ISO GUIDE 34: 2009
WORKING DOCUMENT

NOTES:

1. This working document is intended as a checklist for the assessor when conducting Reference Material Producer (RMP) Accreditation Assessments according to ISO Guide 34: 2009 and APLAC TC 008: 2015.

2. Please note in the Comments column any deficiencies in the RMP's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations.

3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.

4. Assess the system only to the relevant standard and to the requested scope of accreditation. Do not be concerned with system requirements stemming from:

   - Company- or facility-imposed policies
   - Regulatory bodies
   - Subcontractors
   - Other sources

5. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.

6. **Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."**

7. **If, at any time, the assessment team requires assistance in the interpretation of the requirements of ISO Guide 34: 2009 or APLAC TC 008:2015, contact the PJLA office immediately.**

Assessment Number: _____ Date(s): _____

Customer:

_____

Address: _____

_____

Contact/Management Rep.: _____

Lead Assessor: _____

Assessment Team: _____

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
MANAGEMENT REQUIREMENTS				
4.1 Management system				
4.1.1	Does the reference material producer establish, implement and maintain a documented management system appropriate to the scope of its activities, including the type, range and volume of the reference material production it undertakes?			
4.1.1	Is it recognized that a reference material property needs to be characterized mainly to the level of accuracy required for its intended purpose (i.e. appropriate measurement uncertainty for a property value of a certified reference material)? Does the reference material producer describe the procedure for establishing the quality of materials as a component of the management system?			
4.1.1	Does the reference material producer define their scope of activities in terms of the types of reference materials (including the sample matrices, if applicable), the properties to be certified and the ranges of assigned values (and their uncertainties) of the reference materials they produce, and their involvement in the performance of testing, calibration and measurements in relation to homogeneity, stability and characterization assessments and their use of subcontractors in these tasks?			
4.1.1	APLAC T008: The management system of a RMP need not be complex. Its format will depend on a number of factors including the size of the RMP, number of staff members, and the range, volume and complexity for the work it performs. In cases where a RMO is part of a larger organization, RMP activities my already be incorporated in a document covering the organization's total range of operations.	Note	Note	

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.1.2	Does the reference material producer define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of reference material production, including material quality (e.g. homogeneity and stability with respect to specified properties), characterization (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures for data evaluation) and material handling, storage and transport procedures?			
4.1.2	Are the reference material producer's management system policies related to quality, including a quality policy statement, documented in a quality manual (however named)? Is it issued under the authority of the top management?			
4.1.2	Does the quality policy include and is not limited to the following commitments: a) to produce reference materials which conform to the requirements of this Guide and to the definitions given in ISO Guide 30; b) to produce, where applicable, certified reference materials according to the requirements of ISO Guide 35 and accompanied by certificates meeting the requirements of ISO Guide 31; c) to conduct all testing and calibration in support of the production of reference materials in compliance with the requirements of ISO/IEC 170252); d) to require that all personnel concerned with the quality of any aspect of reference material production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work; e) for the management to continually improve the effectiveness of the management system and to be committed to good professional practice and to the quality of its reference materials?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.1.2	APLAC T008: Clause 4.21.2.c) requires the RMP to conduct all testing and calibration in support of the production of reference materials in compliance with ISO/IE 17025. Guidance on this compliance is given in clauses 3.7, 3.8, and 3.9 of APLAC TC 008	Note	Note	See elsewhere
4.1.2	Are the overall objectives reviewed during the management review?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.1.3	Does the reference material producer document all of its policies, systems, programs, procedures, instructions, findings, etc., to the extent necessary to enable the producer to ensure the quality of the reference materials produced? Documentation used in this management system shall be communicated to, understood by, available to and implemented by all personnel concerned. In particular, the producer shall have a management system that covers the following: a) arrangements for ensuring the suitable choice (e.g. type of material, concentration range, etc.) of the candidate reference materials; b) processing procedures; c) assessment of the required degree of homogeneity of the reference material; d) assessment of the stability of the reference material and determination of the period of validity of the certificate or statement; e) procedures for undertaking characterization (if applicable); f) assessment of commutability (where appropriate); g) practical realization of metrological traceability of measurement results to a stated reference; h) assignment of property values, including preparation of certificates or statements in accordance with ISO Guide 31 when appropriate; i) arrangements for ensuring adequate storage facilities; j) arrangements for suitable identification, labelling and packaging facilities, packing and delivery procedures in compliance with international safety regulations, and customer service; k) assessment of post-certification stability monitoring as required for the extension of the assigned period of validity of the reference material certificate (if applicable); l) compliance with ISO Guide 30 and with appropriate sections of ISO Guides 31 and 35?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.1.3	Does the documented management system specify which activities are undertaken by the reference material producer and, where relevant, which activities are undertaken by subcontractors? Does it include policies and procedures used by the producer to ensure that all activities conducted by subcontractors comply with the relevant clauses of this Guide?			
4.1.3	Does the documented management system define the roles and responsibilities of the technical management and the quality manager (however named), including their responsibilities for ensuring compliance with this Guide?			
4.2 Organization and management				
4.2.1	Is the reference material producer, or the organization of which it is part, an entity that can be held legally responsible?			
4.2.2	Is the reference material producer organized and operate in such a way that it meets all the applicable requirements of this Guide, whether carrying out work at its permanent facilities or at sites (including associated temporary or mobile facilities) away from its permanent facilities?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.2.3	Does the reference material producer: a) have managerial personnel, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of reference materials and to initiate actions to prevent or minimize such departures; b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work; c) have policies and procedures to ensure the protection of its customer's confidential information and proprietary rights; d) have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity; e) define, with the aid of organizational charts, the organization and management structure of the reference material producer, its place in any parent organization, and the relations between management, technical operations, support services, subcontractors and the quality management system; f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of reference materials produced; g) have technical management, including a technical manager, who has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the reference material production; h) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this Guide are implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on production policy or resources; i) appoint deputies for key managerial personnel such as the technical and quality managers?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.2.1	APLAC T008: Clause 4.2.1 Technical management may be a designated technical manager or may consist of a combination of designated technical managerial personnel each of them responsible for specified areas. Is the responsibility for technical issues for all accredited activities (shall) fully covered by the technical management?			
4.3 Document and Information Control				
4.3.1	Does the reference material producer establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that form part of its management system. These may include documents of external origin, such as standards, guides, test and/or calibration methods, as well as specifications, instructions and manuals related to the reference material under production?			
4.3.1	NOTE In this context, "document" means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These may be on various media, whether in hard copy or electronic, and they may be in digital, analogue, photographic or written form.			
4.3.2.1	Are all documents issued to personnel as part of the management system suitably controlled? Does this include review and approval for use by authorized personnel prior to issue? Is a master list or equivalent, identifying the current revision status of documents in the management system, established and it is readily available to preclude the use of invalid and/or obsolete documents?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.3.2.2	Do the procedures adopted ensure that: a) authorized editions of appropriate documents are available at all locations where operations essential to the effective production of reference materials are performed; b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; d) obsolete documents retained for either legal or information preservation purposes are suitably marked?			
4.3.2.3	Are management system documents generated by the reference material producer uniquely identified? Does such identification include the date of issue and/or revision number, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies)?			
4.3.3.1	Are changes to documents reviewed and approved by designated personnel performing the same function as that conducted for the original review and approval unless specifically decided otherwise? Do the designated personnel have access to pertinent background information upon which to base their review and approval?			
4.3.3.2	Where practicable, is the nature of the change identified in the document or appropriate attachments?			
4.3.3.3	If the reference material producer's document control system allows for the amendment of documents by hand, pending the re-issue of the documents, are the procedures and authorities for such amendments defined? Are amendments clearly marked, initialed and dated? Is a revised document formally re-issued as soon as practicable?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.3.3.4	Are procedures established to describe how changes in documents are maintained in computerized systems are made and controlled?			
4.4 Request, Tender and Contract Reviews				
4.4.1	Is each request, tender or contract concerning the production of a reference material reviewed, following documented policies and procedures, established by the reference material producer to ensure that a) the requirements are adequately defined, documented and understood; b) the reference material producer has the capability and resources to meet the requirements; c) in the case of contracts, any differences between the contract or order requirements and those in a tender are resolved to the satisfaction of the reference material producer and the customer?			
	NOTE 1 Capability means that the reference material producer has access to, for example, the necessary equipment, intellectual and information resources and that its personnel have the skills and expertise necessary for the production of those reference materials in question. The review of the capability can include an assessment of previous reference material productions and/or the organization of inter-laboratory characterization programs using samples of similar composition to the reference materials to be produced.			
	NOTE 2 A contract can be any written or verbal agreement to provide a customer with reference materials from stock or custom-produced.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.4.1	APLAC TC 008: When reviewing requests, tenders and contracts, does the RMP ensure (shall) that the requested matrix, property values and their metrological traceability and measurement uncertainty meet the need of the customer? In some cases, is the stability time required also be included in the review (should)? If necessary, does the RMP give advice to the customers and help them to determine their needs?			
4.4.2	Are records of such reviews, including any changes maintained? Are records maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract or request?			
4.4.3	Does the review include any work that has to be contracted by the reference material producer?			
4.5 Use of Subcontractors				
4.5.1	Does the reference material producer have policies and use documented procedures to select competent subcontractors and establish and maintain procedures to ensure that all tasks performed by subcontractors comply with specifications set by the reference material producer for such tasks? Does the reference material producer also ensure that subcontractors comply with any clauses of this Guide relevant to the tasks performed by them for the reference material producer?			
4.5.1	APLAC TC 008: Has the RMP documented (shall) in the quality manual or related documents, their policy and procedures for subcontracting? Note: There are some processes that the RMP shall not subcontract. These are listed in ISO Guide 34 clause 5.3.1 (see also Note 1 under clause 3.2 of ISO Guide 34:2009. Consult also APLAC TC 008 and included Table in section 2.3.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.5.2	Does the reference material producer select subcontractors on the basis of their ability to meet the requirements stipulated by the reference material producer in terms of both their technical competence and any specific quality management system requirements relevant to their tasks? Are the technical requirements that the subcontractors meet equivalent to either all, or the applicable, technical requirements specified in Clause 5 of this Guide?			
4.5.2	APLAC TC 008: For testing and calibration subcontractors, ISO Guide 34 accepts accreditation to ISO/IEC 17025 as evidence of their competence. Are these accreditations (should) granted by accreditation bodies which are signatories to the respective ILAC MRA? Does the scope of accreditation cover the specific tests and/or calibrations performed in support of producing the RM? (language in APLAC TC 008 are “shoulds”)			
4.5.3	Is work carried out by subcontractors performed according to the specifications set by the reference material producer? Subcontractors can be paid or non-paid; in all cases, does a protocol specify the requirements for executing their tasks? For subcontractors executing measurements or testing, do the specifications include requirements as described in ISO/IEC 17025? Do producers ensure that they are provided, by the subcontractors, with the information to ensure compliance with the requirements of ISO/IEC 17025?			
4.5.3	APLALC TCC 008: Referring to clause 3.15 of APLAC TC 008 – does the RMP have a written agreement (whatever form) with the subcontractors?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.5.3	Does the reference material producer assess the competence of the subcontractors by appropriate means? While it is encouraged that subcontractors executing measurements and testing be accredited to ISO/IEC17025, this is not a mandatory requirement. There are other ways to assess subcontractor competence, e.g. audit, performance on quality control materials, historical performance on inter-laboratory comparisons (see also 5.3.2).			
4.5.4	Does the reference material producer maintain a register of all subcontractors used and does it include a record of any assessments made of their abilities to carry out contracted tasks according to the requirements of this Guide? Do these records include any quality assurance approval the subcontractor holds?			
4.6 Procurement of Services and Supplies				
4.6.1	Does the reference material producer have policies and procedures in place for the selection of services and supplies that affect the quality of its reference materials?			
4.6.1	APLAC TC 008: Two commonly encountered situations RMPs have to procure services and supplies: 1) procurement of consumables and perishable items (eg. Media, chemical reagents, glassware, etc. 2) procurement of equipment (it is recommended that priority or preference should be given to certified (refer to IAF MRA) and accredited (refer to ILAC MRA) organizations. In the case of 1) records should be kept of different brands/sources of such items that influence the validity of the RMs produced and, where appropriate, records of acceptance tests and other reviews or evaluations of each new bath prior to use. See section 4.13. Is consideration given (should) to excluding supplies from suppliers that are inappropriate/invalid or have a known history of supplying such items?	Note	Note	

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.6.2	Does the reference material producer use only those services and supplies that comply with specified requirements to ensure the quality of the reference materials it produces?			
4.6.2	APLAC TC 008: When purchasing of candidate material for further processing, are the requirements given in other sections such as clauses 5.4, 5.5, 5.8 etc. of ISO Guide 34:2009, (should be) followed? Regarding testing and calibration service, do the provisions on use of subcontractors for testing and calibration apply?	Note	Note	
4.6.3	When no formal approval of the quality of services and supplies is available, does the reference material producer have procedures to ensure that purchased supplies and services comply with specified requirements, and are records of actions taken maintained?			
4.6.3	APLAC TC 008: Since both clauses 4.5 and 4.6 of ISO Guide 34:2009 are applicable to subcontractors can the RMP demonstrate that they have reviewed their subcontractors as being competent for the subcontracted work?			
4.6.4	Does the reference material producer ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined in specifications for production, characterization and certification of the reference materials it produces?			
4.6.5	Does the reference material producer maintain records of the suppliers and subcontractors from whom it obtains services and supplies? Do these records include any quality assurance approval the suppliers and/or subcontractors hold?			
4.7 Customer Service				
4.7.1	Is the reference material producer willing to cooperate with customers or their representatives in clarifying the customer's requests and questions?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.7.1	APLAC TC 008: There are requirements for customer service given in other sections of ISO Guide 34 , e.g. clauses 5.14.5 and 5.18.4, etc.	Note	Note	
4.7.2	Does the reference material producer seek feedback, both positive and negative, from its customers? Is the feedback used and analyzed to improve the management system, reference material production activities and customer service?			
4.8 Complaints				
4.8.1	Does the reference material producer have a policy and procedure for the resolution of complaints received from customers or other parties? Are records maintained of all complaints and of the investigations and corrective actions taken by the reference material producer (see also 4.10)?			
4.9 Control of Nonconforming Work and/or Reference Materials				
4.9.1	Does the reference material producer have a policy and procedures that are implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.9.1	Do the policy and procedures ensure that: a) responsibilities and authorities for the management of non-conforming work are designated; b) the actions, which shall be taken when any non-conforming work and/or reference materials are identified, are defined, together with a system which ensures that they are effectively implemented; c) an evaluation of the significance of the non-conforming work is made; d) where necessary, work is halted and, if appropriate, issue of the affected reference material and its certificates (and statements) withheld; e) remedial actions are taken within a defined time-frame; f) where necessary, the customers who, within an appropriate period, have purchased the reference material are notified of the possible effects identified and, where necessary, non-conforming reference materials and/or their certificates/statements already distributed, are recalled; g) the responsibility for authorization of the resumption of work is defined?			
4.9.1	Is the decision on recall of reference materials taken in a timely manner to limit the use of non-conforming reference materials by customers if applicable?			
4.9.1	Is the identification of non-conforming reference materials or problems with the management system or with certification activities identified at various places within the management system, such as customer complaints, quality control, checking of consumable materials, staff observations or supervision, certificate checking, management reviews and internal or external audits?			
4.9.1	APLAC TC 008: When the investigation of the non-conforming work indicates that there is an underlying cause with the possibility of recurrence (corrective actions in addition to correction are needed), are the requirements in 4.92 of ISO Guide 34 conformed to (shall)?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.9.1	APLAC TC 008: Are all personnel of the RMP familiar with the procedures for handling non-conforming work and/or RMs? Do they follow the documented procedures whenever non-conforming work and/or RM is identified?			
4.9.2	Where the evaluation indicates that the non-conforming work and/or reference materials could recur or that there is doubt about the reference material producer's compliance with its own policies and procedures, are the corrective action procedures in 4.10 promptly followed to identify the causes of the problem and to eliminate them?			
4.10 Corrective Actions				
4.10.1	Does the reference material producer establish a policy and procedures and designate appropriate authorities for implementing corrective actions when non-conforming reference materials, non-conforming work on the production of reference materials or departures from the policies and procedures in the management system have been identified?			
	NOTE A problem with the management system or with technical operations may be identified through a variety of activities within the management system, such as control of non-conforming reference materials, internal or external audits, management reviews and feedback from customers or staff observations.			
4.10.2	Do corrective action procedures start with an investigation to identify the root causes of the problem?			
4.10.2	Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, *inter alia*, the nature of the reference material and its specifications, methods and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes. Is this reviewed for both in-house production and, where required, any work performed by subcontractors?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.10.3	Where corrective actions are needed, does the reference material producer identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?			
4.10.3	Are corrective action taken to eliminate the causes of non-conformities or other departures appropriate to the magnitude of the problem and commensurate with the risks encountered?			
4.10.3	Does the reference material producer document and implement any required changes to the operational procedures resulting from corrective action investigations?			
4.10.4	After having implemented the corrective actions, does the reference material producer monitor the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems?			
4.10.5	Where the identification of non-conformities or departures casts doubt on the producer's compliance with its own policies and procedures, or on its compliance with this Guide, does the producer ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?			
4.11 Preventive Actions				
4.11.1	Are required improvements and potential sources of non-conformities, either technical or concerning the management system, identified? When improvement opportunities are identified or if preventive action is required, are action plans developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement?			
4.11.2	After the implementation of the preventive actions, does the reference material producer monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action?			
4.12 Improvement				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.12	Does the reference material producer continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?			
4.13 Records				
4.13.1.1	Does the reference material producer establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records?			
4.13.1.1.a	Quality records are records providing objective evidence of the extent of the fulfilment of the requirements for quality or the effectiveness of the operation of the management system. They include reports from internal audits and management reviews, and corrective and preventive action records.			
4.13.1.1. b	Technical records are accumulations of data and information which result from carrying out testing and (if applicable) calibration procedures and which indicate whether specified quality or process parameters are achieved. They include forms, contracts, work sheets, work books, check sheets, control charts/graphs, calibration reports/certificates, reports, certificates and other statements to customers.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.1.1	APLAC TC 008: Do technical records, (shall as applicable), include all original observations and raw data and provide a traceable link between the RMs produced and the information on the certificates or documentation of the RMs? Note: if the RMP uses an Information Management System the system should meet all the relevant requirements, including audit trail, data security, safety and integrity. It should be fully validated and records of validation maintained. RMP should keep back-up copies of electronic records within the retention period. Electronic records should remain accessible during the retention period even though the hardware and software are updated.			
4.13.1.1	Does the reference material producer ensure that it has recorded such information that might be needed in a future dispute situation?			
4.13.1.2	Are all records legible and stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss? Are retention times of records established in accordance with legal, accreditation body or customer requirements, where relevant, and are they documented?			
4.13.1.2	Records may be in the form of any type of media, such as hard copy or electronic media.			
4.13.1.3	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct information entered alongside? Are all such alterations to records signed or initialed by the person making the correction? In the case of records stored electronically, are equivalent measures taken to avoid the loss or change of original information?			
4.13.1.4	Are all records held securely and, where appropriate, in confidence?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.1.5	Does the reference material producer have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data?			
4.13.2	Does the reference material producer establish and maintain a record system to suit its particular circumstances and to comply with any applicable regulations? Does the reference material producer arrange for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the reference material remains valid?			
4.13.2	APLAC TC 008: Does the record system (should) allow for ready retrieval of original observations and data pertinent to any issued reports or certificates?			
4.13.2	Are the results of each calibration or measurement (or series of either) carried out by the reference material producer reported in accordance with ISO/IEC 17025?			
4.13.2	4.13.2 refers to internal reports of the reference material producer which should not be confused with a certificate of analysis or certification report which is supplied with a reference materials to the customer.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.3	APLAC TC 008: For each RM produced, the records system should retain and provide ready access to the following detailed information: (i) the full description of the RM; (ii) the unique identification of the RM; (iii) the test or calibration method or procedure used in the production process; (iv) identification of equipment and RMs used in the production process; (v) all data relating to the preparation and manufacturing of the candidate materials, including any batch details, where necessary; (vi) original observations during the test or calibration and calculations based on the observed data; (vii) data and the statistical calculations for homogeneity and stability studies; (viii) data used in the assignment of property values and their uncertainties, including those data which have been rejected and the reasons for rejection; (ix) identification of persons performing the work; (x) an exact copy of the issued documentation or certificate of the RM produced.			
4.14.4	APLAC TC 008: Are original observations (should be) recorded immediately into bound notebooks, or onto properly designed worksheets using indelible pen. Are instrument printouts (should be) kept when they are available? Where data processing systems are used, are records of raw data (should be) retained unless data are automated?			
4.14.15	APLAC TC 008: Errors in calculations and incorrect transfer of data are major causes of incorrect results. Are calculations and data transfers (should be) checked by another person, then initialed and dated by the reviewer except in the case when there is no other suitable person available for this purpose?			
4.14 Internal Audits				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.14.1	Does the reference material producer, periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the requirements of this Guide? Does the internal audit programme address all elements of the management system, including the technical and production activities leading to the finished product (reference material)? Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management? Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited? Personnel shall not audit their own activities?			
4.14.1	APLAC TC 008: Are internal auditors (shall) familiar with the requirements of ISO Guide 34 and the requirements of ISO Guides 30, 31, 35 and ISO/IEC 17025 (or ISO 15189 for medical RMs), and the requirements of this document (APLAC TC 008)?			
	NOTE The cycle for internal auditing should normally be completed in one year.			
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the integrity of the reference materials or on the correctness of their documentation, does the reference material producer take timely corrective actions and notify, in writing, its customers whose activities may have been adversely affected?			
4.14.3	Are all audit findings and corrective actions that arise from them recorded? Does the reference material producer's management ensure that these actions are discharged within an appropriate and agreed timescale?			
4.14.4	Are follow-up activities verified and are records of the implementation and effectiveness of the corrective actions taken?			
4.15 Management Reviews				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.15.1	In accordance with a predetermined schedule and procedure, does the reference material producer's top management periodically conduct a review of its management system and production processes to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements? Does the review shall take account of ↓ the suitability of policies and procedures; ↓ reports from managerial and supervisory personnel; ↓ the outcome of recent internal audits; ↓ corrective and preventive actions; ↓ assessments by external bodies; ↓ changes in volume and type of work; ↓ feedback from customers; ↓ recommendations for improvement including complaints; ↓ other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the reference materials?			
	Do results feed into the corporate planning program, and include the goals, objectives and action plans for the coming year and communicated to the staff if appropriate?			
	NOTE A typical period for conducting a management review is once every year.			
4.15.2	Are findings from management reviews and the actions that arise from them recorded? Does the management ensure that these actions are discharged within an appropriate and agreed timescale?			
TECHNICAL REQUIREMENTS				
5.1 General				
5.1.1	This Guide covers the production of certified and non-certified reference materials. For non-certified reference materials, the production requirements are less stringent than for certified reference materials. Homogeneity and stability assessments are always required to establish that the degree of homogeneity and stability is fit for purpose (see 5.12, 5.13, and 5.14).			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.1.1	Where replacement batches of reference materials are produced by applying the same procedures used for previous batches to similar starting materials which lead to final products with equivalent properties, are appropriate verification assessments required to ensure that uncertainty estimations obtained on previous batches remain applicable for the new batch; see 5.4.3 n)?			
5.1.1	To fulfill the minimum requirements for a non-certified reference material, the following may not be necessary: a) designing inter-laboratory exercises, assessing commutability, assigning property values and establishing uncertainty budgets [5.4.3 j), k), l), m)]; b) providing detailed information to users on the homogeneity study; however, information on the degree of homogeneity shall be provided (5.13.1); c) providing detailed information to users on the stability study; however, information on the degree of stability shall be provided (5.14.1); d) characterization of the material (5.15); e) assignment of property values and their uncertainties (5.16); f) establishing metrological traceability of assigned values (5.12.4).			Note which of these is performed. DO NOT WRITE A FINDING IF THE MATERIAL IS A REFERENCE MATERIAL (non-certified)
5.1.1	APLAC TC 008: There are technical standards published by international organizations, or other well recognized professional bodies, that may be applicable to the production of certain RMs. If such applicable technical standard exists, does the RMP (should, as far as possible) follow such standards in its production of the RMs (see section 3.2 of this document and clause 5.4.1 of ISO Guide 34:2009)?			
5.2 Personnel (Not required for surveillance unless critical changes have occurred)				
5.2.1	Is the producer of reference materials, where possible, competence in the production of the particular type of reference material (or related material), as well as having access to experience in the measurement of the properties being determined?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.2.1	It is recognized that, for the production of novel reference materials, persons or organizations with suitable competence may not be available. In such cases, does the reference material producer demonstrate the accumulation of knowledge and experience through the production records of its reference materials if appropriate?			
5.2.2	Does the reference material producer ensure the adequate competence of all personnel who undertake activities relating to the production of reference materials? Is there sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions?			
5.2.3	Does the reference material producer formulate goals with respect to education, training and skills of its personnel? Does the reference material producer have a policy and procedures for identifying training needs and providing training of personnel? Is the training program relevant to the present and anticipated tasks of the producer? Is the effectiveness of training actions evaluated?			
5.2.3	Is the need to retrain staff periodically considered (e.g. the reference material producer should have in place a policy for retraining staff when a method or measurement technique is not in regular use) if appropriate? Does staff training and retraining policies take into account technological changes and aim at continuous upgrading of skills if appropriate?			
5.2.4	Does the reference material producer maintain an up-to-date record of job descriptions for the managerial, technical and support staff involved in reference material production activities?			
5.2.5	Does the reference material producer use personnel who are employed by, or under contract to, the producer? Where contracted and additional technical and support personnel are used, does the producer ensure that such personnel are supervised and competent and that they work in accordance with the producer's management system?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.2.6	Does the reference material producer authorize specific personnel to perform particular activities relating to reference material production? Does the reference material producer maintain an up-to-date record of the authorizations, competence and educational and professional qualifications of all staff members? Do these records provide evidence that individual staff members have been adequately trained and that their competence to complete particular types of material processing and measurement has been assessed? Is this information readily available and does it include the date on which authorization and/or competence is confirmed?			
5.3 Subcontractors				
5.3.1	Where a reference material producer uses subcontractors to undertake part of the procedure for the production, including processing, homogeneity and stability testing, characterization, handling, storage or distribution of a reference material, is the producer able to demonstrate that the subcontractor is competent to perform the concerned part of the procedure, and that the work carried out and/or the results produced are of the required quality? When assessing the competence of a subcontractor, does the reference material producer acquire and evaluate information on the subcontractor's knowledge of the subject and details of past experience in the field and make sure that experienced staff is available as well as appropriate accommodation and environmental conditions, instrumentation and measuring equipment as required?			
5.3.1	Are the following processes not carried out by subcontractors: project planning, selection of subcontractors and the assignment of and decision on property values? Also, is authorization of property values and issue of certificates/statements/analysis reports/information sheets (or however named) done by the reference material producer?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.3.2	Is evidence of the subcontractor's competence established and records of its competence maintained? This can be done by different means. Accreditation to ISO/IEC 17025 when testing or calibration is carried out, or certification of the quality management system to ISO 9001 for other (non-testing/calibration) activities by a recognized body, is generally appropriate. In cases where accreditation is not practical, is evidence of subcontractors successfully participating in a relevant proficiency testing scheme and producing acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate reference material considered appropriate. In cases where the competence of subcontractors cannot be ascertained via provision of documentary evidence, the reference material producer may need to assess the competence of the subcontractor on-site or may need to supervise on-site the operations carried out by the subcontractor.			Indicate how competence is established and maintained for each subcontractor.
5.3.2	Does the producer consider distributing materials of a comparable matrix whose property values are well established and at appropriate concentration levels, etc., prior to or together with distributing any candidate reference material samples to help in the evaluation of the subcontractor?			Possible mechanism but not required.
5.3.3	In certain cases, the reference material producer may have no laboratory facilities or processing facilities, or may choose not to use its own facilities. Does the RMP ensure that all work carried out by subcontractors who may contribute to the assignment of the property values of interest is fit for that purpose and in compliance with this Guide and ISO/IEC 17025 for measurement, calibration and testing? Under these circumstances does the reference material producer" ↓ employ personnel having knowledge to ensure that subcontracted activities are executed in compliance with this Guide and ISO/IEC 17025 for measurement and testing, and ↓ evaluate the results of all subcontracted activities (e.g. analytical and statistical aspects)?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.3.4	Does the reference material producer ensure that all details of the methodology, results and the descriptions of procedures of any subcontractor are available? Are suitable details of methodology maintained by the reference material producer to allow the technical evaluation of data? If required, does the RMP ensure that a register/database of all subcontractors and the accreditation for testing, calibration and measurement activities, certification of the management system or other forms of competence status are maintained?			
5.4 Production Planning				
5.4.1	Does the reference material producer identify and plan those processes, which directly affect the quality of reference material production and shall ensure that they are carried out in accordance with specified procedures? Where available, are procedures given in technical standards for the production of specific reference materials used?			
5.4.1	APLAC TC 008: It is critical that, before the start of the production of RM, a detailed production plan is available. Is the need for pilot studies considered at the planning stage? Is the production plan fully documented (should be)? Does the RMP provide evidence that the requirements for each step given in ISO Guide 34 are considered at the planning stage? If necessary are recommendations from advisory groups sought?			
5.4.2	Is technical input of the different subcontractors involved identified and the necessary information documented and regularly reviewed? A mechanism (e.g. a management/technical advisory group) may be established to make recommendations on how to plan the production processes.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.2	APLAC TC 008: The production plan may need to be reviewed regularly during the production process. If it is necessary to make any change to the plan, are the effects of the change on the conformity with the requirements of ISO Guide 34 evaluated (should be)? Are changes approved (should be) by the person authorized, in accordance with clause 5.2.6 of ISO Guide 34:2009, to perform production planning of the RM? Are changes fully documented, (should be) and include (should) the reasons and justifications for the changes? If the changes can affect the contract with the customer, is the customer consulted (should)? Is the customer's agreement with the changes obtained and records maintained as required by clause 4.4.2 of ISO Guide 34:2009?			
	NOTE These could include recommendations for production, setting up a monitoring system (to ensure timeliness and quality for each production phase) and having an evaluation procedure to assess the production processes retrospectively.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.3	In planning the production processes, does the reference material producer have procedures and service facilities, for: a) definition of storage conditions; b) material selection (including, where appropriate, sampling); c) maintaining suitable environments for all aspects of production (5.6); d) material processing (5.8); e) measuring/testing (5.9, 5.10); f) validation of measurement methods (5.9); g) verification and calibration of equipment (5.10); h) assessing material homogeneity (5.13); i) assessing material stability (5.14); j) designing and organizing appropriate interlaboratory exercises for the purpose of assigning property values, if applicable (5.15); k) assessing commutability (where appropriate) (Annex B); l) assigning property values based on the results of measurements, if applicable (5.16); m) establishing uncertainty budgets and estimating uncertainties of the assigned property values, if applicable (5.16); n) defining acceptance criteria for verifying that uncertainty estimates are applicable for replacement batches of reference materials produced under conditions described in 5.1; o) establishing metrological traceability of the measurement result(s) (5.12); p) issuing certificates and/or other documentation (5.17); q) ensuring adequate storage facilities and conditions (5.7); r) ensuring appropriate labelling and packaging of the samples meeting safety regulations (5.7); s) ensuring appropriate transport arrangements which comply with shipping regulations (5.18); t) ensuring post-certification stability monitoring, if applicable (5.14); u) ensuring an adequate post-distribution service for reference material customers (5.18)?			
5.5 Production Control				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5	Does the reference material producer identify the verification procedures necessary to ensure the quality of each stage of reference material production, and shall assign adequate resources and personnel for such activities? Do these activities include inspection, testing and monitoring of all stages of production?			
5.5.1	APLAC TC 008: Although effective control of each stage of the production process is needed, there are also certain critical steps in each stage where the quality of the RM can be significantly affected. Is an analysis of such critical control points carried out and an action plan designed to ensure that these critical control points are effectively controlled and monitored, to ensure the quality of RMs?			
5.5.2	APLAC TC 008: Are records (shall) maintained to provide evidence that there is effective control of each stage of RM production, e.g. records of inspection, testing, etc. ?			
5.6 Accommodation and Environmental Conditions				
5.6.1	Does the reference material producer ensure that all laboratory accommodation, calibration and measurement areas (if applicable), material processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material processing and packaging, as well as proper performance of calibration and measurements (if applicable)?			
5.6.1	Are precautions taken against possible contamination of the reference material during its processing and characterization? Are all reference material processing and testing areas, in addition to satisfying requirements for humidity and temperature, protected from vibration, airborne dust and microbiological contamination, magnetic fields and electromagnetic radiation (as appropriate)? Are the technical requirements for accommodation and environmental conditions that can affect the results and processes of the production of reference materials documented?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	NOTE For example, the packaging of a cement material requires conditions of low humidity, while the processing and characterization of a material in which the content of traces of lead is to be measured requires clean room conditions to prevent contamination from dust containing lead. Clean room conditions may also be required for other types of trace analysis. Proper choice of container material and adequate cleaning procedures are also important to avoid contamination. Processing of reference materials of genetically modified organisms requires measures to prevent DNA/protein cross-contamination.			
5.6.1	APLAC TC 008: Is the suitability of the accommodation and environmental conditions for the production of a specific RM (shall be) assessed based on their effect on the quality and validity of the RM being produced, including how they affect the: (a) integrity of the RMs; (b) performance of laboratory equipment; (c) competent performance of laboratory staff; (d) compliance with the conditions specified in the production plan?			
5.6.2	Where appropriate, is the environment in which the reference material production activities undertaken monitored with appropriately calibrated equipment, controlled and recorded, such that results and processes are not adversely affected?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.6.2	APLAC TC 008: Consideration of environmental effects on RMs includes precautions necessary to prevent contamination and degradation (refer to 5.7.2 of ISO Guide 34). Are the areas for the material preparation, preconditioning, testing or calibration and storage shall be free from dust, fumes and other factors (such as excessive temperature, humidity and direct sunlight) which may affect the integrity of the RMs.? If the RMs produced require refrigeration, refrigerators or freezers of adequate capacity and capable of maintaining the required temperatures, are these available (shall) and temperatures monitored?			
5.6.3	Are appropriate health, safety and environmental protection precautions implemented where necessary (e.g. when handling pesticides or serum)?			
5.6.3	APLAC TC 008 The potential effects of environment on equipment performance include: corrosion, temperature, humidity, vibration, electrical power stability, dust and electromagnetic influences. Are the location of all items of equipment likely to be affected by these factors (should be) chosen to eliminate or minimize any adverse effects?			
5.6.4	APLAC TC 008: Accommodation and environmental conditions should also be assessed based on their effects on staff competence in performing specific activities. Is there (should be) sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimize noise?			
5.7 Material Handling and Storage				
5.7.1	In order to avoid any contamination, does the reference material producer identify, preserve and separate (i.e. from other chemicals and samples) all candidate materials and reference materials, from the time of processing through to their distribution to users?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.7.1	APLAC TC 008: It should be emphasized that the requirements of this section apply to all stages of the production - from the receipt of the raw material to the finished RM. If during some stages of production, the material has to go out of the direct control of the RMP, does the RMP (shall) provide necessary instructions to the party responsible for handling the material? When storing the material, are the storage environmental conditions (shall be) specified?			
5.7.2	Does the reference material producer ensure adequate packaging of all reference materials (e.g. where appropriate, use light shielding, air-free, moisture-free or inert-gas packaging) and provide secure storage areas/stock rooms which prevent damage or deterioration of any item or material between characterization and distribution? Are appropriate procedures for dispatch stipulated?			
5.7.2	APLAC TC 008: When the same equipment is used for different materials, does the facility (shall) ensure that no cross-contamination or carry-over contamination is taking place?			
5.7.3	Is the condition of all stored/stocked items and materials assessed at appropriate intervals throughout the storage period, in order to detect possible deterioration?			
5.7.3	APLAC TC 008: Are all persons handling the materials (hall be trained) on the proper handling procedures? Are they (shall be) aware of the precautions to be taken while handling the material, as required by clause 5.2.2 of ISO Guide 34:2009?			
5.7.4	Does the reference material producer control packing and labeling processes to the extent necessary to ensure conformity with safety and transport requirements?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	NOTE The proper distribution of samples can present a severe problem for some types of material which require uninterrupted storage in a freezer, or which should not be exposed to X-rays, shocks or vibrations. Most types of chemical material benefit from air-tight packaging to avoid oxidation by atmospheric oxygen and/or contamination by atmospheric contaminants (e.g. fuel vapours or engine exhaust gases) which may be encountered during transport.			
5.7.4	Does the reference material producer ensure that the integrity of each individual reference material unit is maintained until the seal has been broken or up to the point when presented for analysis? Is the producer not held responsible for the material once its seal has been broken? Is the reference material packaged in unit quantities sufficient for a single use when required?			
5.7.4	APLAC TC 008: It is the responsibility of the RMP to ensure that the packing and labelling of the RMs meet the safety and transport regulatory requirements. However, it should be emphasized that assessment of the compliance with the regulatory requirements is outside the authority of accreditation bodies.	Note	Note	
5.7.5	Is the reference material label securely attached to the product container of an individual reference material unit, and is it designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the reference material, i.e. the period during which the reference material is available from the reference material producer extended by the period of validity of its certificate? Does the label identify the material, the producer, its batch and catalogue numbers, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as the individual sample number), where appropriate, to its statement or certificate? Do the labels also, where appropriate, comply with requirements related to safety and risk regulations, e.g. show toxicity symbols, risk and safety phrases?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.7.5	Where the physical size of the reference material unit limits the amount of information that can be contained on the label, is the information included elsewhere (e.g. in a certificate) and is the user directed to this information from the label? At a minimum, is a unique identity number given if appropriate?			
5.7.6	Does the reference material producer make arrangements to ensure the integrity of each reference material throughout the entire production process? Where contractually specified, is this protection extended to include delivery to destination?			
5.8 Material Processing				
5.8.1	Does the reference material producer establish procedures to ensure that the item or material has undergone adequate processing for its intended use? Do procedures for material processing include, where appropriate: a) qualitative analysis for verification of material type and/or identity; b) synthesis, purification (e.g. distillation, extraction), transformation into the final form (e.g. machining, grinding, blending, sieving and riffling, extrusion, melting); c) homogenization; d) proper handling (e.g. protection from contamination and use of inert equipment); e) measurements for processing control (e.g. particle size distribution, moisture content); f)cleaning of sample containers; g) stabilization of material (e.g. drying, irradiation, sterilization); h) packaging (e.g. bottling, ampouling) of the batch?			
5.8.1	APLAC TC 008: When the same equipment is used for processing different materials, is the equipment (shall be) thoroughly cleaned between uses to prevent possible cross contamination?			
5.8.2	APLAC TC 008: Are all material processing procedures (should be) carried out by trained personnel and are requirements of clause 5.2.2 of ISO Guide 34:2009 applied?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.8.3	APLAC TC 008: Preparation of the material (such as drying, mixing of ingredients, spiking with analytes, etc) is a form of material process.	Note	Note	
5.8.4	APLAC TC 008: When candidate RMs are sent to subcontractors for testing, are they (should be) uniquely labeled, suitably packed and stored in suitable conditions during transport? Are instructions on the storage conditions (should be) given to the subcontractors?			
5.8.5	APLAC TC 008: In cases where the certified values are based on data obtained in the material processing procedure, are the requirements relating to the assignment of property values and their uncertainties applied to the material process procedures? In such cases, do the material process procedures (should) comply with the requirements for measurement methods and metrological traceability given in Sections 5.9 and 5.12 of ISO Guide 34:2009? Are the requirements for measuring equipment given in Section 5.10 of ISO Guide 34:2009 also applied to those items of equipment used in the material processing stage which contribute to the uncertainty of the assigned values of the RMs?			
5.9 Measurement Methods				
5.9.1	Does the reference material producer meet the requirements of ISO/IEC 170253) with respect to tests, calibrations and measurements under their responsibility (including preparation of items, sampling, handling, preservation, storage, packaging, transport to subcontractors, estimation of measurement uncertainty and analysis of measurement data)? Are these activities consistent with the required accuracy, where appropriate, of the assigned values of the reference material, and with any standard specifications relevant to the measurement concerned?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.9.2	Are measurement methods developed in-house, by the reference material producer, validated and authorized before use? Are such methods thoroughly investigated, and clearly and exactly describe the necessary conditions and procedures for which the measurement of the property values of interest is valid at the level of accuracy commensurate with the intended use of the reference material? Are records of the method of validation retained? Does the validation meet the requirements of ISO/IEC 17025?			
5.9.3	Where sampling is carried out as part of the measurement method (e.g. sub-sampling a representative quantity from a batch of material), does the reference material producer use documented procedures and appropriate statistical techniques to take test portions?			
5.10 Measuring Equipment				
5.10.1	Is measuring equipment used in reference material production in compliance with ISO/IEC 17025? Is the measuring equipment properly calibrated, verified and maintained, with all procedures being documented and the results recorded? Where appropriate, is periodic performance checks carried out and recorded (e.g. to check the response, stability, linearity, resolution, alignment, repeatability) to ensure that the measurement equipment is performing adequately? Is the frequency of such performance checks determined by experience and based on the type and previous performance of the equipment? Are intervals between checks shorter than the defined time within which the equipment has been found to drift outside acceptable limits, in accordance with the requirements of ISO 10012?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.2	Is any item of equipment that has been subjected to overloading or mishandling, shown to provide suspect results, or shown by verification or otherwise to be defective, clearly identified, withdrawn from service and, wherever possible, stored at a specified location until repaired and shown by calibration, verification or testing to perform satisfactorily? Does the reference material producer review the implications for results obtained using such equipment, with particular regard to the extent of the calibration deviation, the results involved and the allowable tolerance on the results? Where results have been significantly in error, does the reference material producer have the results checked and take appropriate remedial action? Are records of the review and any checks/remedial action maintained?			
5.10.3	Is each item of equipment, including any measurement standard, that is used in the calibration/validation of equipment/measurement methods used for reference material production, where appropriate, be labeled, marked or otherwise identified to indicate its calibration status and expiry date? Does this also include reference materials, standard solutions and chemical reagents used in chemical analysis, microbiological testing, etc?			
5.10.4	Is all measuring and testing equipment having an effect on the traceability and accuracy of the measurement results calibrated and/or verified before being commissioned into service? Does the reference material producer have an established program for the calibration and verification of measuring and testing equipment?			
5.10.5	Is the overall program of calibration and/or verification of equipment designed and operated so as to ensure that, wherever applicable, measurement results obtained by the reference material producer are traceable to a stated reference through an unbroken chain of calibrations with stated uncertainties? Does the calibration certificates of measurement instruments, wherever appropriate, indicate the metrological traceability to this stated reference?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.11 Data Evaluation				
5.11.1	Does the reference material producer ensure that calculations and data transfers are subject to appropriate checks, including those from its own sources?			
5.11.1	APLAC TC 008: Homogeneity and stability assessments, characterization and assignment of property values and their uncertainties all involve evaluation of data. Does the RMP (shall) use appropriate statistical techniques for data evaluation? Are the general and statistical principles for certification of a given RM in ISO Guide 35, where appropriate, (shall be) followed?			
5.11.2	Where computers or computer-controlled systems are used for the capture, processing, evaluation, recording, reporting, storage or retrieval of calibration or testing data, does the reference material producer ensure that a) computer software developed in-house or off-the-shelf software further developed for specific use, which affects the characterization or the properties of the reference material, shall be validated and shown to be adequate for use; b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing; c) equipment is maintained to ensure proper functioning and is provided with the environmental and operating conditions necessary to maintain data integrity; d) appropriate procedures are established and implemented for the maintenance of data security, including prevention of unauthorized access to, and amendment of, computer records?			
5.11.3	Are all technical data relating to the production of reference materials retained in accordance with the requirements of 4.13.2?			
5.12 Metrological Traceability				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.12.1	Does the reference material producer provide documentary evidence on the metrological traceability, of the measurement results to a stated reference?			
5.12.1	APLAC TC 008: See section 3.10	Note	Note	
	NOTE The concept of "metrological traceability" includes identification of the property of interest of the reference material, the numerical value and the stated reference.			
5.12.2	Is the stated reference a definition of a measurement unit through its practical realization, a measurement procedure including the measurement unit, or a measurement standard? Wherever possible, is the metrological traceability achieved through an unbroken chain of calibrations, all having stated uncertainties? Where this cannot be achieved, does the reference material producer provide satisfactory evidence of the correlation of results with other stated values, either by exhaustive evaluation of the measurement process or by comparison with known and accepted certified reference materials, which have certified values preferably with comparatively small uncertainty and which are higher in the metrological traceability hierarchy with few steps of comparison?			
5.12.2	Does the concept of "metrological traceability" apply to the measurement results for the assessment of homogeneity and stability as well as to the assignment of values as the result of the characterization process?			
5.12.2	The definition of reference material as "sufficiently homogeneous and stable *with respect to one or more specified properties*" inherently requires a clear definition of these properties. Is the metrological traceability of measurement results to the chosen reference ensured to make relevant statements on the degree of homogeneity and stability?			
5.12.3	Do different requirements apply for relative assessments and absolute assessments?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.12.3.1	For studies in which results are compared relative to each other (e.g. homogeneity studies, stability studies with measurements performed under repeatability conditions in isochronous schemes), is it ensured that: a) the measurand in the study is the same as the one for which the value is assigned (i.e. the chosen method is selective); b) the calibration function for the measurement procedure is valid in the range of the measurement results; c) the measurement procedure is sufficiently precise to make meaningful statements about the variation of the measurement results of the measurand? In this case, no traceability to a higher order reference system is required.			
5.12.3.1	ISO Guide 35:2006, 7.4, allows homogeneity testing only on a subset of the assigned values. In this case, is there documentary evidence provided that the measurand quantified indeed correlates with the measurand for which the value is assigned in the material in question?			
	NOTE 1 In principle, no trueness of measurement results has to be established for this kind of study.			
	NOTE 2 These requirements are met if appropriate selectivity, working range and precision of a method have been established.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.12.3.2	For studies in which the absolute values are compared (e.g. characterization studies, stability studies with measurements under reproducibility conditions), is it ensured that: a) the measurand in the study is the same as the one for which the value is assigned (i.e. the chosen method is selective); b) the calibration function for the measurement procedure is valid in the working range of the measurement results; c) the measurement procedure has an appropriate limit of quantification; d) the measurement procedure is sufficiently precise to make meaningful statements about the variation of the measurement results; e) the measurement procedure is calibrated with standards traceable to the same reference as the assigned value (refer to Annex A for more information); f) all other relevant input quantities have been appropriately calibrated?			
	NOTE These requirements are met if appropriate selectivity, limit of quantification, working range, precision and trueness of a method have been established.			
5.12.4	To ensure the metrological traceability of the assigned values, does the reference material producer provide documentary evidence that all measurement results used for value assignment are traceable to the same reference as the assigned value?			
	NOTE A combination of results obtained by different methods and/or laboratories – all being traceable to the same reference – is also traceable to this reference.			
	An additional discussion on the concept and requirements of metrological traceability is given in Annex A of ISO Guide 34.			
5.13 Assessment of Homogeneity				
5.13.1	Assessment of homogeneity is always required to establish that the degree of homogeneity of the reference material with respect to the property(ies) of interest is fit for purpose.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	The definition of reference material as "*sufficiently* homogeneous" inherently requires quantification or limits for heterogeneity to demonstrate fitness for purpose. Therefore, the provisions of ISO Guide 35 for homogeneity testing also apply for the production of non-certified reference materials.			
5.13.1	APLAC TC 008: Under normal circumstances, the degree of homogeneity assessment of a RM with respect to the property of interest should be performed. If the homogeneity of a property value is based on the assessment of another value, has correlation been demonstrated with analytes that are tested for homogeneity? Note: See the requirement given in clause 5.12.3.1 of ISO Guide 34:2009 in case homogeneity testing is done only on a subset of the assigned values.			
5.13.2	APLAC TC 008: When data from assessment of homogeneity are used for assigning the property values, the requirements for metrological traceability (Section 5.12 of ISO Guide 34:2009) and characterization (Section 5.15 of ISO Guide 34:2009) applied to the test procedures used?			
5.13.2	Does the reference material producer carry out an assessment of the homogeneity of any candidate reference material? In most cases, does this involve analyzing a representative number of randomly, systematically or stratified randomly chosen units? Is testing, calibration, measurement, sampling or other activities performed for the assessment of homogeneity carried out in compliance with ISO/IEC 17025? Are measurement procedures selected so that the repeatability is fit for the purpose required? Are the homogeneity studies designed and performed in accordance with ISO Guide 35? Although the measurement values do not have to be communicated to customers, is the degree of homogeneity (e.g. expressed as maximum between- bottle variation) indicated in the documentation accompanying the reference material?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.13.2	If the material is produced in several batches, does the reference material producer test the equivalence of the batches (or to assign property values to each batch separately)?			
5.13.2	Is the assessment performed after the material has been packaged in its final form unless stability studies indicate that storage should be maintained in bulk form? In some cases, are intermediate homogeneity checks found to be necessary (e.g. prior to bottling/ampouling)?			
	NOTE 1 For reference materials that are expected to be homogeneous on physical grounds, the main purpose of homogeneity testing is to detect unforeseen problems, for example point contamination during packaging into individual units, or incomplete dissolution or equilibration of an analyte in a solvent (which could lead to steadily changing concentrations). For these types of examples, systematic sampling (e.g. one from every 50 samples produced in a continuous process; sampling at regular intervals for each sub-batch in those cases where the sub-batch can be defined) may be a better way to detect inhomogeneity than random sampling. A statistical trend analysis may also be helpful in detecting inhomogeneity.			
	NOTE 2 A relatively inhomogeneous material may be the best available, and may therefore still be useful as a reference material, provided the uncertainties of the assigned property values take due account of this.			
5.13.3	Is the amount of tested material on which the homogeneity of the reference material has been established specified in the documentation supplied by the reference material producer? Does this documentation also state the minimum sample size for use (see ISO Guide 31)?			
	NOTE Although ISO Guide 31 is strictly speaking established for certified reference materials, the requirement for indicating the minimum sample size is also valid for non-certified reference materials.			
5.14 Assessment of Stability				
5.14.1	Assessment of stability is always required to establish that the degree of stability of the reference material is fit for purpose.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	The definition of reference material as "*sufficiently* stable" inherently requires quantification or limits for degradation to demonstrate fitness for purpose. Therefore, the provisions of ISO Guide 35 for stability testing also apply for the production of non-certified reference materials.			
5.14.1	APLAC TC 008: Under normal circumstances, stability assessment for each and every certified property value should be performed. If the stability of a property value is based on the assessment of another value, has correlation been demonstrated with analytes that are tested for stability?			
5.14.2	Is the stability of the reference material assessed? Are testing, calibration, measurement, sampling and other activities performed for the assessment of stability carried out in compliance with ISO/IEC 17025? Is stability testing performed only if sufficient homogeneity is demonstrated? Is the stability studies sha designed and performed in accordance to ISO Guide 35?			
5.14.2	The evaluation of measurement data as described in ISO Guide 35 covers only apparently stable materials. In case of detectable degradation, is both the degradation and its uncertainty included in the assessment?			
5.14.2	Are the properties of interest of the candidate reference material evaluated for the adopted storage conditions? Are the effects of, for example, light, moisture and temperature evaluated in function of time for estimating a lifetime of the reference material and hence establishing a period of validity of the certificate?			
5.14.2	Although the measurement values do not have to be communicated to customers, is the degree of stability indicated in the documentation accompanying the reference material?			
5.14.2	APLAC TC 008: Prediction of stability using a model is acceptable if such model is well established and widely accepted in the discipline concerned.	Note	Note	
5.14.3	Is the stability of the material under transport conditions assessed?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.14.3	APLAC TC 008: In cases where data from assessment of stability are used for assigning the property values, are the requirements for metrological traceability (Section 5.12 of ISO Guide 34:2009) and characterization (Section 5.15 of ISO Guide 34:2009) applied to the test procedures used?			
5.14.4	Where appropriate, is an assessment of the stability of the reference material performed at periodic intervals after characterization, to confirm that all values are maintained from production until the expiry date? Does the reference material producer provide a period of validity of the certificate which is stated in the documentation accompanying the material? Is it made clear on the documentation on which starting date the period of validity is based (e.g. the date of certification, the date of shipment of the reference material or the date of opening the packaging)?			
5.14.4	APLAC TC 008: Does stability assessment (should) include assessment of the effects of transport? Note: This includes studies with actual packaging and transport shipping under maximum stress conditions, e.g., distance, and temperature.			
5.14.5	Does the reference material producer inform its customers about shelf-life changes of the reference material including possible consequences for its use?			
5.14.5	APLAC TC 008: Does the stability assessment (should) include assessment of the effects of use? Note: This includes studies with multiple subsamples and any requirements for changed temperature for storage before subsampling. Is any associated uncertainty (could be) expressed within the long term stability assessment or as considerations described in the in the certificate?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.14.6	APLAC TC 008: When homogeneity and stability data obtained in previous batches are used, does the RMP (shall) demonstrate that the data are still applicable to the current batch? Does the RMP (shall) re-assess homogeneity and / or stability if there is a change of procedure, or the source of the candidate materials, for producing the RMs? Does the RMP (shall) also re-assess homogeneity and / or stability when any deviation from previous data has been observed? Note: The extent of the check from batch to batch can vary depending on the type of RM and the consistency of the process.			
5.15 Characterization				
5.15	For certified reference materials, does the producer use and document technically valid procedures to characterize its reference materials? Does the characterization comply with the requirements of ISO Guide 35 and ISO/IEC 17025 for testing, calibration and related activities?			
5.15	There are several technically valid approaches for characterizing a reference material. Do these include carrying out measurements using a) a single (primary) method in a single laboratory; b) two or more independent reference methods in one or several laboratories; c) one or more methods of demonstrable accuracy, performed by a network of competent laboratories; d) an approach providing method-specific, operationally defined property values, using a network of competent laboratories?			
5.15	Depending on the type of reference material, its intended use, the competence of the laboratories involved and the quality of methods employed, is one approach chosen as appropriate?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.15	Are results obtained from proficiency testing used only if the competence of the laboratories involved has been checked and it has been ensured that the measurements done comply with ISO/IEC 17025 (see also 5.3)?			
5.15	Is the single (primary) method approach carried out only when the procedure and expertise enable it to ensure metrological traceability? Is a property value reliably assessed when its value is confirmed by several laboratories working independently and using more than one method, for each of which the accuracy has been well established?			
5.15.1	APLAC TC 008: When a property value is method-specific or operationally defined, does the RMP (shall) use that method that defines the property value for characterization? Are details of the characterization procedures used (shall) be recorded? When more than one laboratory is engaged for characterization, do all of them (shall) use the same method? Such property values are only meaningful when applied to the same method. Therefore, to be more useful, are the methods used (shall) those published by standard writing bodies or widely recognized professional bodies in the concerned field?			
5.16 Assignment of Property Values and Their Uncertainties				
5.16.1	Does the reference material producer use documented procedures, as outlined in ISO Guide 35, for the assignment of property values?			(Assessor: list the procedures used for meeting the requirements of ISO Guide 35)

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.16.1	Do these procedures include, as appropriate: a) details of the experimental designs and statistical techniques used; b) policies on treatment and investigation of statistical outliers and/or the use of robust statistics; c) whether weighting techniques are used for contributions to assigned property values derived from different methods with different measurement uncertainties; d) the approach used to assign uncertainties to the property values; e) any other significant factors which may affect the assignment of property values?			
5.16.1	Does the reference material producer never rely entirely on only a statistical analysis of the characterization data when assessing the property values of interest? Are outliers not excluded on statistical evidence until they have been thoroughly investigated and, where possible, the reasons for the discrepancies identified? Alternatively, the use of robust statistics may be appropriate in some cases.			
5.16.1	Does the reference material producer following the criteria for assignment of property values? When several methods have been used to characterize a reference material, difficulty may arise when the results show significant differences, in which case a property value based on the mean is inappropriate. It is essential in such cases that the reference material producer and its subcontractors have considerable experience of the different methods and are able to give more or less weight to the results from the use of a particular measurement method. In some cases, the results may be weighted according to the inverse of the variance of each method. In some cases, measurement methods will produce irreconcilable results and it may be necessary to assign separate property values according to the methods used (i.e. a method-specific approach).			
5.16.1	In assigning the property values of interest, does the reference material producer consider establishing a group of independent experts whose responsibility is to check that all work, data and documents are fit for their purpose?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.16.1	APLAC TC 008: As CRMs are often used by laboratories for establishing their metrological traceability, it is important that the uncertainties of the assigned values are estimated using methods which are generally more rigorous than for other purposes. The uncertainties include not just the measurement uncertainty of the characterization procedure but also other contributions.	Note	Note	
5.16.2	An important aspect of establishing the property values of the reference material being produced is an assessment of their uncertainties. Does the reference material producer carry out an assessment of the measurement uncertainties to be included in the assignment of the property values in accordance with the requirements of the GUM (ISO/IEC Guide 98-3)? In the process of estimating uncertainties of the property values of interest, are any uncertainties resulting from between-unit variations and/or from possible doubts on stability (both during storage and during transportation) assessed in accordance with ISO Guide 35 and included in the assigned uncertainty?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
ISO Guide 35: 5.12	Is the following presented in the project design for preparation of the CRM? a) definition of the reference material, i.e. the matrix, the properties to be certified and their desired levels, and the level of uncertainty desired; b) design of a sampling procedure; c) design of a sample preparation procedure; d) selection of measurement methods appropriate for homogeneity and stability testing; e) design of the characterization of the reference material; f) sampling; g) sample preparation; h) choice of suitable methods for the characterization; i) homogeneity testing; j) stability testing; k) characterization of the reference material; l) combination of the results from homogeneity testing, stability testing and characterization, including a full evaluation of measurement uncertainty; m) design of a certificate and, if appropriate, a certification report. More details on these elements are presented in ISO Guide 35.			
5.16.2	A statement of the measurement uncertainty is mandatory for certified values. In case values are assigned to non-certified reference materials (e.g. “indicative values” or “information values”), a statement of uncertainties is highly recommended to improve the use of the material.			
5.16.2	APLAC TC 008: Uncertainty in this Section covers both “measurement uncertainty” of a quantity value and “uncertainty” associated with a nominal property (i.e. property of a phenomenon, body, or substance, where the property has no magnitude e.g. color chart, DNA sequence, etc).	Note	Note	
5.16.3	APLAC TC 008: Does the estimation of uncertainty (should) include at least the effects of characterization, homogeneity, transport, and long term storage? If any of these effects are known to be negligible, that can be described here.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.16.4	APLAC TC 008: *Where practicable* does the measurement / characterization model (shall) include contributions applicable to a best typical batch production and include contributions from short term stability (u_{sts}), long term stability (u_{lts}) and homogeneity (between bottle variation u_{bb})? Note: These batch dependent contributions may be based on expected conditions as applicable for each material type.			
5.16.5	APLAC TC 008: The uncertainty of property values from single-artifact CRMs that are certified based on a single calibration may be carried out using the normal procedures as outlined in the GUM. In theses cases does the uncertainty calculation of this type of CRM (shall) also include long term stability effects? *Note An example of this type of CRM would be a hardness block.*			
5.16.6	APLAC TC 008: Does the RMP (shall) have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment, a change of subcontractors, a change of material suppliers or other changes that would significantly affect the magnitude of relevant uncertainty components?			
5.17 Certificates or Documentation for Users				
5.17	Does the reference material producer issue a certificate for certified reference materials and provide appropriate documentation for non-certified reference materials in the form of a statement, analysis report, or information sheet howsoever named?			
5.17	Do the contents of certificates for certified reference materials comply with the requirements of ISO Guide 31? If the certificate also contains non-certified values, is a clear distinction made between certified and non-certified values?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
ISO Guide 31	Is the following information considered for inclusion on the certificate for a CRM? 5.2 Name (*) and address of certifying body (RMP) 5.3 Title of document 5.4 Name of material (*) 5.5 Reference material code (*) and batch number 5.6 Description of CRM (*) 5.7 Intended use (*) 5.8 Instructions for correct use (*) including minimum sample size (**) 5.9 Hazardous situation 5.10 Level of homogeneity (**) 5.11 Certified values and their uncertainties (*) 5.12 Traceability 5.13 Values obtained from individual laboratories or methods (*) 5.14 Uncertified values 5.15 Date of certification 5.16 Period of validity (*) 5.17 Further information 5.18 Names and signature of certifying officers 6.0 (*) Required elements plus information on appropriate storage (see 5.17 below) (*) Guide 34 requires these to be reported (**). Elements without (*) above from Guide 31 may be presented in order to enhance the information and are recommended to provide the user with needed information.			
5.17	Does the documentation for non-certified reference materials include information on homogeneity and stability and on the period of validity of the stated information? Does it also contain information for the user on the proper application and storage conditions of the reference material?			
	NOTE In some cases which are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.17.1	APLAC TC 008: A RMP may perform testing and/or calibrations related to the production of RMs. Do such tests and calibrations having a significant effect on the production of RMs (shall) meet the applicable requirements of ISO/IEC 17025? Note: It should be noted that the requirement for reporting of results under clause 5.10 of ISO/IEC 17025:2005 allows for reporting in a "simplified way" for internal customers and also that the requirements of clause 5.10 do not apply to certificates and documentation issued with the RMs. See also clause 4.13.2 of ISO Guide 34:2009.			
5.17.2	APLAC TC 008: A RMP is allowed to contract out some of its tasks to competent subcontractors. Note: It may not be necessary to indicate which parts of the production process have been subcontracted in the certificate of CRMs or the documentation for RMs.	Note	Note	
5.17.3	APLAC TC 008: Do certificates or documentation for a certified RM or non-certified RM (should) contain a unique identification of its production process? Note: This identification may take the form of a reference number, the name of the process or in other suitable information.			
5.17.4	APLAC TC 008: There are reference cultures kept in various economies such as American Type Culture Collection (ATCC), Type Culture Collection of Chinese Academy of Science (CGMCC), National Collection of Type Cultures (NCTC), UK, and European Collection of Animal Cell Cultures. Traditional, biochemical tests and culturing techniques are used to define the identity of microorganisms and recently DNA sequencing is also being used. For biological CRMs, do the traceability statement (shall) state which reference cultures, or which definition, is used as the reference?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.17.5	APLAC TC 008: For some biological CRMs, both the DNA sequence as well as the identity of the microorganism are given on the certificate. Does the certificate of such CRMs shall state clearly the certified property value, i.e. whether it is the identity or the DNA sequence or both? If the DNA sequence is not the certified values, but only used for characterizing the microorganism, is this then (shall be) stated clearly in the certificate?			
5.17.6	APLAC TC 008: In addition, for some biological CRMs are produced by sub-culturing of a reference culture higher in the metrological hierarchy such as those kept by a national institute as listed in 5.17.4 above. Is a clear indication of the reference culture as well as the number of passages and the sub-culturing techniques (shall be) provided in the certificate?			
5.17.7	APLAC TC 008: In cases where the biological CRMs are used for matching the test results (such as DNA sequence or serological / biochemical tests) with that of the test specimens, is the test (DNA sequence or serological / biochemical tests) used to characterize the microorganisms as well as the test results (shall be) given in the certificate?			
5.17.8	APLAC TC 008: For those CRMs where the identity of a chemical compound is the certified property value, does the certificate (shall) include both the identity as well as the purity of the compound and, if applicable, other information such as its molecular structure and the confirmatory technique(s) used to identify the compound?			
5.18 Distribution Service				
5.18.1	Is the distribution process carefully studied to avoid deterioration of the reference material (see 5.14.3)? Does the producer determine the conditions of shipment, the maximal time the shipment may endure under the conditions chosen and what documentation is required to allow customs clearance?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	NOTE For some reference materials, additional documentation related to, for example, origin, conformity of the material to safety requirements, might be required for customs clearance.			
5.18.2	Does the reference material producer maintain an up-to-date record of all reference material sales or distribution?			
5.18.3	Does the reference material producer offer customer's reasonable guidance and technical support related to the reference materials it produces?			
5.18.4	Does the reference material producer employ best efforts to notify customers of any change to the assigned value or uncertainty for any products not expired?			
5.18.5	Where goods are subject to resale through an authorized distributor, with whom the producer has a contractual relationship, does the reference material producer pass on to its authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and to make arrangements with the distributor to ensure that its activities are executed in accordance to the relevant parts of this Guide?			
5.18.6	Where goods are subject to resale by other organizations, the producer has no control over these organizations' activities after they have purchased. Therefore, the requirements regarding distribution service to such resellers are limited to the first reseller as with any direct customer.			

Additional Requirements (Required for surveillance and re-accreditation assessments)

Objective Evidence of Laboratory's utilization of PJLA's accreditation symbol must be included in the package. This includes but not limited to (Website page, letterhead, test or calibration report including subcontracted results if utilized and calibration labels)

If any of the requirements of SOP-3 are not followed a nonconformance must be written

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
Use of the Symbol	For applicant laboratories: Does the applicant laboratory use the PJLA Logo? Note Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval.			
	Is the accredited RMP utilizing the correct symbol (i.e. RMP)?			
	Is the symbol reproduced in a size that is clearly distinguishable?			
	Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited RMP)? Is the symbol identifiable?			
	Is the accredited RMP properly stating their accreditation status? Example: "Accredited to ISO Guide 34:2009"			
	Is the accredited RMP properly using the symbol on: a) promotional material and business stationary? b) certificates or labels? ISO Guide 31) c) website? d) technical literature? e) business reports f) quotations or proposals for work? (symbols may only be listed for accredited RMP)			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Is the accredited RMP appropriately using the symbol by **not** placing the symbol on: a) legal documents (i.e. contracts or checks) b) on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation? c) any documentation of sites that are not accredited by PJLA d) on subcontractor's certificates or documentation? e) on products or items which the RMP has produced?			
	Subcontracted Tests or Calibrations			
	If the accredited RMP included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have: a) obtained approval from the subcontracted laboratory? b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate? c) objective evidence that the subcontractor itself is accredited for the specific tests or calibrations concerned and results have been included in the subcontractor's endorsed report or certificate?			
****To be reviewed at all assessments (Accreditation, Surveillance and Reaccreditation****				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
PL-1 Proficiency Testing Requirements for Applicant and Laboratories that are part of the RMP operations (NOT a Subcontractor)				
	For applicant laboratories: Is there objective evidence for PT activity for at least item to be included within proposed scope of accreditation? Are the results meaningful i.e. demonstrating the laboratory's competence in performing specified tests or calibrations?			
	For accredited laboratories: Is there a documented proficiency testing plan or schedule? Does this plan or schedule include all items included on the scope of accreditation to be tested within a four year period? Has the laboratory completed at least one proficiency test each year? Has the proficiency plan or schedule been approved by PJLA?			
	For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
PL-2 Measurement Traceability Policy				
	Does the RMP have documented policies and procedures regarding measurement traceability and reference this traceability on certificates or reports? Does the RMP have documented procedures detailing the verification, transport and storage of reference materials?			
	Has the RMP employed the services of an external calibration or RM provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s)/test(s) performed or ISO Guide 34:2009 for RMP? If not, can the RMP demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI?			
	Does the RMP have on file and available the current certificates and scopes of accreditation for the external calibration or testing laboratories or RMP employed?			
PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories				
	For applicant laboratories that are part of the RMP operations: (Not subcontractors) Has the RMP applied its documented procedure to provide measurement uncertainties for every RM or CRM listed in its scope of accreditation?			
	APLAC TC008 (sections 6.5 – 6.12): Has the RMP determined the Reference Value Capabilities (RVC) which (shall) include the RMP's estimate of its least uncertainty of measurement (U_{CRM}) for each property value's range it reports? Note: Per APLAC TC 008 (section 6.6) CRMs that are an identification value (such as species identification) or where the property value is an ordinal number (such as color fastness chart) do not require an uncertainty of measurement on the scope of accreditation.			

For accredited laboratories: Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget? (as appropriate - see note above) Does the RMP include a metrological statement or reference estimated uncertainties on certificates or reports?			
APLAC TC 008 (section 6) Have the current Reference Value Capabilities (RVC) been determined, reviewed and/or modified?			
Surveillance of Previous Nonconformities and Corrective Action			
The assessor shall verify that previous nonconformities have been resolved and that corrective actions have been effectively implemented.			

Additional Notes: