

ISO 17034:2016-11 (E)

General requirements for the competence of reference material producers

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	3
4.1	Contractual matters	3
4.2	Impartiality	3
4.3	Confidentiality	4
5	Structural requirements	4
6	Resource requirements	5
6.1	Personnel	5
6.2	Subcontracting	5
6.3	Provision of equipment, services and supplies	6
6.4	Facilities and environmental conditions	7
7	Technical and production requirements	7
7.1	General requirements	7
7.2	Production planning	7
7.3	Production control	8
7.4	Material handling and storage	8
7.5	Material processing	9
7.6	Measurement procedures	9
7.7	Measuring equipment	10
7.8	Data integrity and evaluation	10
7.9	Metrological traceability of certified values	10
7.10	Assessment of homogeneity	11
7.11	Assessment and monitoring of stability	11
7.12	Characterization	12
7.13	Assignment of property values and their uncertainties	13
7.14	RM documents and labels	14
7.15	Distribution service	15
7.16	Control of quality and technical records	16
7.17	Management of non-conforming work	16
7.18	Complaints	17
8	Management system requirements	18
8.1	Options	18
8.1.1	General	18
8.1.2	Option A	18
8.1.3	Option B	18
8.2	Quality policy (Option A)	18
8.3	General management system documentation (Option A)	19
8.4	Control of management system documents (Option A)	19
8.5	Control of records (Option A)	19

8.6	Management review (Option A)	20
8.7	Internal audit (Option A)	20
8.8	Actions to address risks and opportunities (Option A)	21
8.9	Corrective actions (Option A)	21
8.9.1	General	21
8.9.2	Cause analysis	21
8.9.3	Selection and implementation of corrective actions	21
8.9.4	Monitoring of corrective actions	22
8.9.5	Additional audits	22
8.10	Improvement (Option A)	22
8.11	Feedback from customers (Option A)	22
Annex A (informative) Summary of production requirements for RMs and CRMs		23
Bibliography		24