ISO 17034 ASSESSMENT WORKSHEET

Self-assessment

This self assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
4 General requirements		
4.1 Contractual matters		
4.1.1	Request for tenders or contracts • the requirements for RMs are defined, documented and understood; • the RMP has the capability.	
4.1.2	The review includes any work that needs to be subcontracted.	
4.1.3	The RMP shall maintain records of these reviews.	
4.2 Impartiality		
4.2.1	The RMP shall be structured and managed so as to safeguard impartiality.	
4.2.2 a)	The RMP shall have arrangements to ensure that it is free from any undue pressures.	
4.2.2 b)	The RMP shall identify risks to its impartiality.	
4.2.2 c)	The RMP shall be able to demonstrate, if a risk to impartiality is identified, how the risk is managed.	
4.2.2 d)	The RMP shall have top management commitment.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
4.3 Confidentiality		
4.3.1	The RMP shall be responsible for and shall treat in an appropriate manner all information obtained.	
4.3.2	When the RMP is required by law or authorised by contractual arrangements to release confidential information, the individual or the body concerned shall be notified.	
5 Structural requirements		
5.1	The RMP shall be a legal entity.	
5.2	The RMP shall be organised and shall operate in such a way that it meets all the applicable requirements of this International Standard.	
5.3 a)	The RMP shall have a description of its legal status.	
5.3 b)	The RMP shall define the parts of the organisation covered by the management system.	
5.3 c)	The RMP shall specify responsibilities and authorities.	
5.3 d)	The RMP shall have managerial personnel and technical personnel, with the authority needed.	
5.3 f)	The RMP shall appoint personnel (however named) who shall have defined responsibility and authority.	
5.3 g)	The RMP shall have adequate provision to cover liabilities.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
5.4 a), b), c)	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 Personnel		
6.1.1	The RMP shall ensure that all personnel involved are supervised and competent and working in accordance with the management system.	
6.1.2	All personnel, including, subcontractors, or individuals acting on the RMP's behalf, shall comply with the policies and procedures.	
6.1.3	The RMP shall ensure the competence of all personnel.	
6.1.4	The RMP shall have procedures for identifying training needs.	
6.1.5	The RMP shall maintain records of job descriptions.	
6.1.6	The RMP shall authorise competent personnel to perform particular activities.	
6.2 Subcontracting		
6.2.1	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.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
6.2.2	Subcontractors shall be selected based of their ability to meet the stipulated by the RMP.	
6.2.3	The following processes shall not be subcontracted: • production planning; • selection of subcontractors; • assignment of property values and their uncertainties; • authorisation of property values and their uncertainties; • authorisation of documents.	
6.2.4	The RMP shall ensure all tasks performed by subcontractors comply with the requirements.	
6.2.5	Evidence of the subcontractor's competence shall be maintained.	
6.2.6	The RMP shall evaluate the competence of the subcontractor.	
6.2.7	Results and the descriptions of procedures used by subcontractors are to be available to allow the technical evaluation of data.	
6.2.8	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 Provision of equipment services and supplies		
6.3.1	The RMP shall have procedures in place for the selection of equipment, services and supplies.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
6.3.2	The RMP shall use only equipment, services and supplies that comply with specified requirements.	
6.3.3	The RMP shall ensure that equipment and consumable materials are not used until they have been deemed in compliance with requirements.	
6.3.4	The RMP shall maintain records of purchases of equipment, services and supplies.	
6.4 Facilities and environmental conditions		
6.4.1	The RMP shall ensure all facilities are appropriate.	
6.4.2	When the environmental conditions could have an adverse effect on the RM, the environmental conditions shall be monitored.	
6.4.3	All RM production areas shall be protected from adverse environmental influences.	
6.4.4	Access to areas shall be controlled.	
7 Technical and production requirements		
7.1 General Requirements		
7.2 Production planning		
7.2.1	The RMP shall identify and plan processes and the production plan shall be documented.	
7.2.2	Technical input of subcontractors shall be specified and documented and regularly reviewed.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
7.2.3 a)	The RMP shall address material selection (including, where appropriate, sampling).	
7.2.3 b)	During the planning stage the RMP shall address how the verification the identity of the material will be done.	
7.2.3 c)	The RMP shall maintain suitable environments.	
7.2.3 d)	The RMP shall address material processing.	
7.2.3 e)	The RMP shall address choice of measurement procedures.	
7.2.3 f)	The RMP shall address validation of measurement procedures.	
7.2.3 g)	The RMP shall address verification and calibration of measuring equipment.	
7.2.3 h)	The RMP shall specify acceptance criteria for, homogeneity.	
7.2.3 i)	The RMP shall specify acceptance criteria for stability.	
7.2.3 j)	The RMP shall design and organizing appropriate characterisation.	
7.2.3 k)	The RMP shall assess commutability.	
7.2.3 l)	The RMP shall assign property values.	
7.2.3 m)	The RMP shall establish uncertainty budgets.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
7.2.3 n)	The RMP shall define acceptance criteria for measurand levels and their uncertainties.	
7.2.3 o)	The RMP shall establish metrological traceability of measurement result/s.	
7.2.3 p)	The RMP shall issue RM documents.	
7.2.3 q)	The RMP shall ensure adequate storage conditions.	
7.2.3 r)	The RMP shall ensure appropriate labelling and packaging.	
7.2.3 s)	The RMP shall ensure appropriate transport.	
7.2.3 t)	The RMP shall ensure post-production stability monitoring.	
7.2.3 u)	The RMP shall ensure an adequate post-distribution service.	
7.2.4	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.	
7.3 Production control		
	The RMP shall verify the production plan its implementation and deviations from the plan shall be documented and approved.	
7.4 Material handling and storage		
7.4.1	The RMP shall make arrangements to ensure the integrity materials throughout the production process.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
7.4.2	The RMP shall identify, preserve and separate materials from chemicals and other samples.	
7.4.3	The RMP shall ensure adequate packaging of all RMs.	
7.4.4	The condition of all RMs shall be assessed at appropriate intervals throughout the storage period.	
7.4.5	The RMP shall control packaging and labelling and have procedures for transport to the customer.	
7.4.6	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.	
7.5 Material processing		
7.5.1	The RMP shall ensure that the material has undergone adequate processing for its intended use.	
7.5.1 a)	Procedure shall ensure qualitative analysis for verification of material type and/or identity.	
7.5.1 b)	Procedure shall address synthesis, purification, incubation, and transformation into the final form.	
7.5.1 c)	Procedure shall address homogenisation.	
7.5.1 d)	Procedure shall ensure proper handling.	
7.5.1 e)	Procedure shall address measurements for control of material processing.	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
7.5.1 f)	Procedure shall address pre-treatment, cleaning or sterilisation of processing equipment and sample containers.	
7.5.1 g)	Procedure shall address stabilisation of material.	
7.5.1 h)	Procedure shall address packaging.	
7.5.1 i)	Procedure shall address safety precautions.	
7.5.2	Equipment used in material processing shall be operated in accordance with documented procedures.	
7.6 Measurement procedures		
	Relevant requirements of ISO/IEC 17025 are met and be consistent with the required accuracy of the property values of the RM and any specifications. To achieve this requirement, the provider should consider at least the following: a) the methods are appropriate to the intended use and are the latest edition unless it is not appropriate or possible to do so; b) in-house, non-standard methods are developed by qualified personnel with adequate resources; c) non-standard methods be appropriately validated before use;	

Clause No.	Requirement	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)
	d) non-standard methods, including in-house methods and methods used outside of their intended scope, are validated to confirm they are fit for the intended use. The validation must be as extensive as is necessary and a statement as to whether the method is fit for the intended use made; and e) the range and accuracy of values obtainable from methods are relevant to the intended use.	
7.7 Measuring equipment		
	Measuring equipment shall be in compliance with the relevant requirements of ISO/IEC 17025. To achieve this requirement, the provider should consider at least the following: a) the RMP and/or its subcontractors have access to the measuring and test equipment required. The equipment is fit for purpose and has been verified as complying with specified requirements; and b) when the measurement accuracy and measurement uncertainty affect the validity of a RM property value, measuring equipment is calibrated.	

7.8 Data integrity and evaluation		
7.8.1	The RMP shall ensure that all calculations and data transfers are checked.	
7.8.2 a)	The RMP shall ensure computer software is validated and shown to be adequate for use.	
7.8.2 b)	The RMP shall ensure protecting the integrity of data.	
7.8.2 c)	The RMP shall ensure equipment and software are maintained to ensure data integrity.	
7.8.2 d)	The RMP shall ensure appropriate procedures are established and implemented for the maintenance of data security.	
7.8.3	Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate.	
7.9 Metrological traceability of certified values		
7.9.1	When producing CRMs, the metrological traceability of the certified values shall be established in compliance with the relevant requirements of ISO/IEC 17025. The RMP shall provide evidence of the metrological traceability of the certified value to a stated reference.	
7.9.2	The stated reference shall be a definition of a measurement unit through its practical realisation, or a measurement procedure including the measurement unit, or a measurement standard.	

7.9.3	Where it is technically possible, the RMP shall 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, the RMP shall 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. characterisation studies with measurements under reproducibility conditions), it shall be ensured that the measurements are calibrated with standards with metrologically traceable values.	
7.9.6	Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability.	
7.10 Assessment of homogeneity		
7.10.1	The RMP shall carry out an assessment of the homogeneity in the final packaged form.	
7.10.2	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.	
7.10.3	Validated measurement procedures shall be selected so that the precision and selectivity are fit for the purpose required.	
7.10.4	Where homogeneity needs to be determined experimentally, the RMP shall determine the homogeneity for every property of interest.	

7.10.5	For certified values, homogeneity shall be quantified as an uncertainty contribution to the certified value or shall be shown to be a negligible.	
7.11 Assessment of stability		
7.11.1 a)	The RMP shall assess the stability of all relevant properties of an RM under proposed storage conditions.	
7.11.1 b)	The RMP shall assess the stability of all relevant properties of an RM under proposed conditions of transport.	
7.11.1 c)	The RMP shall establish any necessary advice on storage and use of the material to maintain stability.	
7.11.1 d)	The RMP shall select a scheme for monitoring the stability of materials held in long term.	
7.11.1 e)	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.	
7.11.1 f)	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.	
7.11.2	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.	

7.11.3	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.	
7.12 Characterization		
7.12.1	Where the RMP assigns property values, characterisation of the RM is required.	
7.12.2	The RMP shall clearly define whether a quantitative or a qualitative property will be characterised and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure.	
7.12.3	The RMP shall select a characterisation strategy appropriate for the intended use of the RM.	
7.12.4	The RMP shall specify the characterisation 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 characterisation; 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 characterised.	

7.12.5	When evaluating the characterisation data, the RMP shall perform a technical evaluation of the data and documents involved in characterisation 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 characterisation.	
7.13 Assignment of property values and their uncertainties		
7.13.1	The RMP shall use documented procedures for the assignment of property values.	
7.13.2 a)	Procedures shall include details of the experimental designs and statistical techniques used;	
7.13.2 b)	Procedures shall include policies on treatment and investigation of anomalous results.	
7.13.2 c)	Procedures shall include whether weighting techniques are used.	
7.13.2 d)	Procedures shall include the approach used to assign uncertainties.	
7.13.2 e)	Procedures shall include any other significant factors that may affect the assignment of property values.	
7.13.3	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.	
7.13.4	Outliers shall not be excluded solely on statistical evidence until they have been investigated. Robust statistical methods may be applied where appropriate.	

7.13.5	For certified values, the RMP shall identify the uncertainty contributions to be included in the assigned uncertainty.	
7.13.6	For certified values, the RMP shall consider, at a minimum, uncertainty contributions of each of the following: a) characterisation, including any difference between multiple procedures used for characterisation; b) between-unit and within-unit inhomogeneity; c) changes of property values during storage; d) changes of property values during transport.	
7.14 RM documents and labels		
7.14.1	The RMP shall issue and make available a reference material certificate for CRMs and product information sheet for other reference materials.	
7.14.2	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).	
7.14.3	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.	
7.14.4	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.	

7.14.5	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.	
7.15 Distribution service		
7.15.1	The distribution process shall be specified including precautions needed to avoid deterioration of the RM.	
7.15.2	The RMP shall maintain records of all RM sales and distribution.	
7.15.3	The RMP shall offer to users reasonable guidance and technical support.	
7.15.4	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.	
7.15.5	Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, the RMP shall pass on to the authorised 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.	
7.16 Control of quality and technical records		
7.16.1	The RMP shall establish and maintain procedures for quality and technical records.	
7.16.2	The RMP shall ensure that it has recorded such information that might be needed in a future dispute situation.	

7.16.3	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable.	
7.16.3 Note	Records can be in the form of any type of media.	
7.16.4	When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible, etc.	
7.16.5	All records shall be held securely and in confidence.	
7.16.6	The RMP shall have procedures to protect electronically held data.	
7.16.7	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.	
7.16.8	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 Management of non-conforming work		
7.17.1	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.	
7.17.2 a)	Procedures shall ensure responsibilities and authorities for the management of non-conforming work are designated.	

7.17.2 b)	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.	
7.17.2 c)	Procedures shall ensure an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action.	
7.17.2 d)	Procedures shall ensure work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld.	
7.17.2 e)	Procedures shall ensure remedial actions such as customer notifications are taken.	
7.17.2 f)	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.	
7.17.2 g)	Procedures shall ensure the responsibility for authorisation of the resumption of work is defined.	
7.17.2 h)	Procedures shall ensure where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken.	
7.17.3	The decision on recall of RMs shall be taken in a timely manner.	
	The identification of non-conforming RMs can occur at various places within the management system.	

7.18 Complaints		
7.18.1	The RMP shall have a documented process to receive, evaluate and make decisions on complaints.	
7.18.2	A description of the handling process for complaints shall be available to any interested party.	
7.18.3	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	The RMP shall be responsible for all decisions at all levels of the handling process for complaints.	
7.18.5	Investigation and decision on complaints shall not result in any discriminatory actions.	
7.18.6	The process for handling complaints shall include: a) a description of the process for receiving, validating, investigation the and deciding what actions are to be taken; b) tracking and recording; c) appropriate action is taken.	
7.18.7	The RMP receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.	
7.18.8	Whenever possible, the RMP shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.	

7.18.9	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	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	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.	
8.1.2	**Option A**	
8.1.2.1	The documented management system shall address the scope of its RM production activities, including the type, range and scale of RM production.	
8.1.2.2	The scope of the RM activities shall be defined and documented.	
	The management system shall address the requirements contained in clauses 8.2 through to 8.11.	

8.1.3	**Option B** When taking Option B, the RMP must demonstrate and have record of the ISO 9001 certification that covers all activities that contribute to RM production.	
	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.	
8.2 Quality policy(Option A)		
8.2.1	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.	
8.2.2	Requirement for authority of policy by top management.	
8.2.3	The quality policy shall include the following list of commitments: a) to commit to the requirements of ISO 17034; b) to conduct all testing and calibration activities to the requirements of ISO/IEC 17025; c) all personnel will work to the management system; d) management will commit to continuous improvement and good professional practice.	
8.2.4	Objectives to be reviewed during management review.	

8.3 General management system documentation (Option A)		
	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.	
8.4 Control of management system documents (Option A)		
8.4.1	The RMP shall control the documents that relate to the fulfilment of this International Standard	
8.4.2 a)	The RMP shall ensure documents are approved by authorised personnel.	
8.4.2 b)	The RMP shall ensure documents are periodically reviewed and updated.	
8.4.2 c)	The RMP shall ensure changes and the current revision status of documents are identified.	
8.4.2 d)	The RMP shall ensure relevant versions of applicable documents are available at points of use.	
8.4.2 e)	The RMP shall ensure documents are uniquely identified and where necessary their distribution controlled.	
8.4.2 f)	The RMP shall ensure the unintended use of obsolete documents is prevented.	

8.5 Control of records (Option A)		
8.5.1	The RMP shall establish procedures for the controls needed for records.	
8.5.2	The RMP shall establish procedures for the retention of records.	
8.6 Management review (Option A)		
8.6.1	Schedule and Procedure In accordance with a predefined schedule and procedure, top management shall conduct management reviews, with a list of activities/topics. • Suitability of policies and procedures • Reports from managers and supervisors • Internal audits • Corrective actions • Risk identification • Assessments by external bodies • Changes to work scale and type • Customer feedback • Improvement • Resources, training, etc • Quality objectives	
8.6.2	Finding and actions from these reviews shall be recorded and discharged within a timescale.	
8.7 Internal audits (Option A)		
8.7.1	Schedule and Procedure Sets the requirement to periodically conduct Internal Audits to a predetermined schedule and procedure.	

8.7.2	When audit findings cast doubt the RMP shall take timely corrective actions.	
8.7.3	All audit findings and corrective actions that arise from them shall be recorded.	
8.7.4	Follow-up activities shall 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	The RMP shall consider the risks and opportunities to:	
8.8.1 a)	give assurance that the management system can achieve its intended result(s);	
8.8.1 b)	enhance desirable effects;	
8.8.1 c)	prevent, or reduce, undesired effects;	
8.8.1 d)	achieve improvement.	
8.8.2 a)	The RMP shall take actions to address these risks and opportunities.	
8.8.2 b)	The RMP shall take actions to integrate and implement the actions into its management system processes.	
8.8.2 c)	The RMP shall take actions to evaluate the effectiveness of these actions.	
8.8.3	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 Corrective actions (Option A)		
8.9.1	The RMP shall establish a policy and procedure(s) and shall designate appropriate authorities for implementing corrective actions.	
8.9.2	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.	
8.9.3.1	The RMP shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	
8.9.3.2	Corrective actions shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.	
8.9.3.3	Changes to the operational procedures resulting from corrective action investigations shall be documented and implemented.	
8.9.4	Corrective actions shall be monitored to ensure elimination of root causes.	
8.9.5	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 Improvement (Option A)		
8.10.1	The RMP shall continually improve the effectiveness of its management system.	
8.10.2	Required improvements and potential sources of non-conformities shall be identified.	
8.10.3	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.	
8.11 Feedback from customers (Option A)		
	The RMP shall seek feedback, both positive and negative, from its customers.	