occurs?						15	
4.1.4	If any staff involved in testing are also involved in other activities within the organization, are there any conflicts of interest?						–20	
4.1.5 a	Does the laboratory have a responsible person to manage and improve the QMS with adequate time and resources available (i.e. a Quality Manager)?						20	
4.1.5 b	Are personnel free from pressure and influences which may adversely affect the quality of their work (e.g. excessive hours, additional jobs etc)?						15	
4.1.5 c	Is there a policy or procedure for protecting customer confidentiality?						3	
4.1.5 d	Is there a policy or procedure guiding personnel on avoiding activities which reduce customer confidence in its activities?						1	
4.1.5 e	Is there an up to date organizational chart demonstrating the structure of the organization and its personnel?						2	
4.1.5 f	Do all personnel involved in the QMS have an up to date job description?						2	
4.1.5 g	Is there adequate supervision of personnel (including trainees) by competent persons?						4	
4.1.5 h	Is there an appointed manager (e.g. Laboratory Manager) with responsibility for the required resources of the laboratory?						20	
4.1.5 i	Is there a Quality Manager appointed with adequate resources and authority to perform their function?						20	
4.1.5 j	Are there suitable trained deputies identified for all key personnel?						3	
4.1.5 k	Are personnel aware of how their role contributes to the QMS?						3	
4.1.6	Is there effective communication in place regarding the QMS, which involves top management?						3	
	Total (Possible score - 205)							

4.2 Management System (Quality Policy, Quality Manual and policies and procedures)

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.2.1	Are there documented policies and procedures (i.e. Quality Manual, SOPs) relevant to the testing activities of the laboratory?						4	
	Do these policies and procedures cover all aspects of testing activities?						4	
	Are personnel aware of, and familiar with, these policies and procedures?						4	
	Are policies and procedures available at the point of use (e.g. in the laboratory in which the procedure is performed)?						4	
4.2.2	Is there a Quality Policy, issued under the authority of top management, included in the QMS?						4	
4.2.2 a	Does this include top management's commitment to good professional practice and the quality of the testing provided to customers?						20	
4.2.2 b	Does this include a statement of the laboratory's standard of service?						20	
4.2.2 c	Does it state the purpose of the QMS in relation to quality?						20	
4.2.2 d	Does it state that personnel involved in testing must be familiar with the QMS policies and procedures and ensure that they are implemented?						20	
4.2.2 e	Is there a commitment by top management to comply with ISO/IEC 17025:2005 and continually improve the QMS?						20	
4.2.3	Is there evidence of the commitment of top management to development and implementation of the QMS and its continual improvement?						4	
4.2.4	Is there evidence that top management communicate the importance of meeting customer's statutory and regulatory requirements?						4	
4.2.5	Does the Quality Manual make reference to policies and procedures and outline the structure of the QMS?						20	
4.2.6	Does the Quality Manual define the roles and responsibilities of the Technical Manager(s) and Quality Manager?						20	
4.2.7	Is there an effective change control procedure in place to protect the integrity of the QMS when changes or improvements are required?						4	
	Total (Possible score - 284)							

4.3 Document Control

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.3.1	Is there an effective document control system in place?						5	
4.3.2.1	Prior to issue, and use, are quality documents reviewed/approved? Is there a master list of all quality documents available?						5	
4.3.2.2 a	Are quality documents available at their point of use?						3	
4.3.2.2 b	Are quality documents periodically reviewed for continued suitability?						4	
4.3.2.2 c	Are invalid and obsolete quality documents removed from use?						4	
4.3.2.2 d	Are obsolete documents, which are retained, identified as such?						3	
4.3.2.3	Are quality documents uniquely identified (with issue dates, review dates, page numbering, pagination and authorisation)?						4	
4.3.3.1	Are any changes to quality documents authorised and approved?						3	
4.3.3.2	Are changes identified on revised quality documents?						10	
4.3.3.3	Are hand amendments of controlled documents permitted? If so are they clearly identified and revised documents issued promptly?						5	
4.3.3.4	If computerised documents exist are changes described and controlled?						3	
	Total (Possible score 185)							

4.4 Review of requests, tenders and contracts

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.4.1	Does the laboratory review customer requests, tenders and contracts?						5	
4.4.1 a	Is the method for the review defined, documented and understood?						3	
4.4.1 b	Is the laboratory able to meet the documented requirements?						25	
4.4.1 c	Are the test methods used appropriate to customer requirements?						25	
4.4.2	Are records of reviews, significant changes and discussions regarding testing requirements with customers maintained?						3	
4.4.3	Do reviews of work undertaken include subcontracted work?						15	
4.4.4	If deviations from contracts occur are customers informed?						3	
4.4.5	If a contract is amended after it has started, is the contract review process repeated and amendments communicated to all concerned?						3	
	Total (Possible score 150)							

4.5 Subcontracting of tests and calibrations

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.5.1	If work is subcontracted is it to a competent subcontractor (i.e. a subcontractor that holds accreditation to ISO/IEC 17025:2005)?						20	
4.5.2	If subcontracting of tests occurs, are customers informed in writing and their approval sought?						3	
4.5.3	Does the laboratory accept responsibility for the subcontractor's work?						20	
4.5.4	Is there a list of subcontractors used and evidence of their compliance with ISO/IEC 17025:2005?						20	
	Total (Possible score 75)							

4.6 Purchasing services and supplies

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.6.1	Is there a procedure to evaluate suppliers and service agents for suitability where the service or supply may affect laboratory testing?						4	
	Is there a procedure in place for purchasing of reagents and laboratory consumables relevant to testing?						3	
	Is there a procedure in place for the reception of reagents and laboratory consumables relevant to testing?						2	
	Is there a procedure in place for appropriate storage of reagents and laboratory consumables relevant to testing?						3	
4.6.2	Are supplies and reagents checked to ensure they comply with test specifications and requirements?						3	
	Are the checks specified at 4.6.2 documented?						2	
4.6.3	Do purchasing documents for items which may affect the quality of tests describe the exact requirements (e.g. type, class, grade etc)?						2	
4.6.4	Are suppliers of consumables, supplies and services which may affect tests evaluated before being utilised?						2	
	Total (Possible score 105)							

4.7 Service to the customer

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.7.1 a	Does the laboratory permit access to relevant areas of the laboratory to allow customers, or their representatives, to witness testing?						15	
4.7.1 b	Does the laboratory permit access to preparation, packaging and dispatch of test items, if required by the customer?						15	
4.7.2	Does the laboratory seek feedback from customers on the service provided and if so is this analysed and used to improve the service?						4	
	Total (Possible score 50)							

4.8 Complaints

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.8	Does the laboratory have a complaints procedure to record complaints received from customers?						5	
	Are records of complaints retained?						15	
	Are complaints investigated and corrective actions implemented if necessary?						20	
	Total (Possible score 60)							

4.9 Control of nonconforming testing and/or calibration work

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.9.1	Does the laboratory have a policy for dealing with testing which does not conform to its procedures or requirements agreed with the customer?						5	
4.9.1 a	Are responsibilities and actions to be taken when non-conforming work is identified clearly defined?						4	
4.9.1 b	Is an impact assessment performed on the significance of any non-conforming work identified?						3	
4.9.1 c	Is corrective action taken immediately on identifying non-conforming work and its acceptance, if appropriate?						4	
4.9.1 d	Are customers notified and work recalled when non-conforming work is identified?						15	
4.9.1 e	If work is suspended, is the person responsible for authorising resumption of work defined?						15	

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.9.2	If there is the possibility of non-conforming work recurring, or doubt regarding compliance with procedures, is the corrective action procedure followed? (see 4.11.1)						4	
	Total (Possible score 130)							

4.10 Improvement

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.10	Does the laboratory use corrective and preventive actions, findings, audit results, analysis of quality data and review to improve the Quality Management System?						5	
	Total (Possible score 25)							

4.11 Corrective action

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.11.1	Does the laboratory have a policy for implementing corrective actions when non-conforming work or departures from procedures (or potential issues) are identified?						5	
4.11.2	Does the above procedure require an investigation to establish the root cause(s) of the non-conforming work?						15	
4.11.3	If corrective action is required, is the action which is most likely to eliminate the problem and prevent recurrence selected?						20	
	If corrective actions are implemented are these documented in the Quality Management System?						15	
4.11.4	If corrective actions are implemented are the results of these actions monitored to establish effectiveness?						3	
4.11.5	If there is doubt regarding compliance after identification of a non-conformance, are additional internal audits conducted?						3	
	Total (Possible score 105)							

4.12 Preventive action

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.12.1	Are potential sources of non-conformance and opportunities for improvement identified and action plans implemented and monitored to reduce occurrence?						5	
4.12.2	Do preventive action procedures include initiation of action and applying controls to monitor their effectiveness?						20	
	Total (Possible score 45)							

4.13 Control of records

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.13.1.1	Does the laboratory have procedures for the control of records (including audit reports, management review, records of corrective and preventive actions)?						5	
	Does this procedure include identification of records?						20	
	Does this procedure include collection of records?						20	
	Does this procedure include indexing of records?						15	
	Does this procedure include access to records?						15	
	Does this procedure include filing of records?						15	
	Does this procedure include storage of records?						15	
	Does this procedure include maintenance of records?						15	
	Does this procedure include disposal of records?						15	
4.13.1.2	Are records retained and stored to prevent deterioration & loss?						4	
4.13.1.3	Are records held securely and in confidence?						2	
4.13.1.4	If electronic records are held, are these backed up and is access controlled?						2	
4.13.2.1	Do technical records contain all data sufficient to identify all factors involved in testing (i.e. operators, batch numbers, controls, calibration data etc)?						4	
4.13.2.2	Are all observations recorded on technical records made at the time (i.e. not added to records at a later stage)?						2	
4.13.2.3	Are corrections to data on technical records controlled (i.e. crossed out, initialled and dated by the operator)?						2	
	Total (Possible score 227)							

4.14 Internal audits

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.14.1	Is there an annual internal audit schedule which addresses all areas of testing within one year?						5	
	Are internal audits planned and organised by the Quality Assurance Manager?						15	
	Are internal auditors trained, qualified and independent of the area which is subject to audit?						15	
4.14.2	If audit findings cast doubt on the effectiveness or validity of results does the laboratory take immediate corrective action?						5	
	Are customers notified immediately if findings suggest results may have been affected?						15	
4.14.3	Are audits and any findings and corrective actions recorded?						15	
4.14.4	Are corrective actions implemented later reviewed for effectiveness?						3	
	Total (Possible score 125)							

4.15 Management reviews

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
4.15.1	Do the laboratory's top management periodically (e.g. annually) review the Quality Management System for effectiveness, its continued fitness for purpose and identify any improvements?						5	
4.15.2	Are action plans prepared from the management review with appropriate timescales?						3	
	Total (Possible score 40)							

Section 5 Technical requirements

To demonstrate compliance a laboratory should aim to achieve a minimum score of 70% for each part of section 5 (after correction for not applicable (N/A)), but only if corrective and preventive actions (CAPA) are implemented and documented to address any scores of <3.
For part 5.1 and 5.9, which are crucial element of the operational quality system, a minimum score of 80 % is required, but only if corrective and preventive actions are implemented and documented to address any scores of <3.

5.1 General

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.1.1	Does the laboratory acknowledge the influence of various factors in the reliability of tests (measurement uncertainty)?						25	
5.1.2	Does the laboratory take account of the influences above in developing methods, staff training and equipment selection and calibration?						20	
	Total (Possible score 45)							

5.2 Personnel

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.2.1	Are all staff involved in testing, operating critical equipment, evaluating, signing and reporting results competent?						25	
	If laboratory staff are undergoing training are they supervised by suitably competent staff?						3	
	If any laboratory staff are required to express opinions and interpretation on test results, do they have knowledge and understanding of the use, requirements and significance of deviations and use of test results by customers?						3	
5.2.2	Are education, training and skills required by laboratory staff defined by management (i.e. in a job description)?						20	
	Does the laboratory review training needs and provide appropriate training to staff when identified?						3	
	Is training provided to staff appropriate, relevant and reviewed for effectiveness?						3	
5.2.3	Are all staff employed or under contract to the laboratory?						20	
	If contracted or additional staff are used are they competent and supervised at all times to ensure compliance with procedures?						3	

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.2.4	Are job descriptions maintained for all key staff in the laboratory?						15	
5.2.5	Is training and authorisation to perform specific key tasks documented within training files?						2	
	Total (Possible score 165)							

5.3 Accommodation and environment

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.3.1	Are facilities and accommodation suitable for the testing being undertaken by the laboratory, without having an affect on tests?						25	
	Are requirements for facilities and accommodation documented?						15	
	Do the requirements above apply to any sites other than the permanent laboratory?						10	
5.3.2	Are environmental conditions that may affect testing monitored and recorded, and is testing halted if necessary?						3	
5.3.3	Are incompatible procedures separated (by space or time)?						20	
5.3.4	Is access determined and controlled to testing areas?						3	
5.3.5	Are there procedures in place to ensure good housekeeping?						3	
	Total (Possible score 115)							

5.4 Test and calibration methods and method validation

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.4.1	Does the laboratory use appropriate procedures for all aspects of sample processing (e.g. sampling, handling, storage and preparation) including measurement uncertainty and statistical analysis of data, if appropriate?						5	
	Are instructions readily available for all aspects of testing procedures, including the use of equipment?						4	
5.4.2	Are only current, recognised and validated methods (which meet the requirements of the customer) used by the laboratory?						15	
5.4.3	If laboratory developed methods are to be used are these planned and undertaken by competent, trained staff?						20	
5.4.4	If non standard tests are used, are these agreed with the customer, and do they include the customers' requirements?						15	

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.4.5.1	Are non standard methods validated before use?						20	
5.4.5.2	Is validation conducted on laboratory designed/developed methods, standard methods used out with their intended scope and amplifications or modifications of standard methods?						4	
	Are results and data from validation exercises documented and is a statement made regarding whether a method is fit for purpose?						3	
5.4.5.3	Is the range and accuracy of validated methods appropriate to the customers' needs and expectations?						3	
5.4.6.1	If the laboratory performs calibrations, is there a procedure to estimate the uncertainty of measurement for these calibrations?						3	
5.4.6.2	Does the laboratory identify the contributing factors of uncertainty and make a reasonable estimation of these and ensure reported results take account of this?						3	
5.4.6.3	When estimating uncertainty does the laboratory consider all relevant components and use appropriate methods of analysis?						3	
5.4.7.1	Are any calculations and data transfers used in testing periodically checked to ensure they are fit for purpose?						4	
5.4.7.2 a	Are any laboratory derived software systems validated and confirmed as fit for purpose before use?						3	
5.4.7.2 b	Are procedures in place to protect the security, confidentiality and integrity of electronic data?						3	
5.4.7.2 c	Are computer systems maintained appropriately to ensure correct functioning and integrity of data?						3	
	Total (Possible score 275)							

5.5 Equipment (This refers to 'critical' equipment i.e. equipment which is essential to the analysis; the accuracy of which may have an impact on the outcome of testing)

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.5.1	Is the laboratory equipped with all equipment required to perform testing as required by its procedures and customer requirements?						25	
	If any equipment which is outside the control of the laboratory is used in performing tests, are the requirements of ISO/IEC 17025:2005 still met?						20	
5.5.2	Is all equipment in use fit for purpose?						20	

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
	If equipment can have an affect on test results, is it calibrated before being put into service and before use?						5	
5.5.3	Are user instructions or guides available for all equipment and are only authorised operators permitted to use such equipment?						3	
5.5.4	Are all items of critical equipment (and any critical software) uniquely identified?						15	
5.5.5 a	Do maintenance records exist which state the identity of each item of equipment?						15	
5.5.5 b	Do maintenance records exist which state the manufacturer's name, type and serial number of each item of equipment?						15	
5.5.5 c	Do maintenance records exist which state that the equipment complies with specification, for each item of equipment?						15	
5.5.5 d	Do maintenance records exist which state the location of each item of equipment?						15	
5.5.5 e	Do maintenance records exist which include manufacturer's instructions (or their location) for each item of equipment?						10	
5.5.5 f	Do maintenance records exist which include calibration data and date of the next calibration, for each item of equipment?						15	
5.5.5 g	Do maintenance records exist which include the maintenance plan of each item of equipment?						10	
5.5.5 h	Do maintenance records exist which detail any damage, malfunction, modification or repair for each item of equipment?						10	
5.5.6	Do procedures exist for handling, transport, storage and maintenance of all measuring equipment?						2	
5.5.7	If an item of equipment is outside of specified limits is it taken out of service immediately and identified as such to prevent use?						3	
	Is an impact assessment performed on testing reported prior to identification of equipment being outside specified limits?						2	
5.5.8	Does all equipment which is calibrated have an indication of the calibration status and due date for re-calibration?						10	
5.5.9	If equipment goes off site is it calibrated upon return?						2	
5.5.10	Is there a procedure for intermediate checks on equipment?						3	
5.5.11	If correction factors are required is there a procedure to ensure copies (e.g. in software) are correctly updated?						2	
5.5.12	Are equipment and software protected from adjustments which could affect test results?						2	
	Total (Possible score 315)							

5.6 Measurement traceability

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.6.1	Is all equipment that contributes to the accuracy of the measurement calibrated?						25	
5.6.2.2.1	Can the laboratory ensure that critical equipment provides the measurement uncertainty required?						2	
5.6.2.2.2	Are calibrations traceable to reference materials or standards?						4	
5.6.3.1	Are reference standards calibrated before use?						3	
5.6.3.2	Are reference materials traceable to SI-units or certified reference materials?						2	
5.6.3.3	Are procedures and schedules to control the quality of the standards available?						3	
5.6.3.4	Is the stability and quality of the standards guaranteed?						3	
	Total (Possible score 110)							

5.7 Sampling

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.7.1	Are procedure for sampling based on statistics available?						5	
5.7.2	Are deviation from the sampling protocol recorded and communicated?						4	
5.7.3	Is all relevant information regarding the sampling recorded e.g. procedure used (including statistical methods), operator, environmental conditions, diagrams etc.						4	
	Total (Possible score 65)							

Section 5.7 is only relevant if the laboratory is responsible for the sampling before the analytical work. Otherwise the laboratory should use a disclaimer to state that the results are only connected to the sample material received.

5.8 Samples / testing materials

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.8.1	Are procedures available for transport and storage of testing material that ensure their stability?						5	
5.8.2	Are procedures available regarding the unique identification of testing material that is used during the primary process?						4	
5.8.3	Is the testing material checked at receipt according to the specifications and are any deviations recorded and communicated with the client?						4	
5.8.4	Are procedures and facilities available to avoid a negative influence on the integrity of the testing material and ensure protected storage?						4	
	Total (Possible score 85)							

5.9 Assuring the quality of test and calibration results

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.9.1	Are procedures for quality control and the statistical evaluation of test results available?						5	
5.9.2	Is quality data reviewed and, if required, is corrective action undertaken to avoid reporting incorrect results?						5	
	Total (Possible score 50)							

5.10 Reporting the results

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.10.1	Do reports of results contain all relevant information?						5	
5.10.2 a	Do reports contain an appropriate title?						10	
5.10.2 b	Is the laboratory address, where the analytical work is conducted, included in reports?						10	
5.10.2 c	Do reports have a unique identification number?						15	
5.10.2 d	Do reports include the name and address of the client?						10	
5.10.2 e	Are the test methods used clearly described?						15	
5.10.2 f	Does the report contain a unique identification and description of the tested material?						15	
5.10.2 g	Does the report contain the date of receipt and if necessary the date of analytical testing?						10	

Clause	Requirement	Yes(1) No (0)	Score (0 –5)	N/A (0)	N/K (0)	Comment	Score weight	Total score
5.10.2 h	Do reports include a clear description of the sampling strategy, if this is conducted by the laboratory?						15	
5.10.2 i	Do reports state the units of the tests reported?						15	
5.10.2 j	Do reports contain the name and signature of the person authorising the report?						15	
5.10.2 k	Do reports contain a claim that the results are only connected to tested material?						10	
5.10.3.1 a	Are deviations regarding the performance of test reported?						15	
5.10.3.1 b	Is testing against specification mentioned?						10	
5.10.3.1 c	Does the report contain information about measurement uncertainty?						10	
5.10.3.1 d	Are opinions and interpretations included?						10	
5.10.3.1 e	Is additional information requested by the client included?						10	
5.10.3.2 a	Is the date of sampling stated in the report?						10	
5.10.3.2 b	Is an exact description of the material that was sampled stated in the report?						10	
5.10.3.2 c	Is the location, including any sampling plan, stated in the report, if necessary?						10	
5.10.3.2 d	Is there a reference to the sampling protocol stated?						10	
5.10.3.2 e	Are conditions during sampling that could influence the interpretation of results stated?						10	
5.10.3.2.f	Are standards or specifications for sampling and deviations or additions stated?						10	
5.10.5	Are interpretation and opinions clearly marked in the report?						10	
5.10.6	Is data obtained by outsourcing clearly indicated in the report?						10	
5.10.7	If electronic transfer of data is used does it conform to the requirements of ISO/IEC 17025:2005? (see 5.4.7)						10	
5.10.8	Is the design of the report fit for purpose and suitable for all data, without leading to confusion by the recipients?						10	
5.10.9	Are amendments distributed in an additional report that refers to the original report?						10	
	Total (Possible score 330)							