ISO 17034:2016
WORKING DOCUMENT INSTRUCTION PAGE

NOTES:

1. This working document is intended as a checklist for the assessor when conducting RMP (RMP) Accreditation Assessments according to ISO 17034:2016.

2. Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These notes may be useful when preparing the assessment report, the NCR summary 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. At a minimum should be 1 comment per major element of the checklist. (e.g. 4.1, 4.2, 5.8, 5.10 etc)

3. Do not recommend specific solutions to nonconformances, 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 17034:2016, contact the PJLA office immediately.

Organization Name:	
Address: (Mailing)	
Address: (Physical Location)	
Telephone:	
Fax:	
E-mail:	
Web Address:	
Assessment Location (If different):	
Assessment Number:	
Assessment Date(s):	
Assessment Organization:	
Assessor(s):	
Signature:	

Section	Assessment	Yes	No	Comments
4 General requirements				
4.1 Contractual matters				
4.1.1	Are any request, tender or contract concerning the production of an RM reviewed, following documented policies and procedures established by the RMP, to ensure that:			
	the requirements for RMs and their production are adequately defined, documented and understood?			
	the RMP has the capability and resources to meet the requirements?			
Note 1	*Capability means that the RMP has access to, for example, the necessary equipment, knowledge and information resources and that its personnel have the skills and expertise necessary for the production of those RMs in question. The review of capability can include an assessment of previous RM production and/or the organization of interlaboratory characterization programmes using samples of similar composition to the RMs to be produced.*			
Note 2	*A contract can be any written or verbal agreement.*			
Note 3	*A request to prepare a specific RM can originate from the RMP.*			
APAC TEC1-008 4.1.1	When ensuring the requirements for a RM is adequately defined, documented and understood, the RMP will need to consider that the matrix, property values and the value's metrological traceability and measurement uncertainty meet the needs of the given application or field of application. In some cases, the stability time required should also be included in the review. If necessary, the RMP should give advice to the customers and help them to determine their needs.	Note	Note	
4.1.2	Does the review include any work that needs to be subcontracted by the RMP?			

Section	Assessment	Yes	No	Comments
4.1.3	Does the RMP maintain records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work?			
4.2 Impartiality				
4.2.1	Is the RMP structured and managed so as to safeguard impartiality?			
Note	*Impartiality implies that decisions are based on objective criteria and not on the basis of bias, prejudice, or preferring the benefit of one person over another for improper reasons.*			
4.2.2	Does the RMP:			
	a) 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?			
	b) identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel; however, such relationships do not necessarily present an RMP with a risk to impartiality?			
	c)have the ablility to demonstrate, if a risk to impartiality is identified, how it eliminates or minimizes such risk?			
	d) have top management commitment to impartiality?			
Note	*A relationship that threatens the impartiality of the RMP can be based on ownership, governance, management, personnel, shared resources, finances or contracts for purposes other than the sale or production of RMs.*			
4.3 Confidentiality				

Section	Assessment	Yes	No	Comments
4.3.1	Is the RMP responsible for and treat in an appropriate manner all information obtained, including confidential information? Where information is received from another individual or body, is such information regarded as confidential unless the individual or body concerned places the information in the public domain or agrees to its disclosure to others?			
4.3.2	When the RMP is required by law or authorized by contractual arrangements to release confidential information is the individual or the body concerned, unless prohibited by law, notified of the information provided?			
5 Structural requirements				
5.1	Is the RMP a legal entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs?			
5.2	Is the RMP organized and operate in such a way that it meets all the applicable requirements of this International Standard, whether carrying out work at its permanent facilities or at other sites (including associated temporary or mobile facilities)?			
	Does the RMP:			
	a) have a description of its legal status, define the organizational and management structure of the RMP, its place in any parent organization and the relations between management, technical operations, support services and subcontractors?			
	b) define the parts of the organization covered by the management system for the production of RMs?			
	c) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of RMs produced?			

Section	Assessment	Yes	No	Comments
5.3	d) 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 RMs and to initiate actions to prevent or minimize such departures?			
	e) have technical management with 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 RM production?			
	f) appoint personnel (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this International Standard are implemented and followed at all times – these appointed personnel shall have direct access to the highest level of management at which decisions are taken on RM production policy or resources?			
	g) have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities?			
5.4	Does the RMP management ensure that:			
	a) internal and external communication mechanisms are established?			
	b) communication takes place regarding the effectiveness of the management system?			
	c) the importance of meeting customer and other requirements is communicated to the RMP personnel?			
6 Resource requirements				
6.1 Personnel				
6.1.1	Does the RMP ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system?			

Section	Assessment	Yes	No	Comments
6.1.2	Does personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf, comply with the policies and procedures for management of confidential information that are set by the RMP?			
6.1.3	Does the RMP ensure the competence of all personnel, including technical management personnel, operating under its management system who undertake activities relating to the production of each particular type of RM? Is there sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions?			
6.1.4	Does the RMP have procedures for identifying training needs and providing training of personnel.? Is the training program relevant to the present and anticipated tasks of the RMP?			
6.1.5	Does the RMP maintain records of job descriptions for its personnel involved in RM production activities?			
6.1.6	Does the RMP authorize competent personnel to perform particular activities relating to RM production? Does the RMP maintain records of the authorizations, competence, educational and professional qualifications of those personnel.? Do these records provide evidence that individuals have been adequately trained and that their competence to perform particular activities in the RM production has been assessed? Is this information readily available and include the date on which the authorization and/or competence has been confirmed?			
6.2 Subcontracting				

Section	Assessment	Yes	No	Comments
6.2.1	Where an RMP uses subcontractors to undertake part of the production, including sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM, the RMP are there procedures to ensure that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards?			
Note 1	*It is possible that an RMP does not have its own laboratory facilities or processing facilities, or it can choose not to use its own facilities.*			
Note 2	*Subcontractors can be paid or unpaid.*			
6.2.2	Does the RMP select subcontractors on the basis of their ability to meet the requirements stipulated by the RMP?			
6.2.3	Has the RMP ensured not to subcontract the following processes: — the production planning? — the selection of subcontractors? — the assignment of property values and their uncertainties? — the authorization of property values and their uncertainties? — the authorization of RM documents?			
6.2.4	Has the RMP established and maintained procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP and with any relevant clauses of this International Standard?			
6.2.5	Has evidence of the subcontractor's competence been established and maintained, including records of evaluations and any audits made of their capability to carry out contracted tasks?			

Section	Assessment	Yes	No	Comments
Note	*Examples of evidence are assessments of tasks performed for the RMP in the past, evidence of successful participation in relevant proficiency testing, conformity assessment certificates relevant for the task contracted and acceptable results on well-characterized materials of similar or equivalent nature to that of thecandidate RM.*			
6.2.6	Where the competence of subcontractors cannot be ascertained via provision of documentary evidence, doe the RMP shall evaluate the competence of the subcontractor or supervise the operations carried out by the subcontractor?			
6.2.7	Does the RMP ensure that results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data?			
6.2.8	When working with subcontractors, does the RMP have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity?			
Note	*For testing activities, this includes knowledge of the task involved and familiarity with this International Standard and ISO/IEC 17025 for calibration and testing.*			
6.3 Provision of Equipment, Services and Supplies				
6.3.1	Does the RMP have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced?			
6.3.2	Does the RMP use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces?			
6.3.3	Does the RMP ensure that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities?			

Section	Assessment	Yes	No	Comments
6.3.4	Does the RMP maintain records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data?			
Note	*6.3 applies to all equipment including material processing and measuring equipment. 7.7 includes more provisions on operation of measuring equipment.*			
6.4 Facilities and Environmental Conditions				
6.4.1	Does the RMP ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable)?			
6.4.2	When the environmental conditions could have an adverse effect on the RM, have the environmental conditions in which the RM production activities are undertaken been monitored with appropriately calibrated equipment, and controlled and recorded, such that results and processes are not adversely affected?			
6.4.3	Are all RM processing and calibration and testing areas, in addition to satisfying requirements for humidity and temperature, protected, where appropriate, from other environmental factors such as incompatible activities, vibration, aerosols, airborne dust and microbiological contamination, magnetic fields, light and electromagnetic and/or ionising radiation?			
6.4.4	Are access to and use of areas controlled as appropriate to maintain the quality of the RMs?			
7 Technical and Production Requirements				
7.1 General requirements				

Section	Assessment	Yes	No	Comments
7.1	Does the RMP address the requirements in this clause for the production of RMs, including CRMs?			
Note 1	*A CRM has at least one certified value.*			
Note 2	*7.9 applies only to certified values.*			
Note 3	*7.2 to 7.18 contain requirements for certified values and other property values where necessary. Annex A is a summary of production requirements for RMs and CRMs.*			
7.2 Production planning				
7.2.1	Does the RMP identify and plan those processes that directly affect the quality of RM production, and the production plan shall be documented?			
Note	*A mechanism (e.g. a management/technical advisory group) can be established to make recommendations on part or all of the production processes, for example, assigning the property values of interest.*			
7.2.2	Is technical input of subcontractors involved specified and the required information documented and regularly reviewed?			
7.2.3	Does the RMP address, during the planning stage, the following:			
	a) material selection (including, where appropriate, sampling)?			
	b) verification of the identity of the material?			
	c) maintaining suitable environments for all aspects of production (see 6.4)?			
	d) material processing (see 7.5)?			
	e) choice of measurement procedures (see 7.6,)?			
	f) validation of measurement procedures (see 7.6)?			
	g) verification and calibration of measuring equipment (see 7.7)?			
	h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling (see 7.10)?			
	i) specification of acceptance criteria for, and assessment and monitoring of, stability, including sampling (see 7.11)?			
	j) designing and organizing appropriate characterization, including sampling (see 7.12)?			
	k) assessing commutability (where appropriate)?			

Section	Assessment	Yes	No	Comments
Note	*Guidance on the need for commutability assessment of RMs is given in a REMCO position paper[15].*			
7.2.3	l) assigning property values (see 7.13)?			
	m) establishing uncertainty budgets and estimating uncertainties of certified value(s) (see 7.13)?			
	n) defining acceptance criteria for measurand levels and their uncertainties?			
	o) establishing metrological traceability of measurement result(s) and certified value(s) (see 7.9)?			
	p) issuing RM documents (see 7.14)?			
	q) ensuring adequate storage facilities and conditions (see 7.4)?			
	r) ensuring appropriate labelling and packaging of the RMs (see 7.14)?			
	s) ensuring appropriate transport arrangements (see 7.15)?			
	t) ensuring post-production stability monitoring, if applicable (see 7.11)?			
	u) ensuring an adequate post-distribution service for RM users (see 7.15)?			
7.2.4	Where multiple batches of RMs with equivalent properties are produced by using similar starting materials and by applying the same procedures, does verification ensure that information obtained from previous batches remains applicable for the new batch (see 7.2.3)?			
Note 1	*Multiple batches can be batches of the same material produced at the same time, or can be successive batches of material produced at substantially different times.*			
Note 2	*Further guidance for multiple batch productions is given in ISO Guide 35.*			
Note 3	*Where multiple batches are produced, some tests can be omitted or simplified for some batches (see 7.10.2 and 7.11.3).*			
APAC TEC1-008 7.2.3	It is understood that pilot studies may sometimes need to be carried out and the need of any pilot study should be considered at the planning stage.	Note	Note	

Section	Assessment	Yes	No	Comments
7.3 Production Control				
7.3	Does the RMP verify that the production plan has been implemented as specified, and are deviations from the plan documented and approved?			
7.4 Material Handling and Storage				
7.4.1	Does the RMP make arrangements to ensure the integrity of its candidate RMs and RMs throughout the production process? Are precautions taken against adverse environmental influences (see 6.4) and possible contamination of the candidate RM during its processing?			
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 can also be required for other types of trace analysis. Proper choice of container material and adequate cleaning procedures are also important to avoid contamination.*			
7.4.2	Does the RMP identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution to users?			
Note	*It can be useful to uniquely identify each unit of a (candidate) RM in order to facilitate subsequent sampling, trend analysis, distribution services or complaints investigation.*			
7.4.3	Does the RMP ensure adequate packaging of all RMs (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?			

Section	Assessment	Yes	No	Comments
7.4.4	Are the condition of all RMs assessed at appropriate intervals throughout the storage period, in order to detect possible deterioration?			
7.4.5	Does the RMP control packaging and labelling processes to the extent necessary to ensure conformity with safety and transport requirements? Are procedures for transport to the customer defined?			
7.4.6	Does the RMP take measures to ensure that the integrity of each individual RM unit is maintained until the seal, if any, has been broken or up to the point when first used?			
7.5 Material Processing				
7.5.1	Does the RMP establish procedures to ensure that the material has undergone adequate processing for its intended use? Do procedures for material processing address at least the following:			
	a) qualitative analysis for verification of material type and/or identity?			
	b) synthesis, purification (e.g. distillation, extraction), incubation, and 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) (see 7.4)?			
	e) measurements for control of material processing (e.g. particle size distribution, moisture content)?			
	f) pre-treatment, cleaning or sterilization of processing equipment and sample containers?			
	g) stabilization of material (e.g. drying, irradiation, sterilization)?			
	h) packaging (e.g. bottling, ampouling) of the material?			
	i) safety precautions?			
7.5.2	Equipment used in material processing shall be operated in accordance with documented procedures?			

Section	Assessment	Yes	No	Comments
Note	*Manufacturer's instructions are one form of documented procedure.*			
APAC TEC1-008 7.5	When candidate RMs are sent to subcontractors for testing, they should be uniquely labeled, suitably packed and stored in suitable conditions during transport. Instructions on the storage conditions should be given to the subcontractors	Note	Note	
7.6 Measurement procedures				
7.6	Does the RMP ensure that the relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing? Are these activities, where appropriate, consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned?			
APAC TEC1-008 7.6	The applicable requirements of ISO/IEC 17025 apply to measurement procedures. See Section 4, assessment of RMPs for additional guidance on application of the requirements of ISO/IEC 17025 for measurement procedures.	Note	Note	
7.7 Measuring equipment				
7.7	Does the RMP ensure that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025?			
Note	*Additional information on the management of measurement systems, including information on equipment that is found to drift outside acceptable limits, can be found in ISO 10012.*			
APAC TEC1-008 7.7	The applicable requirements of ISO/IEC 17025 apply to measuring equipment. See Section 4, assessment of RMPs for additional guidance on application of the requirements of ISO/IEC 17025 for measuring equipment.	Note	Note	
7.8 Data integrity and evaluation				
7.8.1	Does the RMP ensure that all calculations and data transfers are subject to appropriate checks?			
	Does the RMP ensure that:			

Section	Assessment	Yes	No	Comments
7.8.2	a) computer software developed in-house or off-the-shelf software further developed for specific use is validated and shown to be adequate for use?			
Note	*Examples of software validation can be a computer-based spreadsheet calculation that is checked by manual calculation or using test data sets with known solutions?*			
7.8.2	b) procedures are established and implemented for protecting the integrity of data; such procedures include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing?			
	c) equipment and software are maintained to ensure proper functioning and are 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 and changes to records, including computer records?			
7.8.3	Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate for their application?			
Note 1	*Validation of statistical procedures can include evidence of a sound theoretical basis (usually by reference to appropriate literature), known performance under the expected conditions of use and assumptions or conditions which can be shown to apply to the data sufficiently for the purpose at hand.*			
Note 2	*Additional information on control of data is provided in ISO/IEC 17025.*			
7.9 Metrological traceability of certified values				
7.9.1	When producing CRMs, have the metrological traceability of the certified values been established in compliance with the relevant requirements of ISO/IEC 17025? Does the RMP provide evidence of the metrological traceability of the certified value to a stated reference?			

Section	Assessment	Yes	No	Comments
Note 1	*A combination of results obtained by different measurement procedures and/or laboratories all being traceable to the same reference is also traceable to that reference.*			
Note 2	*The evidence can be based on evaluation of the measurement process or on confirmation of metrological traceability by comparison of results with independent traceable values.*			
Note 3	*Clear identification of the property of interest, traceability of the numerical value and the stated reference contribute to the traceability of results.*			
Note 4	*ISO/TR 16476 contains additional information on establishment and expression of metrological traceability of certified values.*			
7.9.2	Is the stated reference a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard?			
7.9.3	Where it is technically possible, does the RMP demonstrate that the stated reference is traceable to the International System of Units (SI)?			
7.9.4	Where metrological traceability to the SI units is not technically possible, does the RMP demonstrate metrological traceability to an appropriate reference (see traceability requirements in ISO/IEC 17025)?			
7.9.5	For studies in which the values need to be traceable to a higher order reference system (e.g. characterization studies with measurements under reproducibility conditions), is it ensured that the measurements are calibrated with standards with metrologically traceable values?			
7.9.6	Are secondary parameters that have a significant influence on the certified value or its uncertainty have evidence of metrological traceability?			
Note	*Examples of secondary parameters are temperature and humidity.*			

Section	Assessment	Yes	No	Comments
APAC TEC1-008 7.9	Additional guidance on reference materials and metrological traceability I s provided in Section 2 of this document. It should be noted that ILAC Policy on the Traceability of Measurement Results, P10, may also be applied to other conformity assesment activities where testing and/or calibration are involved.	Note	Note	
7.10 Assessment of homogeneity				
7.10.1	Does the RMP carry out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose?			
Note 1	*Assessment of homogeneity can include the use of prior evidence (including prior experimental evidence), the conduct of an experimental homogeneity study on the candidate RM or both. In most cases, an experimental study is necessary. Guidance on the need for an experimental homogeneity study is provided in ISO Guide 35.*			
Note 2	*In most cases, experimental homogeneity tests require measurements of a representative number of randomly chosen units. The units can be chosen for example by random selection, stratified random selection or systematic selection from a random start point.*			
7.10.2	When the material is produced in multiple batches, does the equivalence of the batches demonstrate or the homogeneity of each batch evaluated separately?			
7.10.3	Is validated measurement procedures selected so that the precision and selectivity are fit for the purpose required?			
APAC TEC1-008 7.10.3	It should be noted that the requirements for measurement procedures in clause 7.6 also apply to the assessment of homogeneity.	Note	Note	

Section	Assessment	Yes	No	Comments
7.10.4	Where homogeneity needs to be determined experimentally, does the RMP determine the homogeneity for every property of interest unless it can be shown, using scientific evidence or previous experience, that particular groups of properties are sufficiently closely associated that measurement of one property in such a group furnishes evidence of homogeneity for other properties in the same group?			
Note	*Guidance for homogeneity testing and the establishment of minimum sample size is given in ISO Guide 35.*			
7.10.5	For certified values, is homogeneity quantified as an uncertainty contribution to the certified value or shown to be a negligible contribution to the uncertainty of the certified value?			
7.11 Assessment and monitoring of stability				
7.11.1	Does the RMP:			
	a) assess, by experimentation if necessary, the stability of all relevant properties of an RM under proposed storage conditions and choose pre-treatment, packaging and storage conditions in accordance with the results of the assessment?			
	b) assess, by experimentation if necessary, the stability of all relevant properties of an RM under proposed conditions of transport, and choose transport conditions to maintain stability during transport?			
	c) establish any necessary advice on storage and use of the material to maintain stability at the user‘s premises?			
	d) select a scheme for monitoring the stability of materials held in long term storage that permits prompt detection of change, taking into account the possible rate of change?			
	e) where the stability of a certified value cannot be ensured, make due allowance in the stated uncertainty for possible change in the value prior to use or, where the change with time can be predicted, provide a means of correcting the certified value and its uncertainty for the expected change over time?			

Section	Assessment	Yes	No	Comments
	f) where repeated sampling from an RM unit or repeated use of an entire RM unit is permitted by the instructions for use, assess the possible effects on the stability of the material and take appropriate action?			
Note 1	*Where repeated sampling is permitted [see bullet f) above], appropriate actions can be, for example, provision of detailed instructions for handling and use after opening of the RM unit.*			
Note 2	*ISO Guide 35 provides detailed guidance on procedures in bullets a) to f) above.*			
Note 3	*The results of stability assessments can contribute to uncertainty evaluation (see 7.13.6).*			
APAC TEC1-008 7.11.1	Prediction of stability using a model is acceptable if such model is well established and widely accepted in the discipline concerned. It is noted, the requirements for measurement procedures in clause 7.6 also apply to the assessment of stability	Note	Note	
7.11.2	Does the RMP conduct an experimental assessment of stability before release unless the RMP has evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions?			
Note	*"Closely similar" materials are materials characterized for the same properties, which share the same matrix composition, processing conditions, similar or less effective packaging, etc.*			
APAC TEC1-008 7.11.2	Under normal circumstances, stability assessment for each and every property value should be performed. It is not appropriate to assume the stability of a property value based on the assessment of another value unless correlation is demonstrated.	Note	Note	
7.11.3	Where an RM is produced in multiple batches that are not individually tested for stability, does the RMP verify the stability of a sufficient number of different batches experimentally to providen confidence in the stability of all batches?			

Section	Assessment	Yes	No	Comments
Note 1	*Verification can be a simple test to confirm that different batches behave similarly or, for successive batches, do not change over their lifetime, while the experimental assessment of stability typically involves an extended study aimed at determining rates of change.*			
Note 2	*Further guidance for multiple batch productions is given in ISO Guide 35.*			
APAC TEC1-008 7.11.3	A change of procedure, or the source of the candidate materials, or a deviation from previous data may necessitate a reassessment of stability.	Note	Note	
7.12 Characterization				
7.12.1	Where the RMP assigns property values, is there characterization of the RM?			
7.12.2	Does the RMP clearly define whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure?			
7.12.3	Does the RMP select a characterization strategy appropriate for the intended use of the RM?			
Note 1	*Such characterization can include, but is not limited to, the following approaches:*			
	a) using a single reference measurement procedure (as defined in ISO/IEC Guide 99) in a single laboratory;			
	b) characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories;			
	c) characterization of an operationally-defined measurand using a network of competent laboratories;			
	d) value transfer from an RM to a closely matched candidate RM performed using a single measurement procedure performed by one laboratory;			

Section	Assessment	Yes	No	Comments
	e) characterization based on mass or volume of ingredients used in the preparation of the RM.			
Note 2	*ISO Guide 35 provides guidance on characterization.*			
APAC TEC1-008 7.12.3	When a property value is method-specific or operationally defined, only results using the same method are meaningful. Therefore to be more useful, methods published by standard writing bodies or widely recognized professional bodies in the concerned field are recommended.	Note	Note	
7.12.4	Does the RMP specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability and measurement uncertainty are reported on the RM documentation? To this end, does the RMP:			
	a) document a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterization?			
	b) for certified values, demonstrate the competence of each involved laboratory by using data from each laboratory that was not obtained on the material to be characterized?			
APAC TEC1-008 7.12.4	It is noted, the requirements for measurement procedures in clause 7.6 also apply to the characterization of assigned property values.	Note	Note	
7.12.5	When evaluating the characterization data, does the RMP perform a technical evaluation of the data and documents involved in characterization to confirm adherence to the measurement plan as defined in 7.12.4, bullet a), and, in the case of deviations from the plan, assess whether the deviation necessitates exclusion of the data from characterization?			
7.13 Assignment of property values and their uncertainties				
7.13.1	Does the RMP use documented procedures for the assignment of property values?			
	Do these procedures include, as appropriate:			

Section	Assessment	Yes	No	Comments
7.13.2	a) details of the experimental designs and statistical techniques used?			
	b) policies on treatment and investigation of anomalous results, including outliers?			
	c) whether weighting techniques are used for contributions to assigned property values derived from different procedures or laboratories with different measurement uncertainties?			
	d) the approach used to assign uncertainties to the property values?			
	e) any other significant factors that may affect the assignment of property values?			
7.13.3	Does the RMP take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest?			
Note	*ISO Guide 35 provides guidance on valid approaches for value assignment.*			
7.13.4	Have outliers not been excluded solely on statistical evidence until they have been investigated and, where possible, the reasons for the discrepancies identified? Are robust statistical methods applied where appropriate?			
Note 1	*An apparent outlier can be the only technically valid result in the data set.*			
Note 2	*ISO Guide 35 provides guidance on the use of robust statistical methods.*			
APAC TEC1-008 7.13.4	It is noted, the requirements for measurement procedures in clause 7.6 also apply to the characterization of assigned property values.	Note	Note	
7.13.5	For certified values, does the RMP identify the uncertainty contributions to be included in the assigned uncertainty?			
Note	*Further guidance on the estimation of uncertainties is given in ISO Guide 35 and ISO/IEC Guide 98-3.*			

Section	Assessment	Yes	No	Comments
APAC TEC1-008 7.13.5	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. It should be noted, however, that the uncertainty calculation of this type of CRM will need to include long term stability effects. Note An example of this type of CRM would be a hardness block. It is necessary to have a system for reviewing and updating 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.	Note	Note	
7.13.6	For certified values, does the RMP consider, at a minimum, uncertainty contributions of each of the following:			
	a) characterization, including any difference between multiple procedures used for characterization?			
	b) between-unit and within-unit inhomogeneity?			
	c) changes of property values during storage?			
	d) changes of property values during transport?			
Note 1	*Other uncertainty contributions can be important such as changes of property values in use or on repeated sampling.*			
Note 2	*Where values other than certified values are assigned to RMs (e.g. "indicative values" or "information values"), a statement of uncertainties can be appropriate to improve the use of the material.*			
APAC TEC1-008 7.13.6	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	
7.13 Assignment of property values and their uncertainties				

Section	Assessment	Yes	No	Comments
7.14.1	Does the RMP issue and make available an RM certificate for CRMs and product information sheet for other RMs?			
7.14.2	Does the contents of RM certificates and product information sheets include the following:			
	a) title of the document?			
	b) unique identifier of the RM?			
	c) the name of the RM?			
	d) name and contact details of the RMP?			
	e) intended use?			
	f) minimum sample size (whenever applicable)?			
	g) period of validity?			
	h) storage information?			
	i) instructions for handling and use that are sufficient to ensure the integrity of the material?			
	j) page number and the total number of pages?			
	k) document version?			
	l) information on commutability of the material (where appropriate)?			
7.14.3	In addition to the minimum requirements given in 7.14.2, do RM certificates contain the following additional information:			
	a) description of the CRM?			
	b) property of interest, property value and associated uncertainty?			
	c) measurement procedure for operationally defined measurands?			
	d) metrological traceability of the certified values?			
	e) name and function of RMP's approving officer?			
Note 1	*Further information on the content of certificates and accompanying documentation is given in ISO Guide 31.*			
Note 2	*Sector-specific requirements for RM certificates and product information sheets can exist and can be considered (e.g. ISO 15194 for in vitro diagnostic medical devices).*			

Section	Assessment	Yes	No	Comments
APAC TEC1-008 7.14.3	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. Additionally, traditional biochemical tests and culturing techniques are used to define the identity of microorganisms and/or DNA sequencing may also be used. The traceability statement for these CRMs will need to identify which reference cultures, or which definition (measurement procedure), is referenced as the stated reference. Where the stated reference is a reference culture, it may be appropriate to also state the number of passages and the sub-culturing techniques on the certificate.	Note	Note	
	For some biological CRMs, both the DNA sequence as well as the identity of the microorganism is given on the certificate in which case it is necessary to clearly identify the certified property value, i.e. whether it is the identity or the DNA sequence or both. Where the property value is operationally defined, it is necessary to clearly state the measurement procedure including the measurement unit, or the measurement standard. This is applicable for biological CRMs used for matching the test results (such as DNA sequence or serological / biochemical tests) with that of the test specimens, in which case the test (DNA sequence or serological / biochemical tests) used to characterize the microorganisms as well as the test results would be reported on the certificate.			

Section	Assessment	Yes	No	Comments
	Where the property value is operationally defined, it is necessary to clearly state the measurement procedure including the measurement unit, or the measurement standard. This is applicable for biological CRMs used for matching the test results (such as DNA sequence or serological / biochemical tests) with that of the test specimens, in which case the test (DNA sequence or serological / biochemical tests) used to characterize the microorganisms as well as the test results would be reported on the certificate. For those CRMs where the identity of a chemical compound is the certified property value it may be warranted to report both the identity and the purity of the compound and, if applicable, other information such as its molecular structure, the confirmatory technique(s) used to identify the compound, the stated reference and the criteria for identity confirmation. A state reference and the criteria for identity confirmation are needed for supporting traceability for such qualitative CRMs.			
7.14.4	Is the RM label securely attached to the product container of an individual RM unit, and designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM, i.e. the period during which the RM is available from the RMP extended by the period of validity of its certificate.? Does the label identify the material, the RMP, its batch, 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 product information sheet or RM certificate?			
7.14.5	Where the physical size of the RM unit limits the amount of information that can be contained on the label, is the information included elsewhere (e.g. in an RM document)? Is a unique identifier given [see 7.14.2, bullet b)]?			
Note	*Further guidance concerning the contents of RM certificates, labels and accompanying documentation can be found in ISO Guide 31.*			

Section	Assessment	Yes	No	Comments
7.15 Distribution Service				
7.15.1	Has the distribution process been specified including precautions needed to avoid deterioration of the RM (see 7.11.1)? Does the RMP determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance?			
Note 1	*The conditions of shipment can include for example shipping temperature, packaging, duration of transport and other precautions necessary for integrity of the material.*			
Note 2	*For some RMs, additional documentation related to, for example, origin and, conformity of the material to safety requirements, might be required for customs clearance.*			
7.15.2	Does the RMP maintain up-to-date records of all RM sales and distribution?			
7.15.3	Does the RMP offer to users reasonable guidance and technical support related to the RMs it produces?			
7.15.4	Does the RMP employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet?			
7.15.5	Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, does the RMP pass on to the authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and make arrangements with the distributor to ensure that its activities are executed in accordance with the relevant clauses of this International Standard?			
7.16 Control of quality and technical records				
Note	*Where RMs are subject to resale by other organizations, the RMP has no control over these organizations' activities after the RMs have been purchased. The requirements regarding distribution service to such resellers are limited to the first reseller.*			

Section	Assessment	Yes	No	Comments
7.16.1	Does the RMP establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records?			
Note 1	*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 action and improvement records.*			
Note 2	*Technical records are accumulations of data and information which result from carrying out RM production, measurement, testing and 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 users.*			
7.16.2	Does the RMP ensure that it has recorded such information that might be needed in a future dispute situation?			
7.16.3	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? Have retention time of records been established in accordance with customer or other relevant requirements, and documented?			
Note	*Records can be in the form of any type of media, such as hard copy or electronic media.*			
7.16.4	When mistakes occur in records, is each mistake be crossed out, not erased, made illegible or deleted, and the correct information entered alongside? Are all such alterations to records signed or initialled, and dated by the person making the correction? In the case of records stored electronically, has equivalent measures been taken to avoid the loss or change of original information?			

Section	Assessment	Yes	No	Comments
7.16.5	Are all records held securely and, where appropriate, in confidence?			
7.16.6	Does the RMP have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data?			
7.16.7	Does the RMP 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 RM remains valid?			
7.16.8	Have the results of each calibration or measurement (or series of either) carried out by the RMP or by a subcontractor reported in accordance with ISO/IEC 17025?			
7.17 Management of non-conforming work				
7.17.1	Does the RMP have 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?			
APAC TEC1-008 7.17.1	Common examples of non-conforming work include environmental conditions in the testing or calibration areas exceeding the specified limits, tests performed using instruments with overdue calibration, acceptance criteria of quality control not met, unsatisfactory performance in proficiency testing schemes, etc. It is important to note the need to keep records of nonconforming work in accordance with ISO 17034 clause 7.16.2 as these might be needed in a future dispute situation	Note	Note	
	Does the procedures ensure that:			
	a) responsibilities and authorities for the management of non-conforming work are designated?			

Section	Assessment	Yes	No	Comments
7.17.2	b) the actions to be taken when any non-conforming work and/or RMs are identified including rootcause analysis and a system that ensures that they are effectively implemented?			
	c) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action?			
	d) where necessary, work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld?			
	e) remedial actions such as customer notifications are taken within a defined time-frame?			
	f) where necessary, best efforts are employed to notify the users of the possible effects, within an appropriate period and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled?			
	g) the responsibility for authorization of the resumption of work is defined?			
	h) where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken?			
7.17.3	Is the decision on recall of RMs taken in a timely manner to limit the use of nonconforming RMs?			
Note	*The identification of non-conforming RMs or problems with the management system or with production activities can occur at various places within the management system, such as complaints, quality control, checking of consumable materials, staff observations or supervision, certificate and other appropriate documentation checking, management reviews and internal or external audits.*			
7.18 Complaints				
7.18.1	Does the RMP have a documented process to receive, evaluate and make decisions on complaints?			

Section	Assessment	Yes	No	Comments
7.18.2	Is a description of the handling process for complaints available to any interested party on request?			
7.18.3	Upon receipt of a complaint, does the RMP confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it?			
7.18.4	Is the RMP responsible for all decisions at all levels of the handling process for complaints?			
7.18.5	Are investigation and decision on complaints not result in any discriminatory actions?			
7.18.6	Does the process for handling complaints include at least the following elements and methods:			
	a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it?			
	b) tracking and recording complaints, including actions undertaken to resolve them?			
	c) ensuring that any appropriate action is taken?			
7.18.7	Is the RMP receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint?			
7.18.8	Whenever possible, does the RMP acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?			
7.18.9	Is the decision to be communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question?			
7.18.10	Whenever possible, does the RMP give formal notice of the end of the complaint handling process to the complainant?			
8 Management system requirements				
8.1 Options				
8.1.1	Does the RMP establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B?			

Section	Assessment	Yes	No	Comments
	Does the RMP define and document its scope of activities?			
8.1.2.2	Does the management system of the RMP address the following: — quality policy (see 8.2)? — general management system documentation (see 8.3)? — control of management system documents (see 8.4)? — control of records (see 8.5)? — management review (see 8.6)? — internal audit (see 8.7)? — actions to address risks and opportunities (see 8.8)? — corrective actions (see 8.9)? — improvement (see 8.10) ? — feedback from customers (see 8.11)?			
	Option B			
8.1.3	If the RMP has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this International Standard (ISO 17034), the RMP also fulfils the management system clause requirements in 8.2 to 8.11.			
8.2 Quality policy (Option A)				
8.2.1	Does the RMP define and document its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production, storage and distribution procedures?			
8.2.2	Has the RMP's management system policies related to quality, including a quality policy statement, been documented under the authority of the top management?			
	Does the quality policy include the following commitments:			
	a) to produce RMs which conform to the requirements of this International Standard?			
	b) to conduct all testing and calibration in support of the production of RMs in compliance with the requirements of ISO/IEC 17025?			

Section	Assessment	Yes	No	Comments
8.2.3	c) to require that all personnel concerned with the quality of any aspect of RM production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work?			
	d) 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 RMs?			
8.2.4	Are the overall objectives reviewed during the management review?			
8.3 General management system documentatin (Option A)				
8.3	Does the RMP document all of its systems, programmes, procedures, instructions, findings, etc., to the extent necessary to enable the RMP to ensure the quality of the RMs produced. Documentation used in this management system shall be communicated to, understood by, available to and implemented by all personnel concerned?			
APAC TEC1-008 8.3	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 of the work it performs. In cases where a RMP is part of a larger organization, RMP activities may already be incorporated in a document covering the organization's total range of operations.	Note	Note	
8.4 Control of management system documents (Option A)				
8.4.2	Does the RMP ensure that:			
	a) documents are approved for adequacy prior to issue by authorized personnel?			
	b) documents are periodically reviewed and updated (as necessary)?			
	c) changes and the current revision status of documents are identified?			
	d) relevant versions of applicable documents are available at points of use?			

Section	Assessment	Yes	No	Comments
	e) documents are uniquely identified and where necessary their distribution controlled?			
	f) the unintended use of obsolete documents is prevented, and suitable identification applied to them if they are retained for any purpose?			
Note 1	*These can include documents of external origin, such as standards, guides, test and/or calibration procedures, as well as specifications, instructions and manuals related to the RM under production*			
Note 2	*In this context, "document" means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These can be on various media, whether in hard copy or electronic, and they can be in digital, analogue, photographic or written form.*			
	Control of records (Option A)			
8.5.1	Has the RMP established procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard?			
8.5.2	Has the RMP established procedures for retaining records for a period consistent with its contractual and legal obligations? Is access to these records consistent with the confidentiality arrangements?			
8.6.1 Management review (Option A)				
8.6.1	In accordance with a predetermined schedule and procedure,does the RMP'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 take account of, but not be limited to:			
	a) the suitability of policies and procedures?			
	b) reports from managerial and supervisory personnel?			
	c) the outcome of internal audits?			

Section	Assessment	Yes	No	Comments
	d) corrective actions?			
	e) result of risk identification?			
	f) assessments by external bodies?			
	g) changes in scale and type of work?			
	h) feedback from customers?			
	i) recommendations for improvement including complaints?			
	j) other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the RMs?			
	k) the quality objectives (see 8.2)?			
Note 1	*Results can feed into the corporate planning programme, can include the goals, objectives and action plans for the coming year and can be communicated to the staff.*			
Note 2	*A typical period for conducting a management review is once every year.*			
8.6.2	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?			
8.7 Internal audit (Option A)				
8.7.1	Does the RMP, 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 International Standard? Does the internal audit programme address all elements of the management system, including the technical and production activities leading to the finished product (RM). It is the responsibility of the RMP to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited? Does personnel not audit their own activities?			

Section	Assessment	Yes	No	Comments
APAC TEC1-008 8.7.1	RMP should perform internal audits at least once a year. The frequency may be adjusted depending on the demonstrable effectiveness of the management system and its proven stability.	Note	Note	
8.7.2	When audit findings cast doubt on the effectiveness of the operations, or on the integrity of the RMs, or on the correctness of their documentation, has the RMP take timely corrective actions and do they notify, in writing, its customers whose activities may have been adversely affected?			
APAC TEC1-008 8.7.2	Internal auditors should be familiar with the requirements of ISO 17034 and ISO/IEC 17025 (or ISO 15189 for medical RMs).	Note	Note	
8.7.3	Are all audit findings and corrective actions that arise from them recorded? Does the RMP's management ensure that these actions are discharged within an appropriate and agreed timescale?			
8.7.4	Do follow-up activities verify and record the implementation and effectiveness of the corrective actions taken?			
8.8	Actions to address risks and opportunities (Option A)			
8.8.1	Does the RMP consider the risks and opportunities to:			
	a) give assurance that the management system can achieve its intended result(s)?			
	b) enhance desirable effects?			
	c) prevent, or reduce, undesired effects?			
	d) achieve improvement?			
8.8.2	Does the organization take actions to:			
	a) address these risks and opportunities?			
	b) integrate and implement the actions into its management system processes?			
	c) evaluate the effectiveness of these actions?			
8.8.3	Are actions taken to address risks and opportunities proportionate to the potential impact on the quality of the RM production and service?			

Section	Assessment	Yes	No	Comments
Note 1	*Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*			
Note 2	*Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.*			
8.9 Corrective actions (Option A)				
8.9.1	Does the RMPestablish a policy and procedure(s) and designate appropriate authorities for implementing corrective actions when non-conforming RMs, non-conforming work on the production of RMs, 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 can be identified through a variety of activities within the management system, such as control of non-conforming RMs, internal or external audits, management reviews and feedback from customers or staff observations.*			
8.9.2	Cause analysis			
	Do corrective action procedures start with an investigation to identify the root causes of the problem? Has the investigation conducted for both in-house production and, where required, any work performed by subcontractors?			
Note	*The root cause is often not obvious and a careful analysis of all potential causes of the problem is required. Potential causes could include the nature of the RM and its specifications, general procedures and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes.*			

Section	Assessment	Yes	No	Comments
	Selection and implementation of corrective actions			
8.9.3.1	Where corrective actions are needed, does the RMP identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?			
8.9.3.2	Are any 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?			
8.9.3.3	The RMP shall document and implement any required changes to the operational procedures resulting from corrective action investigations.			
	Monitoring of corrective actions			
8.9.4	After having implemented the corrective actions, does the RMP monitor the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems?			
8.9.5	Where the identification of non-conformities or departures casts doubt on the RMP's compliance with its own policies and procedures, or on its compliance with this International Standard, does the RMP ensure that the appropriate areas of activity are audited in accordance with 7.17, as soon as possible?			
8.10 Improvement (Option A)				
8.10.1	Does the RMP 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?			
8.10.2	Are required improvements and potential sources of non-conformities, either technical or concerning the management system, identified? When improvement opportunities are identified or if improvement 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?			

Section	Assessment	Yes	No	Comments
8.10.3	After the implementation of the improvement, does the RMP monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action?			
8.10 Feedback from customers (Option A)				
	Feedback from customers (Option A)			
8.11	Does the RMP seek feedback, both positive and negative, from its customers? Is the feedback used and analysed to improve the management system, RM production activities and customer service?			
Additional Requirements (Required for surveillance and re-accreditation assessments) *Objective Evidence of RMP's utilization of PJLA's accreditation symbol must be included in the package. This includes but not limited to (Website page, letterhead, RM/CRM documents and labels)* *If any of the requirements of SOP-3 are not followed a nonconformance must be written*				
Use of the Symbol				
	For applicant RMP: Does the applicant RMP use the PJLA Logo? Note Applicant RMPs 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 lab)? Is the symbol identifiable?			
	Is the accredited RMP properly stating their accreditation status? "Accredited to ISO 17034:2016" or utilizing the ILAC criteria listed in the SOP-3 Procedure?			

Section	Assessment	Yes	No	Comments
	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)			
	Is the accredited RMP appropriately using the symbol by not placing the symbol on: a) legal documents (i.e. contracts or checks)? b) on 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?			
PL-2 Measurement Traceability Policy				
	When metrological traceability is not achievable, has the reference material producer provided 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?			

Section	Assessment	Yes	No	Comments
	Has the RMP employed the services of an external testing laboratory that is accredited to ISO/IEC 17025:2017 for the test(s) performed or ISO 17034:2016 for and any external RMP activities performed? If not, can the RMP demonstrate reverse traceability, an uninterrupted chain, back to an NMI?			
PL-3 Policy on Measurement Uncertainty -No additional PJLA requirements				
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.			