Specific Accreditation Guidance
Reference Material Producers

Gap Analysis of ISO Guide 34:2009 and ISO 17034:2016

January 2018

Purpose

This gap analysis has been designed to assist Reference Material Producers (RMPs) and NATA assessment teams to identify all of the differences between ISO Guide 34:2009 and ISO 17034:2016.

Refer to *Specific Accreditation Criteria – Implementation of ISO 17034:2016 in NATA's Reference Material Producers accreditation program*. This document includes an *ISO 17034:2016 Implementation Checklist* which has been developed to facilitate already accredited RMP facilities to transition to the new standard from ISO Guide 34:2009.

Summary of changes between ISO Guide 34:2009 and ISO 17034:2016

Refer to the Foreword and Introduction sections of the ISO 17034.

ISO 17034 includes the following references:

- ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*) as a normative reference;

- ISO Guide 31 (*Reference materials - Contents of certificates, labels and accompanying documentation*) and ISO Guide 35 (*Reference materials - General and statistical principles for certification*) as informative references.

  Those matters in both Guides considered necessary have been incorporated as requirements in ISO 17034.

- ISO/TR 16476 (*Establishing and expressing metrological traceability of quantity values assigned to reference materials*) as an informative reference.

In addition to the changes between ISO Guide 34 and ISO 17034, the wording in ISO Guide 35 (2017) has also been modified from previous versions to make it clear that if an RMP follows a certain statistical procedure then they must do so in the manner prescribed. If the RMP utilises an alternative approach to assessing stability, homogeneity and/or characterization studies to that prescribed in ISO Guide 35, then they must demonstrate validity of method.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
1	**1**		**Scope**	
		Minor change in intended use of the standard	This International Standard covers the production of all RMs, including CRMs. NOTE RMPs, regulatory authorities, organizations and schemes using peer assessment, accreditation bodies and others can also use this International Standard in confirming or recognizing the competence of RMPs.	The following note from Guide 34 has been removed. *NOTE This Guide is not intended to be used as the basis for conformity assessment by certification bodies.* Use of the Standard as an accreditation tool is now a note, rather than a statement.
2	**2**		**Normative References**	Reference to ISO/IEC 17000 has been made.
		Major change	ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.	Only ISO/IEC 17025 is listed as a normative reference. ISO Guides 30, 31, 35, 98-3 (GUM), 99 (VIM), ISO 9000, ISO 10012, ISO 15189, ISO/IEC 17000 are no longer normative references.
3	**3**		**Terms and definitions**	
		New	ISO and IEC maintain terminological databases for use in standardization at the following addresses: • ISO Online browsing platform: available at **http://www.iso.org/obp** • IEC Electropedia: available at **http://www.electropedia.org/**	Addition of terminological databases as a reference source.
		Minor change	The definitions of Reference Materials and Certified Reference Materials has been aligned with ISO Guide 30:2015.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
		New	Definitions of 'Certified Value', 'Impartiality', 'reference material document' and 'operationally defined measurand' added.	More emphasis on determination and attestation of the (metrological) stated reference for CRMs and the concept of a measurand being 'operationally defined' has been included in ISO Guide 35 and ISO/TR 16476.
		Deleted		Definitions of 'commutability of a reference material', 'metrological traceability' and 'measurement uncertainty' have been removed.
Entire document		New		Restructure of the Standard, as per the other International Standards on conformity assessment, in accordance with the decision made by ISO / CASCO. The revised structure will now cover the main elements: • General requirements • Structural requirements • Resource requirements • Technical and production requirements • Management system requirements
4			**General requirements**	
4.1	**4.4**		**Contractual matters**	
4.1.1	4.4.1	Editorial change	Request for tenders or contracts.	Minor changes to wording.
4.1.1 Note 3		New	A request to prepare a specific RM can originate from the RMP.	Note added for guidance and clarification.
4.1.2	4.4.3	Editorial change	The review includes any work that needs to be subcontracted.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
4.1.3	4.4.2	Editorial change	The RMP shall maintain records of these reviews.	Minor changes to wording.
4.2			**Impartiality**	
4.2.1		New	The RMP shall be structured and managed so as to safeguard impartiality.	
4.2.2 a)	4.2.3 b)	No change	The RMP shall have arrangements to ensure that it is free from any undue pressures.	Previously under ISO Guide 34 clause 4.2 Organisation and management.
4.2.2 b)		New	The RMP shall identify risks to its impartiality.	
4.2.2 c)		New	The RMP shall be able to demonstrate, if a risk to impartiality is identified, how the risk is managed;	
4.2.2 d)		New	The RMP shall have top management commitment.	
4.3			**Confidentiality**	
4.3.1	4.2.3 c)	Minor change	The RMP shall be responsible for and shall treat in an appropriate manner all information obtained, including confidential information.	ISO Guide 34 clause 4.2.3 c) only covered customer's confidential information and propriety rights. ISO 17034 now has expanded this to cover all information obtained from another individual or body.
4.3.2		New	When the RMP is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall be notified.	
5			**Structural requirements**	
5.1	4.2.1	Editorial change	The RMP shall be a legal entity.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
5.2	4.2.2	Editorial change	The RMP shall be organized and shall operate in such a way that it meets all the applicable requirements of this International Standard.	Minor changes to wording.
5.3 a)	4.2.3 e)	Minor change	The RMP shall have a description of its legal status.	Less prescriptive than ISO Guide 34. e.g. not specific to require an organisation chart.
5.3 b)		New	The RMP shall define the parts of the organization covered by the management system.	
5.3 c)	4.2.3 f)	No change	The RMP shall specify responsibilities and authorities.	
5.3 d)	4.2.3 a)	No change	The RMP shall have managerial personnel and technical personnel, with the authority needed.	
5.3 e)	4.2.3 g)	Minor change	The RMP shall have technical management with overall responsibility for the technical operations.	Less prescriptive than ISO Guide 34. e.g. not specific to having a Technical Manager by name.
5.3 f)	4.2.3 h)	Minor change	The RMP shall appoint personnel (however named) who shall have defined responsibility and authority.	Less prescriptive than ISO Guide 34. e.g. not specific to having a single Quality Manager.
5.3 g)		New	The RMP shall have adequate provision to cover liabilities.	
5.4		New	The RMP shall ensure that communication mechanisms are established, takes place and the importance of meeting customers requirements are communicated.	
6			**Resource requirements**	
6.1	**5.2**		**Personnel**	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
6.1.1	5.2.5	Minor change	The RMP shall ensure that all personnel involved are supervised and competent and working in accordance with the management system.	Less prescriptive than ISO Guide 34. A general requirement is stated and is less specific as to whether staff are contracted.
6.1.2	4.5.1	Minor change	All personnel, including, subcontractors, or individuals acting on the RMP's behalf, shall comply with the policies and procedures.	Less prescriptive than ISO Guide 34. Subcontractors are bundled in with all other personnel and are not considered the exception. Confidentiality requirement added.
6.1.3	5.2.2	Editorial change	The RMP shall ensure the competence of all personnel.	Minor changes to wording.
6.1.4	5.2.3	Minor change	The RMP shall have procedures for identifying training needs.	Less prescriptive than ISO Guide 34. The 'effectiveness of the training being evaluated' has been removed.
6.1.5	5.2.4	Minor change	The RMP shall maintain records of job descriptions.	Less prescriptive than ISO Guide 34.
6.1.6	5.2.6	Editorial change	The RMP shall authorize competent personnel to perform particular activities.	Minor changes to wording.
6.2	**5.3**		**Subcontracting**	
6.2.1	5.3.1	Major change	Where an RMP uses subcontractors the RMP shall have procedures to ensure experience and technical competence are sufficient and comply with the relevant clauses of this International Standard.	A requirement to have a procedure has been added.
6.2.1 Note 1	5.3.3	Minor change	It is possible that an RMP does not have its own laboratory or processing facilities.	ISO Guide 34 5.3.3 is now a Note. Subcontracting is now consolidated into one clause.
6.2.1 Note 2	4.5.3	Minor change	Subcontractors can be paid or unpaid.	ISO Guide 34 4.5.3 is now a Note.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
6.2.2	4.5.2	Minor change	Subcontractors shall be selected based of their ability to meet the requirements stipulated.	A more general statement of requirement.
6.2.3	5.3.1	Editorial change	The following processes shall not be subcontracted: • production planning; • selection of subcontractors; • assignment of property values and their uncertainties; • authorization of property values and their uncertainties; • authorization of documents.	Minor changes to wording.
6.2.4	4.5.1	Editorial change	The RMP shall ensure all tasks performed by subcontractors comply with the requirements.	Minor changes to wording.
6.2.5	5.3.2	Editorial change	Evidence of the subcontractor's competence shall be maintained.	Minor changes to wording with much of the information in ISO Guide 34 now included in a Note.
6.2.6	5.3.2	Minor change	The RMP shall evaluate the competence of the subcontractor.	This was implied in ISO Guide 34 but now explicit in ISO 17034.
6.2.7	5.3.4	Editorial change	Results and the descriptions of procedures used by subcontractors are to be available to allow the technical evaluation of data.	Minor changes to wording.
6.2.8		New	The RMP shall have personnel operating under its management system and having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity.	
6.3		New	**Provision of equipment services and supplies**	
6.3.1	4.6.1	Minor change	The RMP shall have procedures in place for the selection of equipment, services and supplies.	Equipment is now bundled in with services and supplies.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
6.3.2	4.6.2	Editorial change	The RMP shall use only equipment, services and supplies that comply with specified requirements.	Minor changes to wording.
6.3.3	4.6.4	Minor change	The RMP shall ensure that equipment and consumable materials are not used until they have been deemed in compliance with requirements.	Less prescriptive than the Guide.
6.3.4	4.6.5	Minor change	The RMP shall maintain records of purchases of equipment, services and supplies.	Improved wording setting a more general requirement.
6.4	**5.6**		**Facilities and environmental conditions**	
6.4.1	5.6.1	Editorial change	The RMP shall ensure all facilities are appropriate.	Minor changes to wording.
6.4.2	5.6.2	Editorial change	When the environmental conditions could have an adverse effect on the RM, the environmental conditions shall be monitored.	Minor changes to wording.
6.4.3	5.6.1	Editorial change	All RM production areas, shall be protected from adverse environmental influences.	Minor changes to wording.
6.4.4		New	Access to areas shall be controlled.	ISO Guide 34, clause 5.6.3, relating to health and safety requirements has been removed from this section. See 7.5.1 i) of 17034.
7			**Technical and production requirements**	
7.1		New	**General requirements** The RMP shall address the requirements in this clause.	ISO 17034 has also added a Note to identify that a CRM has at least one certified value.
7.2	**5.4**		**Production planning**	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.2.1	5.4.1	Editorial change	The RMP shall identify and plan processes and the production plan shall be documented.	Minor changes to wording.
7.2.1 Note	5.4.2	Minor change	A mechanism can be established to make recommendations on the production processes, for example, assigning the property values of interest.	This is now a Note.
7.2.2	5.4.2	Editorial change	Technical input of subcontractors shall be specified and documented and regularly reviewed.	Minor changes to wording.
7.2.3 a)	5.4.3 b)	No change	The RMP shall address material selection (including, where appropriate, sampling);	
7.2.3 b)		New	The RMP shall verify the identity of the material.	
7.2.3 c)	5.4.3 c)	No change	The RMP shall maintain suitable environments.	
7.2.3 d)	5.4.3 d)	No change	The RMP shall address material processing.	
7.2.3 e)	5.4.3 e)	Editorial change	The RMP shall address choice of measurement procedures.	Minor changes to wording.
7.2.3 f)	5.4.3 f)	Editorial change	The RMP shall address validation of measurement procedures.	Minor changes to wording.
7.2.3 g)	5.4.3 g)	Editorial change	The RMP shall address verification and calibration of measuring equipment.	Minor changes to wording.
7.2.3 h)	5.4.3 h)	Major change	The RMP shall specify acceptance criteria for, homogeneity.	More specific regarding specification of criteria.
7.2.3 i)	5.4.3 i)	Major change	The RMP shall specify acceptance criteria for stability.	More specific regarding specification of criteria.
7.2.3 j)	5.4.3 j)	Minor change	The RMP shall design and organise appropriate characterization.	A more general statement.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.2.3 k)	5.4.3 k)	Minor change	The RMP shall assess commutability.	Note added that guidance on the need for commutability assessment of RMs is given in a REMCO position paper.
7.2.3 l)	5.4.3 l)	Editorial change	The RMP shall assign property values.	Minor changes to wording.
7.2.3 m)	5.4.3 m)	Minor change	The RMP shall establish uncertainty budgets.	Now only specific to certified values.
7.2.3 n)	5.4.3 n)	Minor change	The RMP shall define acceptance criteria for measurand levels and their uncertainties.	More general wording used and no longer specific to multiple batches.
7.2.3 o)	5.4.3 o)	Editorial change	The RMP shall establish metrological traceability of measurement result/s.	Minor changes to wording.
7.2.3 p)	5.4.3 p)	Minor change	The RMP shall issue RM documents.	More general statement made.
7.2.3 q)	5.4.3 q)	No change	The RMP shall ensure adequate storage conditions.	
7.2.3 r)	5.4.3 r)	Minor change	The RMP shall ensure appropriate labelling and packaging.	Minor changes to wording. Reference to safety regulations removed.
7.2.3 s)	5.4.3 s)	Minor change	The RMP shall ensure appropriate transport.	No longer makes reference to shipping regulations.
7.2.3 t)	5.4.3 t)	No change.	The RMP shall ensure post-production stability monitoring.	
7.2.3 u)	5.4.3 u)	Editorial change	The RMP shall ensure an adequate post-distribution service.	Minor changes to wording.
7.2.4	5.1.3 third paragraph	Minor change	Where multiple batches of RMs with equivalent properties are produced the RMP shall ensure information obtained from previous batches remains applicable for the new batch.	Minor changes to wording. Notes added for guidance on multiple batches and further guidance is given in ISO Guide 35.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.3	**5.5**	Major change.	**Production control** The RMP shall verify the implementation of the production plan and deviations from the plan shall be documented and approved.	Records that support deviations from the plan have been added.
7.4	**5.7**		**Material handling and storage**	
7.4.1	5.7.6 & second paragraph of 5.6.1	Editorial change	The RMP shall make arrangements to ensure the integrity of materials throughout the production process.	Minor changes to wording.
7.4.1 Note	5.6.1	Minor change	Examples provided.	More general guidance given in this note
7.4.2	5.7.1	Minor change	The RMP shall identify, preserve and separate materials from chemicals and other samples.	More general statement made. Note on uniquely identifying each RM added as guidance.
7.4.3	5.7.2	No change	The RMP shall ensure adequate packaging of all RMs.	
7.4.4	5.7.3	Minor change	The condition of all RMs shall be assessed at appropriate intervals throughout the storage period.	Minor changes to wording.
7.4.5	5.7.4	Major change	The RMP shall control packaging and labelling and have procedures for transport to the customer.	Procedure for transport to the customer added.
7.4.6	5.7.4	Minor change	The RMP shall take measures to ensure that the integrity of each individual RM unit is maintained until the seal is broken or up to the point when first used.	Acknowledgement of the RMP having no responsibility once the seal is broken has been removed.
7.5	**5.8**		**Material processing**	
7.5.1	5.8	Editorial change	The RMP shall ensure that the material has undergone adequate processing for its intended use.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.5.1 a)	5.8 a)	No change	Procedure shall ensure qualitative analysis for verification of material type and/or identity;	
7.5.1 b)	5.8 b)	No change	Procedure shall address synthesis, purification, incubation, and transformation into the final form.	
7.5.1 c)	5.8 c)	No change	Procedure shall address homogenization.	
7.5.1 d)	5.8 d)	No change	Procedure shall ensure proper handling.	
7.5.1 e)	5.8 e)	Editorial change	Procedure shall address measurements for control of material processing.	Minor changes to wording.
7.5.1 f)	5.8 f)	Editorial change	Procedure shall address pre-treatment, cleaning or sterilization of processing equipment and sample containers;	Minor changes to wording.
7.5.1 g)	5.8 g)	No change	Procedure shall address stabilization of material.	
7.5.1 h)	5.8 h)	Editorial change	Procedure shall address packaging.	Minor changes to wording.
7.5.1 i)	5.6.3	Minor change	Procedure shall address safety precautions.	Minor changes to wording.
7.5.2		New	Equipment used in material processing shall be operated in accordance with documented procedures.	Note added recognising manufacturers instructions.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.6	**5.9**	Minor change.	**Measurement procedures** The RMP shall ensure that the relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing. These activities shall, where appropriate, be consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned.	The requirement is now simply to meet the requirements of ISO/IEC 17025. No specific reference to ensuring validity of test method, documented procedures, metrological traceability, proficiency testing, etc. as these requirements are addressed by ISO/IEC 17025. All measurement procedures that contribute to the RM production, characterisation, homogeneity and stability testing fall under this requirement.
7.7	**5.10**	Minor change.	**Measuring equipment** The RMP shall ensure that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025.	The requirement is now simply to meet the requirements in ISO/IEC 17025. No specific reference to requirements for calibration, verifications, etc. as these requirements are addressed by ISO/IEC 17025. All measuring equipment that contribute to the RM production, characterisation, homogeneity and stability testing fall under this requirement. Note added making reference to ISO 10012 regarding equipment drift.
7.8	**5.11**		**Data integrity and evaluation**	
7.8.1	5.11.1	Editorial change	The RMP shall ensure that all calculations and data transfers are checked.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.8.2 a)	5.11.2 a)	Editorial change	The RMP shall ensure computer software is validated and shown to be adequate for use;	A more general statement made.
7.8.2 b)	5.11.2 b)	No change	The RMP shall establish procedures to protect the integrity of data.	
7.8.2 c)	5.11.2 c)	No change	The RMP shall ensure equipment and software are maintained.	
7.8.2 d)	5.11.2 d)	No change	The RMP shall ensure appropriate procedures are established and implemented for the maintenance of data security.	
7.8.3		New	Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate.	Given ISO Guide 35 is no longer a normative reference and is being revised only as a guide, the requirement for valid statistical procedures is now contained under this clause. Note 1 added providing guidance on validation of statistical procedures
7.8.3 Note 2		New	Additional information on control of data is provided in ISO/IEC 17025.	Note added.
7.9	**5.12**		**Metrological traceability of certified values**	Much of the criteria for metrological traceability are now referenced to ISO/IEC 17025. Guidance on metrological traceability has been removed and now provided as a reference to ISO/TR 16476 and ISO Guide 35

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.9.1	5.12.1 & 5.12.4	Major change	When producing CRMs, the metrological traceability of the certified values shall be established in compliance with the relevant requirements of ISO/IEC 17025 and RMP shall provide evidence of the metrological traceability of the certified value to a stated reference.	The requirement now only references metrological traceability requirements specific to certified values. The requirement for metrological traceability of measurement equipment and measurement procedures is provided in clauses 7.6 & 7.7. RMs which are not reported as a CRM must still be characterized with appropriate traceability and sufficient reliability as per the requirement stated in clause 7.12.4.
7.9.1 Note 1	5.12.4	No change	Results obtained by different measurement procedures and/or laboratories all being traceable to the same reference is also traceable to that reference.	
7.9.1 Notes 2, 3 and 4		New	Evidence can be based on evaluation of the measurement process or on confirmation of metrological traceability by comparison of results with independent traceable values. Clear identification of the property of interest, traceability of the numerical value and the stated reference contribute to the traceability of results. ISO/TR 16476 contains additional information on establishment and expression of metrological traceability.	Notes added for guidance as well as informative reference ISO/TR 16476.
7.9.2	5.12.2	Editorial change	The stated reference shall be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard.	Improvement in wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.9.3	5.12.2 and ISO Guide 35	Major change	Where it is technically possible, the RMP shall demonstrate that the stated reference is traceable to the International System of Units (SI).	As ISO Guide 35 is now an informative reference, the requirement for traceability to SI has been added to ISO 17034.
7.9.4	5.12.2 and ISO Guide 35	Major change	Where metrological traceability to the SI units is not technically possible, the RMP shall demonstrate metrological traceability to an appropriate reference (see traceability requirements in ISO/IEC 17025).	Criteria for traceability now references ISO/IEC 17025.
7.9.5	5.12.3.2	Major change	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), it shall be ensured that the measurements are calibrated with standards with metrologically traceable values.	The more prescriptive requirements and requirements for traceability of homogeneity and stability testing have been removed. The requirements for these testing measurements are now referenced directly to the requirements in ISO/IEC 17025.
7.9.6		New	Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability.	Note added recognising secondary parameters such as temperature and humidity.
7.10	**5.13**		**Assessment of homogeneity**	
7.10.1	5.13.1	Editorial change	The RMP shall carry out an assessment of the homogeneity.	Minor changes to wording.
7.10.1 Note 1		New	Note added recognising assessment of homogeneity can include the use of prior evidence, etc. and guidance provided in ISO Guide 35.	Note added.
7.10.1 Note 2	5.13.2	Minor change	Homogeneity tests require measurements of a representative number of units.	Now provided as a note given the requirement for method validity is stated as a general requirement for all methods under clause 7.6.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.10.2	5.13.2 second paragraph	Editorial change	When the material is produced in multiple batches, the equivalence of the batches shall be demonstrated or the homogeneity of each batch shall be evaluated separately.	Improvement to wording.
7.10.3	5.13.2	Major change	Validated measurement procedures shall be selected so that the precision and selectivity are fit for the purpose required.	Now written as a prescriptive requirement.
7.10.4	5.12.3.1 second paragraph after bullets	Editorial change	Where homogeneity needs to be determined experimentally, the RMP shall determine the homogeneity for every property of interest, unless groups of properties are sufficiently closely associated.	The reference to ISO Guide 35 has been removed and replaced by this requirement. ISO Guide 35 allowed homogeneity testing on a subset of the assigned values.
7.10.4	5.13.2	Major change	Note added recognising guidance for homogeneity testing and the establishment of minimum sample size is given in ISO Guide 35.	Previously ISO Guide 35 was stated as a requirement. It is now a guide and replaced by the requirement above.
7.10.5	5.13.2	Editorial change	For certified values, homogeneity shall be quantified as an uncertainty contribution to the certified value or shall be shown to be negligible.	As ISO Guide 35 is no longer a normative reference, this requirement has been added to ISO 17034.
7.11	**5.14**		**Assessment of stability**	
7.11.1 a)	5.14.2	Minor change	The RMP shall assess the stability of all relevant properties of an RM under proposed storage conditions.	Now written as a more prescriptive requirement.
7.11.1 b)	5.14.3	Minor change	The RMP shall assess the stability of all relevant properties of an RM under proposed conditions of transport.	Now written as a more prescriptive requirement.
7.11.1 c)		New	The RMP shall establish any necessary advice on storage and use of the material to maintain stability.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.11.1 d)		New	The RMP shall select a scheme for monitoring the stability of materials held in long term.	
7.11.1 e)	5.14.2 second paragraph	Editorial change	The RMP shall 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.	As ISO Guide 35 is no longer a normative reference, this requirement been added in ISO 17034 and made more prescriptive.
7.11.1 f)		New	The RMP shall 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.	
7.11.1 Note 1		New	Where repeated sampling is permitted appropriate actions can be, for example, provision of detailed instructions for handling and use after opening of the RM unit.	Guidance added.
7.11.1 Note 2	5.14.2 first paragraph	Major change	Recognition of ISO Guide 35 as a guidance document.	In ISO Guide 34, stability studies in compliance with ISO Guide 35 was a requirement. ISO Guide 35 is now an informative reference.
7.11.1 Note 3		New	The results of stability assessments can contribute to uncertainty evaluation.	Note added for guidance.
7.11.2		Editorial change	The RMP shall conduct an experimental assessment of stability unless evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions has been established.	As ISO Guide 35 is no longer a normative reference, this requirement has been added to ISO 17034. Note added regarding “Closely similar” materials.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.11.3		Editorial change	Where an RM is produced in multiple batches that are not individually tested for stability, the RMP shall verify the stability of a sufficient number of different batches experimentally to provide confidence in the stability of all batches.	As ISO Guide 35 is no longer a normative reference, this requirement has been added to ISO 17034. Note 1 added regarding verification to confirm different batches behave similarly. Note 2 added recognising ISO Guide 35 for guidance.
7.12	**5.15**		**Characterization**	
7.12.1		New	Where the RMP assigns property values, characterization of the RM is required.	Characterization of property values was solely related to certified values in ISO Guide 34. It now applies to all assigned property values, certified and non-certified.
7.12.2		New	The RMP shall 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.	Addition of the specification of operationally defined measurands. See addition of definition of operational defined measurand in clause 3.
7.12.3		Editorial change	The RMP shall select a characterization strategy appropriate for the intended use of the RM.	ISO Guide 34 previously referenced the requirements in ISO Guide 35. This requirement has been reworded and added as a general requirement in ISO 17034.
7.12.3 Note 1 a)	5.15 a)	Minor change	Such characterization can include using a single reference measurement procedure in a single laboratory;	While these concepts a) to e) are now listed as a note, they are statements of fact. More description added with reference made to ISO/IEC Guide 99.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.12.3 Note 1 b)	5.15 b) & 5.15 c)	Minor change	Such characterization can include characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories;	
7.12.3 Note 1 c)	5.15 d)	Minor change	Such characterization can include characterization of an operationally-defined measurand using a network of competent laboratories;	Minor changes to wording.
7.12.3 Note 1 d)		New	Such characterization can include value transfer from a RM to a closely matched candidate RM performed using a single measurement procedure performed by one laboratory;	
7.12.3 Note 1 e)		New	Such characterization can include characterization based on mass or volume of ingredients used in the preparation of the RM.	
7.12.3 Note 2		New		ISO Guide 35 referenced as an informative guide.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.12.4	4.1.1 second paragraph	Major change	The RMP shall 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, the RMP shall: 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.	Was previously under Management System Requirements in ISO Guide 34. More prescriptive requirements added.
7.12.5		New	When evaluating the characterization data, the RMP shall 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	**5.16**		**Assignment of property values and their uncertainties**	
7.13.1	5.16.1	Minor change	The RMP shall use documented procedures for the assignment of property values.	Requirement to comply with ISO Guide 35 removed.
7.13.2 a)	5.16.1 a)	No change	Procedures shall include details of the experimental designs and statistical techniques used;	
7.13.2 b)	5.16.1 b)	Minor change	Procedures shall include policies on treatment and investigation of anomalous results.	Prescription for ‘robust statistics’ removed and addressed in more detail under 7.13.4

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.13.2 c)	5.16.1 c)	No change	Procedures shall include whether weighting techniques are used.	
7.13.2 d)	5.16.1 d)	No change	Procedures shall include the approach used to assign uncertainties.	
7.13.2 e)	5.16.1 e)	No change	Procedures shall include any other significant factors that may affect the assignment of property values.	
7.13.3		New	The RMP shall 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.	New requirement with reference to ISO Guide 35 added as a note.
7.13.4	5.16.1 after dot point e)	Minor change	Outliers shall not be excluded solely on statistical evidence until they have been investigated. Robust statistical methods may be applied where appropriate.	Improvement to wording of requirement with guidance and reference to ISO Guide 35 added as notes.
7.13.5	5.16.2	Major change	For certified values, the RMP shall identify the uncertainty contributions to be included in the assigned uncertainty.	Requirement is now specific to certified values. Informative references ISO Guide 35 and Guide 98-3 (GUM) added as note.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.13.6	5.16.2	Major change	For certified values, the RMP shall 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.	Requirement to comply with ISO Guide 35 removed and replaced with direct requirements in this clause. Additional guidance on repeated sampling from a bottle and other non certified values assigned to a CRM added as a note.
7.14	**5.17**		**RM documents and labels**	
7.14.1	5.17 first paragraph	Editorial change	The RMP shall issue and make available a reference material certificate for CRMs and product information sheet for other reference materials.	ISO Guide 34 was more flexible regarding the naming of RM documentation.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.14.2	5.17 second paragraph	Editorial change	The contents of RM certificates and product information sheets shall 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).	Requirement to comply with ISO Guide 31 removed and replaced with direct requirements in this clause.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.14.3	5.17 second paragraph	Editorial change	In addition to the minimum requirements given in 7.14.2, RM certificates shall 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.	Requirement to comply with ISO Guide 31 removed and replaced with direct requirements in this clause.
7.14.3 Notes 1 & 2	5.17 second paragraph	Major change	Notes 1 & 2 reference ISO Guide 31 and sector specific requirements for RM certificates and product information sheets.	ISO Guide 31 is now an informative reference. Additional recognition of sector specific requirements, e.g. ISO 15194 for in vitro diagnostic medical devices, added.
7.14.4	5.7.5	Minor change	The RM label shall be securely attached to the product container of an individual RM unit, and shall be designed to remain legible and intact under the defined storage and handling conditions. The label shall identify the material, the RMP, its batch, and any other information necessary to enable the material to be uniquely distinguished and reference made to its product information sheet or RM certificate.	Changes to wording and removal of safety and risk regulations as a requirement.
7.14.5	5.7.5	Editorial change	Where the physical size of the RM unit limits the amount of information that can be contained on the label, the information shall be included elsewhere. A unique identifier shall be given.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.14.5 Note		Major change	Note giving reference to ISO Guide 31.	ISO Guide 31 is now an informative reference.
7.15	**5.18**		**Distribution service**	
7.15.1	5.18.1	Editorial change	The distribution process shall be specified including precautions needed to avoid deterioration of the RM.	Minor changes to wording.
7.15.1 Note 1		New	Note providing guidance on conditions of shipment.	Note regarding conditions of shipment added for guidance.
7.15.1 Note 2	5.18.1	Editorial change	For some RMs, additional documentation related to origin and, conformity of the material to safety requirements, might be required for customs clearance.	Minor changes to wording.
7.15.2	5.18.2	No change	The RMP shall maintain records of all RM sales and distribution.	
7.15.3	5.18.3	Editorial change	The RMP shall offer to users' reasonable guidance and technical support.	Minor changes to wording.
7.15.4	5.18.4	Editorial change	The RMP shall employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period.	Minor changes to wording.
7.15.5	5.18.5	Editorial change	Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, the RMP shall pass on to the authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and ensure compliance with all relevant clauses of this International Standard.	Minor changes to wording.
7.15.5 Note	5.18.6	Major change	Where RMs are subject to resale by other organizations, the RMP has no control over these organizations' activities after purchase.	Changed from being a requirement in ISO Guide 34 to a note in ISO 17034.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.16	**4.13**		**Control of quality and technical records**	
7.16.1	4.13.1.1	No change	The RMP shall establish and maintain procedures for quality and technical records.	
7.16.1 Note 1	4.13.1.1 a)	Minor change	Quality records are records providing objective evidence of the operation of the management system.	Changed from being a requirement in ISO Guide 34 to a note in ISO 17034.
7.16.1 Note 2	4.13.1.1 b)	Minor change	Technical records are accumulations of data and information which result from carrying out RM production, measurement, testing and calibration.	Changed from being a requirement in ISO Guide 34 to a note in ISO 17034 with minor changes to wording.
7.16.2	4.13.1.1 last paragraph	No change	The RMP shall ensure that it has recorded such information that might be needed in a future dispute situation.	
7.16.3	4.13.1.2	Editorial change	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable.	Minor changes to wording.
7.16.3 Note	4.13.1.2 last paragraph	Minor change	Records can be in the form of any type of media.	Changed from being a requirement in ISO Guide 34 to a note in ISO 17034 with minor changes to wording.
7.16.4	4.13.1.3	No change	When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible, etc.	
7.16.5	4.13.1.4	No change	All records shall be held securely and in confidence.	
7.16.6	4.13.1.5	No change	The RMP shall have procedures to protect electronically held data.	
7.16.7	4.13.2	No change	The RMP shall arrange for all individual measurement observations, calculations, records and be retained for a defined period beyond which it is no longer probable that they will be referred to.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.16.8	4.13.2 second paragraph	No change	The results of each calibration or measurement carried out by the RMP or by a subcontractor shall be reported in accordance with ISO/IEC 17025.	
7.17	**4.9**		**Management of non-conforming work**	
7.17.1	4.9.1	Minor change	The RMP shall have procedures that shall be 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.	Requirement for policy removed.
7.17.2 a)	4.9.2 a)	No change	Procedures shall ensure responsibilities and authorities for the management of non-conforming work are designated.	
7.17.2 b)	4.9.2 b)	Major change	Procedures shall ensure the actions to be taken when any non-conforming work and/or RMs are identified including root cause analysis and a system that ensures that they are effectively implemented.	Root cause analysis added as a requirement.
7.17.2 c)	4.9.2 c)	Major change	Procedures shall ensure an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action.	Identification and implementation of corrective action added.
7.17.2 d)	4.9.2 d)	Editorial change	Procedures shall ensure work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld.	Minor changes to wording.
7.17.2 e)	4.9.2 e)	Editorial change	Procedures shall ensure remedial actions such as customer notifications are taken.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.17.2 f)	4.9.2 f)	Editorial change	Procedures shall ensure best efforts are employed to notify the users of the possible effects and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled;	Minor changes to wording.
7.17.2 g)	4.9.2 g)	No change	Procedures shall ensure the responsibility for authorization of the resumption of work is defined;	
7.17.2 h)		New	Procedures shall ensure where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken.	
7.17.3	4.9.1	Minor change	The decision on recall of RMs shall be taken in a timely manner.	Minor changes to wording.
7.17.3 Note	4.9.1	Minor change	The identification of non-conforming RMs can occur at various places within the management system.	Changed from being a requirement in ISO Guide 34 to a note in ISO 17034 with minor changes to wording.
7.18	**4.8**		**Complaints**	
7.18.1	4.8	Minor change	The RMP shall have a documented process to receive, evaluate and make decisions on complaints.	Removal of the requirement for a policy. Minor changes also to wording.
7.18.2		New	A description of the handling process for complaints shall be available to any interested party.	
7.18.3		New	Upon receipt of a complaint, the RMP shall confirm whether the complaint relates to activities that it is responsible for and, if so, shall deal with it.	
7.18.4		New	The RMP shall be responsible for all decisions at all levels of the handling process for complaints.	
7.18.5		New	Investigation and decision on complaints shall not result in any discriminatory actions.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
7.18.6		New	The process for handling complaints shall include: a) a description of the process for receiving, validating, investigating and deciding what actions are to be taken; b) tracking and recording; c) appropriate action is taken.	
7.18.7		New	The RMP receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.	
7.18.8		New	Whenever possible, the RMP shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.	
7.18.9		New	The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question.	
7.18.10		New	Whenever possible, the RMP shall give formal notice of the end of the complaint handling process to the complainant.	
8			**Management system requirements**	
8.1			**Options**	
8.1.1			**General**	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
		New	The RMP shall 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.	Previously, there was only one way to meet the management system requirements, i.e. what is now Option A. Option B has been introduced for those RMPs who have ISO 9001 certification.
8.1.2			**Option A**	
8.1.2.1	4.1.1 first paragraph	Minor change	The documented management system shall address the scope of its RM production activities, including the type, range and scale of RM production.	Minor changes to wording.
8.1.2.2	4.1.1 third paragraph	Minor change	The scope of the RM activities shall be defined and documented.	The detail as to what is to be defined and documented in a scope of RM production has been removed. NATA's RMP Categories of Reference Material June 2017 details the minimum requirements for information to be included in the scopes of accreditation of accredited RMPs.
8.1.2.3		New	The management system shall address the requirements contained in clauses 8.2 through to 8.11	The clauses 8.2 through to 8.11 address the management system requirements contained in ISO Guide 34 (quality policy 4.1.2, through to management reviews 4.15) which are not already addressed in section 7.
8.1.3			**Option B**	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
		New	An RMP that 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), fulfils the management system clause requirements in 8.2 to 8.11.	Refer to the *ISO 17034 Standard Application Document* on how NATA will assess facilities who have adopted ISO 9001.
8.2	**4.1.2**		**Quality policy(Option A)**	
8.2.1	4.1.2	Minor change	The RMP shall define and document its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production, storage and distribution procedures.	A more general requirement with less prescription compared to ISO Guide 34.
8.2.2	4.1.2 second paragraph	Minor change	Requirement for authority of policy by top management	Minor changes to wording.
8.2.3	4.1.2 third paragraph	Minor change	The quality policy shall include, but not be limited to, a list of commitments.	The specific commitment to produce CRMs to the requirements of ISO Guide 35 and ISO Guide 31 has been removed.
8.2.4	4.1.2 last paragraph	No change	Objectives to be reviewed during management review.	
8.3	**4.1.3**		**General management system documentation (Option A)**	
		No change	All of the RMP systems, programmes, procedures, instructions, findings, etc., shall be documented. Documentation shall be communicated to, understood by, available to and implemented by all personnel concerned.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
8.4	**4.3**		**Control of management system documents (Option A)**	
8.4.1	4.3.1	Minor change	The RMP shall control the documents that relate to the fulfilment of this International Standard	Minor changes to wording. Masterlist, or equivalent, no longer specified.
8.4.2 a)	4.3.2.1	Editorial change	The RMP shall ensure documents are approved by authorized personnel.	Minor changes to wording.
8.4.2 b)	4.3.2.2 b)	Editorial change	The RMP shall ensure documents are periodically reviewed and updated.	Minor changes to wording.
8.4.2 c)	4.3.2.1	Editorial change	The RMP shall ensure changes and the current revision status of documents are identified.	Minor changes to wording.
8.4.2 d)	4.3.2.2 a)	Editorial change	The RMP shall ensure relevant versions of applicable documents are available at points of use.	Minor changes to wording.
8.4.2 e)	4.3.2.3	Minor change	The RMP shall ensure documents are uniquely identified and where necessary their distribution controlled.	Less prescriptive than what was in ISO Guide 34.
8.4.2 f)	4.3.2.2 c)	Editorial change	The RMP shall ensure the unintended use of obsolete documents is prevented.	Minor changes to wording.
8.4.2 Note 1	4.3.1	Minor change	These can include documents of external origin e.g. calibration procedures, manuals, etc.	Now stated as a note.
8.4.2 Note 2	4.3.1 Note	No change	In this context, “document” means any information or instruction including policy statements, text books, etc.	
8.5	**4.13**		**Control of records (Option A)**	
8.5.1	4.13.1	Editorial change	The RMP shall establish procedures for controlling records.	Minor changes to wording.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
8.5.2	4.13.1.2	Editorial change	The RMP shall establish procedures for the retention of records.	Minor changes to wording.
8.6	**4.15**		**Management review (Option A)**	
8.6.1	4.15.1	Minor change	In accordance with a predefined schedule and procedure, top management shall conduct management reviews, with a list of activities/topics to be reviewed.	Few changes made. Quality objectives added as a topic.
8.6.2	4.15.2	No change.	Finding and actions from these reviews shall be recorded and discharged within a timescale.	
8.7	**4.14**		**Internal audits (Option A)**	
8.7.1	4.14.1	Editorial change	Sets the requirement to periodically conduct Internal Audits to a predetermined schedule and procedure.	Minor changes to wording.
8.7.2	4.14.2	No change	When audit findings cast doubt the RMP shall take timely corrective actions.	
8.7.3	4.14.3	No change	All audit findings and corrective actions that arise from them shall be recorded.	
8.7.4	4.14.4	No change	Follow-up activities shall verify and record the implementation and effectiveness of the corrective actions taken.	
8.8		New	**Actions to address risks and opportunities (Option A)**	This clause is significantly more prescriptive than the 'Preventive actions' clause of ISO Guide 34.

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
8.8.1 a) to d)		New	The RMP shall 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.	The requirements of ISO Guide 34, clause 4.11.1 Preventive actions is now listed under 17034 8.10.2 Improvement
8.8.2 a) to c)		New	The RMP shall 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		New	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the quality of the RM production and service.	
8.9	**4.10**		**Corrective actions (Option A)**	
8.9.1	4.10.1	No change	The RMP shall establish a policy and procedure(s) and shall designate appropriate authorities for implementing corrective actions.	
8.9.2	4.10.2	Minor change	Corrective action procedures shall start with an investigation to identify the root causes of the problem for both in-house production and, where required, any work performed by subcontractors.	Minor changes to wording with the second paragraph of clause 4.10.2 of ISO Guide 34 now included as a note.
8.9.3.1	4.10.3 first paragraph	No change	The RMP shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
8.9.3.2	4.19.3 second paragraph	No change	Corrective actions shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.	
8.9.3.3	4.10.3 third paragraph	No change	Changes to the operational procedures resulting from corrective action investigations shall be documented and implemented.	
8.9.4	4.10.4	No change	Corrective actions shall be monitored to ensure elimination of root causes.	
8.9.5	4.10.5	No change	Where there are concerns, the RMP shall ensure that the appropriate areas of activity are audited in accordance with 7.17, as soon as possible.	
8.10	**4.12**		**Improvement (Option A)**	
8.10.1	4.12	No change	The RMP shall continually improve the effectiveness of its management system.	
8.10.2	4.11.1	No change	Required improvements and potential sources of non-conformities shall be identified.	
8.10.3	4.11.2	No change	After the implementation of the improvement, the RMP shall monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action.	Preventive action 4.11 and Improvement 4.12 where separate clauses in ISO Guide 34.
8.11	**4.7.2**	No change	**Feedback from customers (Option A)** The RMP shall seek feedback, both positive and negative, from its customers	

ISO 17034:2016 Clause No.	Corresponding ISO Guide 34 Clause No.	Change	Summary of text/extract from ISO 17034:2016	Comments
Table A.1		New	**Annex A (informative) - Summary of production requirements for RMs and CRMs**	Table A1 gives guidance on the application of the requirements of Clause 7 related to the production of RMs and CMRs. The previous Annexes contained in ISO Guide 34 have been deleted: • Annex A Metrological traceability of certified property values of reference materials; • Annex B Commutability of reference materials; • Annex C ISO/IEC 17025/ISO Guide 34 cross-reference table.