

Transition Plan to ISO/IEC 17034:2016

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In November 2016, ISO 17034 “General requirements for the competence of reference material producers” has been published by ISO.

Based on the resolutions of the International Laboratory Accreditation Co-Operation (ILAC) the General Assembly (GA) in Delhi ISO Guide 34 replaces the standard ISO 17034. A resolution passed by IAF / ILAC General Assembly endorsed a 3 year transition period to ISO 17034:2016 from date of publication.

This document applies to the accreditation RMP that are currently accredited by INAB based on the Guide 34 and those intending to apply for RMP accreditation.

ILAC website www.ilac.org should be consulted for publication of new or revised guidance documents, as the ILAC WG 17034 will review and consider the guides and policies implemented in the regions and advise whether ILAC guidance or policy is needed.

From the 1st November 2019, accreditation to ISO Guide 34 will no longer be available and accreditation certificates to Guide 34 no longer valid.

In order to facilitate a smooth transfer to the new standard, INAB have decided upon the following transition programme:

INAB requests that accredited Reference Material Producers submit a transition action plan to their INAB accreditation officer. The plan shall be sent to INAB before 1st November 2017.

As a minimum the plan shall include:

- All specific actions to be taken to implement the changes,
- The timeframe for completion of such actions,
- The persons responsible for the actions,
- Process in place to monitor progress and completion of the actions.

The action plan will need to demonstrate an analysis of the new standard and effective implementation such that the RMP confirm it is operating to ISO 17034 by 1st May 2018.

All INAB surveillance / reassessments from 1st May 2018 will be carried out to ISO 17034:2016.

From 1st October 2017 all new applicants will be assessed against ISO 17034:2016.

The Accreditation Certificate and Schedule of Accreditation will be adapted to reflect accreditation against ISO 17034:2016 after the surveillance/re-assessment against the new standard has been successfully completed and a decision for renewal of accreditation has been granted. The accreditation number will remain the same. The date on the certificate will be the date of the decision to grant accreditation for the new standard.

Please note, that it is the responsibility of the RMP to familiarise itself with the new standard and implement the changes necessary to comply with ISO 17034:2016.

See template, attached that identifies the clauses of ISO 17034:2016 and provides INAB opinion on the extent of any changes in requirements from ISO Guide 34:2009.

Organisations may obtain a copy of this standard from:

SAI Global.

SAI Global are the official distributor of NSAI Standards contact details:

SAI Global, c/o NSAI, 1 Swift Square, Northwood, Santry, Dublin 9
Publication Sales: info@standards.ie

Tel: (01) 8576730

Fax: (01) 8576729

Web: <http://www.standards.ie>

INAB looks forward to implementing the new standard and working with you to ensure a smooth transition to ISO 17034:2016

Any queries should be directed to your accreditation officer.

Instructions for Using the Template

For Reference Material Producers (RMP):

This template identifies the clauses of ISO 17034:2016 and provides INAB opinion on the extent of any changes in requirements from ISO Guide 34:2009. Details of the actual changes are not provided and as such the RMP will need to use this template in conjunction with copies of ISO 17034:2016 and ISO Guide 34:2009.

The RMP needs to identify the change and then determine the impact on their systems, make and implement alternations as necessary, details of alterations made to your systems should then be recorded in this template and the completed template provided to INAB accreditation officer, prior to assessment to the ISO 17034.

The submission of the template should be supported by documentation demonstrating how new or changed requirements are met, implementation will be assessed at the site visit. If the RMP considers that they currently meet the requirements then this should be stated.

Key - Extent of Change:

- **Structural** – Requirement remains the same but is under a new clause number
- **Minor** – Wording of the requirement has changed but overall intent is consistent
- **Major** – Changes will require the CAB to implement new or change existing practice
- **New** – New requirement not in previous version of the standard

TO BE COMPLETED BY RMP	
Organisation Name	
INAB Accreditation Number	
Completed by	
Date of Completion	

TO BE COMPLETED BY INAB ASSESSORS	
Accreditation Officer	
Assessment Team Members	
Date(s) of review	
Issue Date	

ISO 17034:2016		ISO Guide 34:2009		EXTENT OF CHANGE	TO BE COMPLETED BY RMP	TO BE USED BY INAB ASSESSORS
CLAUSE		RELATED CLAUSE(S)			CHANGES MADE & DOCUMENTATION SUPPLIED	COMMENTS ON COMPLIANCE & REF TO FINDINGS
	Foreword			N/A	N/A	N/A
	Introduction			N/A	N/A	N/A
1.	Scope	1.	Scope	N/A	N/A	N/A
2.	Normative references	2.	Normative References	N/A	N/A	N/A
3.	Terms & Definitions	3.	Terms and Definitions	N/A	N/A	N/A
4.	General requirements			N/A	N/A	N/A
4.1	Contractual matters	4.4	Request, tender and contract reviews	Minor		Comments: Finding Ref:
4.2	Impartiality	4.2.3	Organisation and Management	Major		Comments: Finding Ref:
4.3	Confidentiality			New		Comments: Finding Ref:
5.	Structural Requirements	4.2	Organisation and Management	Major		Comments: Finding Ref:
6.	Resource Requirements			N/A	N/A	N/A
6.1	Personnel	5.2	Personnel	Minor		Comments: Finding Ref:
6.2	Subcontracting	5.3 4.5	Subcontractors Use of Subcontractors	Minor		Comments: Finding Ref:
6.3	Provision of Equipment, service and supplies	4.6	Procurement of services and supplier	Structural		Comments: Finding Ref:
6.4	Facilities and environmental conditions	5.6	Accommodation and Environmental Conditions	Minor		Comments: Finding Ref:
7.	Technical and Production Requirements			N/A	N/A	N/A
7.1.	General Requirements			New		Comments: Finding Ref:
7.2.	Production Planning	5.4	Production	Minor		Comments:

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CLAUSE		RELATED CLAUSE(S)			CHANGES MADE & DOCUMENTATION SUPPLIED	COMMENTS ON COMPLIANCE & REF TO FINDINGS
			Planning			Finding Ref:
7.3.	Production Control	5.5	Production Control	Minor		Comments: Finding Ref:
7.4.	Material Handling and Storage	5.7	Material handling and storage	Minor		Comments: Finding Ref:
7.5.	Material processing	5.8	Material processing	Minor		Comments: Finding Ref:
7.6.	Measurement Procedures	5.9	Measurement Methods	Minor		Comments: Finding Ref:
7.7.	Measuring Equipment	5.10	Measuring Equipment	Minor		Comments: Finding Ref:
7.8.	Data integrity and evaluation	5.11	Data Evaluation	Minor		Comments: Finding Ref:
7.9.	Metrological traceability of certified values	5.12	Metrological Traceability	Major		Comments: Finding Ref:
7.10.	Assessment of homogeneity	5.13	Assessment of homogeneity	Minor		Comments: Finding Ref:
7.11.	Assessment and Monitoring of Stability	5.14	Assessment of Stability	Major		Comments: Finding Ref:
7.12.	Characterisation	5.15	Characterisation	Major		Comments: Finding Ref:
7.13.	Assignment of property values and their uncertainties	5.16	Assignment of property values and their uncertainties	Minor		Comments: Finding Ref:
7.14.	RM documents and labels	5.17 5.7.5 ISO Guide 31	Certificates and documentation for users Material handling and storage	Structural		Comments: Finding Ref:
7.15.	Distribution Service	5.18	Distribution Service	Structural		Comments: Finding Ref:
7.16.	Control of quality and technical records	4.13	Records	Minor		Comments: Finding Ref:

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7.17.	Management of non-conforming work	4.9	Control of non-conforming work and/or reference material	Minor		Comments: Finding Ref:
7.18.	Complaints	4.8	Complaints	Major		Comments: Finding Ref:
8.	Management System Requirements			N/A	N/A	N/A
8.1.	Options			New		Comments: Finding Ref:
8.2.	Quality Policy	4.1.2	Quality Policy	Minor		Comments: Finding Ref:
8.3.	General management system documentation	4.1.1	General	Minor		Comments: Finding Ref:
8.4.	Control of management system documents	4.3	Document and information control	Minor		Comments: Finding Ref:
8.5.	Control of records	4.13	Records	Minor		Comments: Finding Ref:
8.6.	Management Review	4.15	Management reviews	Minor		Comments: Finding Ref:
8.7.	Internal Audit	4.14	Internal Audits	Structural		Comments: Finding Ref:
8.8.	Action to address risks and opportunities	4.11	Preventive actions	Minor		Comments: Finding Ref:
8.9.	Corrective actions	4.10	Corrective actions	Structural		Comments: Finding Ref:
8.10.	Improvement	4.12	improvement	Minor		Comments: Finding Ref:
8.11.	Feedback from customers	4.7	Customer Service	Minor		Comments: Finding Ref:
Anne x A	Summary of production requirements for RMs and CRMs			N/A	N/A	N/A

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Bibliography				N/A	N/A	N/A

