



COAL/COKE QUALITY CONFORMANCE PROGRAM™

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ASSESSOR CHECKLIST: GENERAL CRITERIA (ISO/IEC 17025)

The following pages present a **summary** of the criteria from ISO/IEC 17025-1999, which is the basis for the QAI General Requirements for Accreditation of Laboratories in a checklist format. **The laboratory's policies and procedures must meet the full requirements of ISO/IEC 17025. Laboratories and assessors must refer to the actual standard for the definitive language of the requirements.**

If the 17025 requirements include the need for a written policy, procedure or arrangement, that requirement statement in this checklist is shaded. Quality system documentation and supporting records must be available for the assessor's review.

The laboratory must complete the document reference identifiers in the checklist's second column (labeled Reference"), place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item and submit this checklist as part of the application for accreditation. This serves to help both the laboratory and the assessors prepare for the assessment and may save a significant amount of assessment time and cost. The appropriate "reference" can include quality manual, laboratory manual, SOPs, records, etc. references. The noted references should specify procedure number, page number and section number, if possible, where each checklist item is addressed.

Assessor Instructions: Review the laboratory's documented quality system to verify compliance with the applicable 17025 documentation requirements. Assess to verify that the documented quality system is indeed implemented as described. Record comments related to any requirement on the space provided. Assess the laboratory's technical competence to perform specific tests or specific types of tests. Record comments related to tests on separate sheets. All deficiencies must be identified and explained.

Laboratory Name: _____

Address: _____

City: _____ State: _____

Personnel Information (Names, Titles, and Responsibilities):

Technical Management: _____

Quality Manager: _____

Deputy Quality Manager: _____

Key Technical Staff and Their Unique Capability *: _____

* A "key technical staff person" is anyone whose absence or departure would remove the laboratory's competence to carry out one or more specific tests and result in a reduction in the Scope(s) of Accreditation.

QAI General Requirements for Accreditation of Laboratories Checklist

To the best of my knowledge, all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of the QAI General Requirements for Accreditation of Laboratories. Any areas of noncompliance have been fully described.

QAI Assessor Signature: _____

Date: _____

ISO 17025 Section	Requirement	Compliance			Facility Reference	Comments (Reserved for QAI Assessor)
		Y	N	NA		
4	MANAGEMENT REQUIREMENTS					
4.1	Organization					
4.1.1	The laboratory or the organization of which it is part is an entity that can be held legally responsible?					
4.1.2	Laboratory testing activities are performed in a manner to meet the requirements of ISO 17025 and to satisfy the needs of the client, regulatory authorities or organizations providing recognition?					
4.1.3	The laboratory management system covers work carried out in the laboratory's permanent facilities, sites away from its permanent facilities, or in associated temporary or mobile facilities?					
4.1.4	If the laboratory performs activities other than testing, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing activities defined in order to identify potential conflicts of interest?					
	If the laboratory is part of a larger organization, organizational arrangements are such that departments having conflicting interests do not adversely influence the laboratory's compliance with the requirements of ISO 17025?					
	The laboratory is able to demonstrate impartiality and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment?					
	The third-party laboratory does not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing activities?					
4.1.5	Laboratory requirements:					
	a) Has managerial and technical personnel with authority and resources needed to carryout duties, identify occurrences of departures from the quality system or testing procedures, and to initiate actions to prevent or minimize such departures?					
	b) Has arrangements to ensure management and personnel are free from undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?					

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	c) Has policies and procedures to ensure client's confidential information and proprietary rights, including electronic storage and transmission of results?					
	d) Has policies and procedures to avoid involvement in inappropriate activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?					
	e) Has defined organization and management structure of the laboratory, its position in any parent organization, and the relationships between quality management, technical operations and support services?					
	f) Has specified responsibility, authority and interrelationships of personnel who manage, perform or verify work affecting the quality of tests?					
	g) Provides adequate supervision of testing staff including trainees, by persons familiar with methods and procedures, test purposes, and with the assessment of the test results?					
	h) Has technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations?					
	i) Has a staff member as quality manager (however named) who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed?					
	j) The quality manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources?					
	k) Has deputies for key managerial personnel?(may have more than one function)					
4.2	Quality system					
4.2.1	Appropriate quality system:					
	Established, implemented and maintained quality system?					
	Documented policies, systems, programs, procedures and instructions to assure quality of the test results?					
	Documentation communicated to, understood by, available to, and implemented by appropriate personnel?					

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		Y	N	NA		
4.2.2	Quality manual documents and defines system policies and objectives?					
	Quality policy statement issued under the authority of the chief executive?					
	Quality policy statement contains the following:					
	a) Laboratory management's commitment to good professional practice and to the quality of its testing in servicing its clients?					
	b) Management's statement of the laboratory's standard of service?					
	c) Objectives of quality system?					
	d) Requirement that personnel concerned with testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work?					
	e) Laboratory management's commitment to compliance with ISO/IEC 17025?					
	The quality policy statement is concise and includes the requirements that tests shall always be performed in accordance with stated methods and client's requirements?					
	<i>Note: When the laboratory is part of a larger organization, some quality policy elements may be in other documents.</i>					
4.2.3	Quality manual includes or makes reference to supporting procedures, including technical procedures?					
	Quality manual outlines the structure of documentation used in the quality system?					
4.2.4	Quality manual defines roles and responsibilities of technical management and quality manager, including responsibility for ensuring compliance with ISO 17025?					
4.3	Document control					
4.3.1	General:					
	Procedures established and maintained to control all quality system documents (from internal or external sources)?					
	<i>Note: (regulations, standards, other normative documents, test methods, drawings, software, specifications, instructions, and manuals)</i>					
4.3.2	Document approval and issue:					
4.3.2.1	Quality system documents issued to laboratory personnel is reviewed and approved for use by authorized personnel prior to use?					
	Master list or an equivalent document control procedure identifying the current revision status and document distribution established?					

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4.3.2.2	Procedures adapted ensure that:					
	a) Authorized editions available at all essential locations?					
	b) Documents are periodically reviewed and revised where necessary to ensure continuing suitability and compliance with applicable requirements?					
	c) Invalid or obsolete documents promptly removed from all points of issue, or otherwise assured against unintended use?					
	d) Obsolete documents retained for legal or knowledge preservation purposes suitably marked?					
4.3.2.3	Quality documents uniquely identified:					
	Date of issue or revision identification?					
	Page numbering?					
	Total number of pages or a mark to signify the end of the document?					
	Issuing authority(ies)?					
4.3.3	Document changes:					
4.3.3.1	Document changes reviewed and approved by same function that performed the original review unless specifically designated otherwise?					
	Designated personnel have access to pertinent background information necessary to base review and approval?					
4.3.3.2	Altered or new text identified in the new document or appropriate attachments?					
4.3.3.3	Procedures and authorities for amendment of documents by hand, pending document reissue, defined?					
	Amendments clearly marked, initialed and dated?					
	Revised document formally reissued in timely fashion?					
4.3.3.4	Maintenance and control procedures established for changes in computerized document systems?					

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4.4	Review of requests, tenders and contracts					
4.4.1	Established and maintained procedures for review of requests, tenders and contracts?					
	Policies and procedures for reviews leading to a contract for testing ensures that:					
	a) Requirements, including methods to be used, are defined, documented and understood?					
	b) Capability and resources to meet requirements?					
	c) Appropriate test method selected and capable of meeting client's requirements?					
	Differences between request or tender and contract resolved before work commences?					
	Contract acceptable to both the laboratory and client?					
	The request, tender and contract review is conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects taken into account?					
	<i>Note: For internal clients, reviews of requests, tenders and contracts can be performed in a simplified way.</i>					
	Review of capability establishes that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question?					
	The review encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc?					
	<i>Note: A contract may be any written or oral agreement to provide a client with testing services.</i>					
4.4.2	Records of reviews, including significant changes, maintained?					
	Records of pertinent discussions with clients relating to client's requirements or results of work during contract period maintained?					
	<i>Note: For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing tasks, a more comprehensive record should be maintained.</i>					

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4.4.3	Review includes subcontracted work?					
4.4.4	Client notified of deviations from contract?					
4.4.5	Same contract review process repeated and any amendments communicated to all affected personnel if contract amended after work has commenced?					
4.5	Subcontracting of tests					
4.5.1	Competent subcontractor?					
	Complies with ISO 17025 for the work in question?					
4.5.2	Client notified in writing and received written approval of subcontractor?					
4.5.3	Laboratory responsible to client for subcontractor's work, except where the client or regulatory authority specified subcontractor?					
4.5.4	Register of subcontractors maintained?					
	Evidence of contractor's compliance with ISO 17025 for work in question?					
4.6	Purchasing services and supplies					
4.6.1	Laboratory has and maintains a policy and procedure(s) for selection and purchasing of services and supplies that affect the quality of tests?					
	Laboratory has and maintains procedures for verification of purchase, receipt and storage of reagents and laboratory consumable materials relevant for tests?					
4.6.2	Laboratory has and maintains procedures for verification that purchased supplies, reagents and consumables that affect the quality of tests are not used until inspected and verified as complying with defined test method requirements?					
	Records of actions taken to check compliance maintained?					
4.6.3	Purchasing documents for items affecting laboratory testing contains description of services and supplies ordered?					
	Purchasing documents are reviewed and approved for technical content prior to release?					
	<i>Note: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.</i>					

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4.6.4	Evaluates and maintains evaluation records of suppliers of critical consumables, supplies and services which affect quality of testing?					
	Maintains list of approved suppliers?					
4.7	Service to the client					
	Affords clients and their representatives cooperation to clarify client's requests?					
	Affords clients and their representatives cooperation to monitor laboratory's performance for client's work, provided that confidentiality to other clients is assured?					
4.8	Complaints					
	Laboratory has and maintains policies and procedures for resolution of complaints from clients?					
	Laboratory maintains records of complaints and of investigations and corrective actions?					
4.9	Control of nonconforming testing					
4.9.1	Laboratory has policies and implements procedures when any aspect of its testing, or the results of this work, do not conform to its own procedures or the agreed requirements of the client?					
	Policy and procedures ensure:					
	a) Responsibilities and authorities for management of nonconforming work are designated and actions defined (including halting of work and withholding of test reports, as necessary) when nonconforming work is identified?					
	b) Evaluates significance of nonconforming work?					
	c) Corrective actions taken immediately, with decision about the acceptability of the nonconforming work?					
	d) Client notified and work recalled where necessary?					
	e) Defined responsibility for authorizing the resumption of work?					
4.9.2	When the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the laboratory's corrective action procedures are promptly followed?					

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4.10	Corrective action					
4.10.1	General:					
	Laboratory has policy and procedure and designates authority for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified?					
4.10.2	Cause analysis:					
	Procedures start with investigation to determine root cause(s) of the problem?					
4.10.3	Selection and implementation of corrective actions:					
	Identifies potential corrective actions?					
	Selects and implements the action(s) most likely to eliminate problem and prevent recurrence?					
	Corrective actions appropriate to the magnitude and risk of the problem?					
	Corrective actions documented and changes implemented resulting from investigations?					
4.10.4	Monitoring of corrective actions:					
	Laboratory monitors corrective action results to ensure effectiveness?					
4.10.5	Additional audits:					
	Laboratory ensures that the appropriate areas of activity are audited in accordance with their internal audit plan as soon as possible, when the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with ISO 17025?					
4.11	Preventive action:					
4.11.1	Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, are identified?					
	Action plans developed, implemented and monitored to reduce the likelihood of the occurrence of nonconformances and to take advantage of the opportunities for improvement?					
4.11.2	Procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?					

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4.12	Control of records					
4.12.1	General:					
4.12.1.1	Laboratory has established and maintained procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?					
	Quality records include reports from internal audits and management reviews and records of corrective and preventive actions?					
4.12.1.2	Records legible and stored and readily retrieved?					
	Stored in suitable environment to prevent damage, deterioration and loss?					
	Policy and procedures for record retention times?					
4.12.1.3	Records maintained in a manner that affords security and confidentiality?					
4.12.1.4	Procedures to protect and back-up stored electronic records?					
	Procedures to prevent unauthorized access or amendment to records?					
4.12.2	Technical records:					
4.12.2.1	Laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued, for a defined period?					
	Records for each test contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original?					
	Records include the identity of personnel responsible for the sampling, performance of each test and checking of results?					
4.12.2.2	Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task?					
4.12.2.3	Errors are crossed out, not erased, made illegible or deleted, and the correct value entered alongside?					
	Alterations are signed or initialed by the person making the correction?					
	Equivalent measures are taken to avoid loss or change of original data for records stored electronically?					

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4.13	Internal audits					
4.13.1	Conducts periodic audits, in accordance with a predetermined schedule and procedure to verify that its operations continue to comply with the requirements of the quality system and ISO 17025?					
	Internal audits address all elements of the quality system, including the testing activities?					
	Quality manager plans and organizes the audits as required by the schedule and requested by management?					
	Audits are conducted by trained and qualified personnel who are independent of the activity to be audited, wherever resources permit?					
	The cycle for internal audits is completed in one year?					
4.13.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory takes timely corrective action, and notifies clients in writing if investigations show that the laboratory results may have been affected?					
4.13.3	Internal audit records contain the activity audited, the audit findings and corrective actions taken?					
4.13.4	Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?					
4.14	Management review					
4.14.1	The laboratory's executive management periodically conducts a review of the laboratory's quality system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?					
	Management review takes into account:					
	Suitability of policies and procedures?					
	Reports from managerial and supervisory personnel?					
	Outcome of recent internal audits?					
	Corrective and preventive actions?					
	Assessments by external bodies?					
	Results of interlaboratory comparisons or proficiency tests?					

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	Changes in the volume and type of the work?					
	Client feedback?					
	Complaints?					
	Other relevant factors?					
	Results are fed into the laboratory planning system and include goals, objectives and action plans for the coming year?					
	Management review includes consideration of related subjects at regular management meetings?					
4.14.2	Findings from management reviews and the actions that arise from them are recorded?					
	Management ensures that those actions are carried out within an appropriate and agreed timescale?					
5	TECHNICAL REQUIREMENTS					
5.1	General					
5.1.1	Contributions from factors determining the correctness and reliability of test results considered:					
	Human factors?					
	Accommodation and environmental factors?					
	Test methods and method validation?					
	Equipment?					
	Measurement traceability?					
	Sampling?					
	Handling of test items?					
5.1.2	The laboratory takes into account factors contributing to total uncertainty in developing test methods, training and qualification of personnel and selection and calibration of equipment used in testing?					

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5.2	Personnel					
5.2.1	Laboratory management ensures the competence of all staff that operates specific equipment, performs tests, evaluates results, and signs test reports?					
	Provides appropriate supervision for staff undergoing training?					
	Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?					
5.2.2	Laboratory management formulates goals for education, training and skills of laboratory personnel?					
	The laboratory has a policy and procedures, relevant to present and anticipated tasks, for identifying training needs and providing training of personnel?					
5.2.3	The laboratory uses personnel who are employed by, or under contract to, the laboratory?					
	Ensures contracted and additional technical and key support personnel are supervised and competent and that they work in accordance with the laboratory's quality system of contracted and additional personnel?					
5.2.4	The Laboratory maintains current job descriptions for managerial, technical and key support personnel involved in tests?					
	Responsibilities with respect to performing tests defined?					
	Responsibilities with respect to planning of tests and evaluation of results defined?					
	Responsibilities for reporting opinions and interpretations defined?					
	Responsibilities with respect to method modification and development and validation of new methods defined?					
5.2.5	Management authorization of specific personnel to perform particular types of sampling, tests, issue test reports, give opinions and interpretations, and to operate particular types of equipment?					
	Records maintained of relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel?					
	Information readily available and includes the date authorization and/or competence confirmed?					

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		Y	N	NA		
5.3	Accommodation and environmental conditions					
5.3.1	Laboratory facilities, including but not limited to energy sources, lighting and environmental conditions, are favorable to facilitate correct performance of the tests performed?					
	Ensures that environmental conditions do not invalidate test results or adversely affect the required quality of any measurement?					
	Technical requirements for accommodation and environmental conditions that can affect test results are documented?					
5.3.2	Laboratory monitors, controls and records environmental conditions as required by the relevant methods and procedures or where they may influence the quality of the results?					
	Tests are stopped when environmental conditions jeopardize test results?					
5.3.3	Effective separation between neighboring areas in which there are incompatible activities?					
	Measures taken to prevent cross contamination?					
5.3.4	Access to and use of areas that may affect the quality of test results controlled?					
5.3.5	Good housekeeping practiced and any special procedures prepared where necessary?					
5.4	Test methods and method validation					
5.4.1	General:					
	The laboratory uses appropriate methods and procedures for all tests within its scope?					
	Sampling?					
	Handling?					
	Transport?					
	Storage?					
	Preparation?					
	Estimation of measurement uncertainty?					
	Statistical analysis of test data?					

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	The laboratory has instructions on use and operation of all relevant equipment, handling, and preparation of test items?					
	All instructions, standards, manuals and reference data relevant to the work of the laboratory are up to date and available to personnel?					
	Deviation from test methods occur only when documented, technically justified, authorized, and accepted by the client?					
5.4.2	Selection of methods					
	Laboratory uses appropriate test methods, including methods for sampling, which meet client needs and are appropriate for the tests undertaken?					
	Methods published in international, regional or national standards preferably used?					
	Latest valid edition of standards used unless not appropriate or possible to do so?					
	Standards supplemented with additional details to ensure consistent application when necessary?					
	Use of appropriate methods published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the equipment manufacturer when not specified by client?					
	Use of appropriate and validated laboratory-developed methods or methods adopted by the laboratory?					
	Client informed of method chosen?					
	Laboratory confirmation of method capability before introducing tests?					
	Confirmation repeated when standard method changes?					
	Client notification of inappropriate or out of date methods?					
5.4.3	Laboratory-developed methods					
	Introduction of laboratory-developed methods planned and assigned to qualified personnel with adequate resources?					
	Plans updated as development proceeds and effectively communicated to involved personnel?					

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5.4.4	Non-standard methods					
	Agreement with the client in use of methods not covered by standard methods?					
	Includes clear specification of client's requirements and the purpose of the test?					
	Methods appropriately validated before use?					
	New test methods developed before testing performed and contain at least the following information?					
	a) Appropriate identification?					
	b) Scope?					
	c) Description of the material to be tested?					
	d) Parameters or quantities and ranges to be determined?					
	e) Apparatus and equipment, including technical performance requirements?					
	f) Reference standards and reference materials required?					
	g) Required environmental conditions and any stabilization period required?					
	h) Description of the procedure, including:					
	Affixing of identification marks, handling, transporting, storing and preparation of items?					
	Checks to be made before the work is started?					
	Checks that equipment is working properly and, where required, calibration and adjustment of equipment before each use?					
	Method of recording observations and results?					
	Safety measures to be observed?					
	i) Criteria and/or requirements for approval/rejection?					
	j) Data to be recorded and method of analysis and presentation?					
	k) Uncertainty or the procedure for estimating uncertainty?					

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5.4.5	Validation of methods					
5.4.5.1	Validation confirmed by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled?					
5.4.5.2	Non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods validated to confirm they are fit for intended purpose?					
	Validation records?					
	Validation includes procedures for sampling, handling and transportation?					
	Techniques used for determination of the performance of a method should be one of, or a combination of, the following:					
	a) Calibration using reference standards or reference materials?					
	b) Comparison of results achieved with other methods?					
	c) Interlaboratory comparisons?					
	d) Systematic assessment of the factors influencing the result?					
	e) Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience?					
	Is a new validation performed when changes are made to a validated non-standard method?					
5.4.5.3	Is range and accuracy of values obtainable from validated methods relevant to clients' needs?					
5.4.6	Estimation of uncertainty of measurement:					
5.4.6.1	Procedures to estimate uncertainty of measurement for all calibrations and types of calibrations for a laboratory performing its own calibrations?					

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5.4.6.2	Have and apply procedures for estimating uncertainty of measurement?					
	In cases where test methods preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement, was there an attempt to identify all components of uncertainty and make a reasonable estimation, and ensure that the form of reporting result does not give a wrong impression of uncertainty?					
	<i>Note: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.</i>					
5.4.6.3	Consideration of all uncertainty components of importance in a given situation taken into account using appropriate methods of analysis?					
	<i>Note: Sources contributing to the uncertainty include, but are not limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested, and the operator.</i>					
5.4.7	Control of data					
5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systemic manner?					
5.4.7.2	Computers or automated equipment:					
	a) Software developed by user documented in sufficient detail and suitably validated as being adequate for use?					
	b) Procedures established and implemented for protecting data:					
	Integrity and confidentiality of data entry or collection?					
	Data storage?					
	Data transmission?					
	Data processing?					
	c) Computers and automated equipment maintained to ensure proper functioning and provided with necessary environmental and operating conditions necessary to maintain integrity of test data?					
	<i>Note: Commercial software (e.g. word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. Laboratory software configuration/modifications should be validated.</i>					

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		Y	N	NA		
5.5	Equipment					
5.5.1	Sampling, measurement and test equipment required for correct performance of tests provided?					
	Equipment outside laboratory's permanent control meets the requirements of ISO 17025?					
5.5.2	Equipment capable of achieving the accuracy required and complies with the specifications relevant to the tests concerned?					
	Calibration programs established?					
	Calibration performed/verified before being placed into service?					
5.5.3	Equipment operated only by authorized personnel?					
	Up-to-date instructions on use and maintenance available to the appropriate laboratory personnel?					
5.5.4	Unique identification of equipment?					
5.5.5	Equipment records maintained for each item of equipment:					
	a) Identity of equipment and its software?					
	b) Manufacturer's name, type identification, and serial number or other unique identification?					
	c) Verification that equipment complies with the specification?					
	d) Current location, where appropriate?					
	e) Manufacturer's instructions, if available, or reference to their location?					
	f) Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, due date of next calibration?					
	g) Maintenance plan, where appropriate and maintenance carried out to date?					
	h) Any damage, malfunction, modification or repair to the equipment?					
5.5.6	Procedures for safe handling, transport, storage, use and planned maintenance?					

ISO 17025 Section	Requirement	Compliance			Facility Reference	Comments (Reserved for QAI Assessor)
		Y	N	NA		
5.5.7	Procedures in place for removing from service equipment that has been overloaded, mishandled, produces suspect results, or shown to be defective?					
	Equipment isolated or marked as being of out-of-service until repaired?					
	Proper operation confirmed by calibration and test before being placed back into service?					
	Effect of defect or departure from specified limits on previous results examined and "Control of Nonconforming Work" procedure instituted?					
5.5.8	Equipment requiring calibration clearly labeled to indicate calibration status, including last date calibrated and the date or expiration criteria when recalibration is due?					
5.5.9	Function and calibration of equipment that goes outside the direct control of the laboratory verified and shown satisfactory before being returned to service?					
5.5.10	Procedures defined when intermediate calibration checks are needed?					
5.5.11	Procedures defined when calibrations produce a set of correction factors to ensure that calculations are correctly updated?					
5.5.12	Procedures defined to safeguard against hardware and software adjustments that would invalidate test results?					
5.6	Measurement traceability					
5.6.1	General:					
	Procedures defined to assure all equipment used for testing and any ancillary equipment critical to test results are calibrated before being put into service?					
	<i>Note: Procedures should include a system for selecting, using, calibrating, checking, controlling, and maintaining measurement standards, reference materials used as measurement standards, and measuring and testing equipment used to perform tests.</i>					
5.6.2	Specific requirements					
5.6.2.2	Testing:					
5.6.2.2.1	Ensures that the equipment can provide the uncertainty of measurement needed?					

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		Y	N	NA		
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, calibration provides confidence in measurements by establishing traceability to appropriate measurement standards such as:					
	The use of certified reference materials provided by a competent supplier?					
	The use of specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned?					
	Participation in a suitable Interlaboratory comparison program?					
5.6.3	Reference standards and reference materials					
5.6.3.1	Reference standards					
	Procedures defined for calibration of reference standards?					
	Recognized traceability of reference standards?					
	Used for calibration only?					
	Calibration before and after adjustment?					
5.6.3.2	Reference materials:					
	Traceable to SI units of measurement, or to certified reference materials?					
	Internal reference materials validated against certified reference materials?					
5.6.3.3	Defined procedures and schedules for intermediate checks?					
5.6.3.4	Defined procedures for safe handling, transport, storage and use of reference standards and reference materials?					
5.7	Sampling					
5.7.1	Written sampling plan and procedures for sampling?					
	Availability of sampling plan and procedures at sampling location?					
	Use of recognized sampling standards or appropriate statistical basis?					
	Factors to ensure validity of test results controlled?					
	Availability of sample preparation plan and procedures at sample preparation location?					

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		Y	N	NA		
5.7.2	Client required deviations, additions or exclusions from documented sampling procedures documented in detail, included with all test results and communicated to the appropriate personnel?					
5.7.3	Procedures for recording sampling data and operations including sampling procedure used, identification of sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary?					
5.8	Handling of test items					
5.8.1	Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items, including any provisions to protect the integrity of the test item, and to protect the interests of the laboratory and the client?					
5.8.2	System for identifying test items?					
	Retained throughout the life of the test item in the laboratory?					
	Designed to ensure that test items cannot be confused physically when referred to in records or documents?					
	Accommodate a subdivision of groups of items and the transfer of items within and from the laboratory where appropriate?					
5.8.3	Abnormalities or departures from normal or specified conditions as described in the test method recorded upon receipt?					
	Consultation with client for further instructions on abnormal samples?					
	Recording of client discussion?					
5.8.4	Procedures and appropriate facilities for avoiding deterioration, loss or damage to test items during storage, handling and preparation?					
	Handling instruction provided with sample followed?					
	Maintenance, monitoring and recording of storage environmental conditions when required?					
	Arrangements for storage and security that protect the condition and integrity of secured items when required?					

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		Y	N	NA		
5.9	Assuring the quality of test results					
	Quality control procedures for monitoring the validity of test results in place?					
	Trend detection and application of statistical techniques?					
	Monitoring activities:					
	a) Regular use of certified reference materials?					
	b) Regular use of internal quality control using secondary reference materials?					
	c) Participation in proficiency testing program?					
	d) Replicate tests using the same or different materials?					
	e) Retesting of retained items?					
	f) Correlation of results for different characteristics of an item?					
5.10	Reporting the results					
5.10.1	General:					
	Results reported accurately, clearly, unambiguously, objectively, in accordance with method(s)?					
	Reports include information requested by client, necessary for interpretation of results, all information required by method(s) used?					
	Written agreement for simplified reports with the client?					
	Information not reported to client readily available?					
	Test reports issued as hard copy or by electronic data transfer both meet the requirements of ISO 17025?					
5.10.2	Test reports certificates					
	Test reports include the following information, unless the laboratory has valid reason for not doing so:					
	a) A title (e.g. "Test Report")?					
	b) Name and address of the laboratory and the location where tests were carried out?					

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	c) Unique identification of test report (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the test report?					
	d) Name and address of the client?					
	e) Identification of method(s) used?					
	f) Description, condition, and unambiguous identification of item(s) tested?					
	g) Date of receipt of the test item(s) and date(s) of performance of test?					
	h) Reference to the sampling plan and procedures used where relevant?					
	i) Test results with, where appropriate, units of measurement?					
	j) Name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing test report?					
	k) Statement to the effect that results relate only to the items tested, where relevant?					
	l) Hard copies of test reports include page numbers and total number of pages?					
	m) Statement specifying that the test report shall not be reproduced except in full, without written approval of the laboratory?					
5.10.3	Test reports					
5.10.3.1	Additional requirements where necessary for interpretation of the test results:					
	a) Deviations from, additions to, or exclusions from test method, and information on specific test conditions?					
	b) Where relevant, statement of compliance/non-compliance with requirements and/or specifications?					
	c) Where applicable, statement on the estimated uncertainty of measurement?					
	d) Where appropriate and needed, opinions and interpretations?					
	e) Additional information which may be required by specific methods, clients or groups of clients?					

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		Y	N	NA		
10.3.2	Test reports containing the results of sampling include the following where necessary for interpretation of test results:					
	a) Date of sampling?					
	b) Unambiguous identification of substance, material or product sampled?					
	c) The location of sampling, including any appropriate diagrams, sketches or photographs?					
	d) Reference to sampling plan and procedures used?					
	e) Details of environmental conditions during sampling that may affect the interpretation of results?					
	f) Standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions?					
5.10.5	Basis of opinions and interpretations documented, when interpretation required?					
	Statement of compliance/noncompliance of the results with requirements?					
	Fulfillment of contractual requirements?					
	Recommendations on use of results?					
	Guidance to be used for improvements?					
5.10.6	Testing results obtained from subcontractors					
	Clearly identified?					
	Subcontractor results in writing or electronic?					
5.10.7	Electronic transmission of results					
	Transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means meet the requirements of ISO 17025?					
5.10.8	Format of reports and certificates					
	Designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse?					

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		Y	N	NA		
5.10.9	Amendments to test reports					
	Made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report, serial number ... (or as otherwise identified)"?					
	Amendments meet all requirements of ISO 17025?					
	Complete new test report uniquely identified and referenced to the original it replaces?					

TO BE SIGNED BY THE AUTHORIZED REPRESENTATIVE OF THE LABORATORY:

Print Name: _____ Signature: _____ Date: _____

TO BE SIGNED BY THE ASSESSOR:

Print Name: _____ Signature: _____ Date: _____