[COMPANY LOGO]

[Company Name]

REFERENCE MATERIAL PRODUCER MANAGEMENT SYSTEM

Established in accordance with ISO 17034:2016

RMP-GUIDE

How to Use This Documentation Set

A plain guide to the ISO 17034:2016 reference material producer management system prepared for [Company Name]

Document number	RMP-GUIDE
Revision	00
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1 What this is

1.1 This documentation set is a complete management system for a reference material producer, written to satisfy ISO 17034:2016, the international standard titled General requirements for the competence of reference material producers. Prepared for [Company Name], it contains 202 controlled documents together with 10 validated calculation tools.

1.2 The system is built on three decisions that shape everything in it. First, it uses the Option A route of Clause 8, meaning it is a standalone system that satisfies the standard directly, without depending on a separate ISO 9001 certification. Second, it is built for a producer that does not operate its own testing laboratory, so all characterization, homogeneity and stability measurement is performed by approved subcontracted laboratories under the technical direction of [Company Name]. Third, it covers three families of reference material: matrix solids, petroleum, fuel and gas, and biological, microbiological and in vitro diagnostic materials.

1.3 This guide explains how the set is organized, how the documents work together, how to put the system into use, and what remains for you to complete before assessment. Read this guide first, then read the Quality Manual RMP-QM-01, which is the spine that connects everything else.

> **NOTE** The whole set uses square-bracket placeholders such as [Company Name], [Address] and [ ] wherever a value is specific to your organization. These are deliberate. Section 6 of this guide explains how to complete them.

2 How the set is organized

2.1 The documents are arranged in nine numbered folders. Each folder is a tier of the system, and the tiers build on each other from the top down. The folders and their contents are:

Folder	Tier	What it contains	Count
00 Read Me First	Guidance	This guide and the master document register	2
01 Foundation Documents	Foundation	Who the producer is, what is in scope, what it produces, its liabilities, structure, appointments, obligations and glossary	8
02 Quality Manual	Manual	The single document that maps every clause of the standard to where it is satisfied	1
03 Policies	Policy	The ten top management commitments, from quality and impartiality to corrective action	10
04 Procedures	Procedure	The forty six procedures, one for each activity, covering clauses 4 to 8	46
05 Work Instructions	Work instruction	The twenty eight bench and desk instructions, generic and family specific	28
06 Forms	Record	The seventy nine fillable forms that capture the evidence	79
07 Templates	Template	The seven output templates: production plan, certificate, product information sheet, labels, inserts	7
08 Technical Tools	Calculator	The ten validated Excel calculators for homogeneity, stability, uncertainty and more	10
09 Accreditation Readiness	Readiness	The thirteen documents that carry you through the assessment	13

[COMPANY LOGO]

[Company Name]

REFERENCE MATERIAL PRODUCER MANAGEMENT SYSTEM

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RMP-QP-23

Assessment of Homogeneity

Procedure for designing, specifying, subcontracting and evaluating the assessment of between-unit and within-unit homogeneity of reference materials in their final packaged form, and for quantifying the homogeneity contributions to the uncertainty of a certified value

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Document control

Revision history

Rev	Date	Clause / section affected	Description of change	Prepared by	Approved by
00	[DD Mmm YYYY]	All	First issue. Document created as part of the establishment of the ISO 17034:2016 management system.	[Name]	[Name]

Approval

Action	Name	Position	Signature	Date
Prepared by	[Name]	Quality Manager		
Reviewed by	[Name]	Technical Manager		
Approved by	[Name]	Top Management		

Distribution

Copy no.	Holder	Format	Controlled
Master	Quality Manager	Electronic, read only	Yes
01	Top Management	Electronic, read only	Yes
02	Technical Manager	Electronic, read only	Yes
03	Production personnel, shared drive	Electronic, read only	Yes
[ ]	[Accreditation Body] assessment team	Electronic or hard copy on request	No, issued for assessment

Related documents

Reference	Title	Relationship
ISO 17034:2016	General requirements for the competence of reference material producers	Clauses 7.10.1 to 7.10.5 are discharged by this procedure. Clauses 7.2.3 h) and 7.13.6 b) are supported
ISO Guide 35	Reference materials, guidance for characterization and assessment of homogeneity and stability	Adopted for the one-way ANOVA model, the upper-limit estimate and the isochronous logic referenced by RMP-QP-24
RMP-QP-21	Statistical Procedures	Governs the validated statistical tools, TOOL-01 and TOOL-02, applied in this procedure
RMP-QP-09	Technical Evaluation of Subcontractor Data	Subcontractor raw data are evaluated on RMP-F-19 under this procedure before any homogeneity result is used
RMP-QP-24	Assessment and Monitoring of Stability	Shares the study material, the subcontractor and the single-run principle. u_bb and u_lts combine in the same budget
RMP-QP-28	Value Assignment and Uncertainty	Receives u_bb and u_wb as contributions to u_CRM on RMP-F-44
RMP-POL-08	Outliers, Anomalous Results and Robust Statistics	Governs the treatment of variance outliers and unit-mean outliers found in the homogeneity data
RMP-FD-08	Glossary and Uncertainty Notation	Defines the symbols u_bb, u_wb, s_bb and u*_bb used throughout

Reference	Title	Relationship
RMP-QP-13	Production Planning	The production plan TPL-01 fixes batch size, packaging form and the properties to be certified, which set the homogeneity design

Contents

This table of contents is generated automatically. To populate or refresh it in Microsoft Word, press Ctrl+A then F9, or right click the field and select Update Field, Update entire table.

1 Purpose

1.1 ISO 17034:2016 clause 7.10.1 requires the reference material producer to assess the homogeneity of the material for the property values to be certified or otherwise specified, and clause 7.10.5 requires that, for a certified value, the contribution of inhomogeneity to the uncertainty is either quantified or shown to be negligible. This procedure establishes how [Company Name] designs the homogeneity study, writes the protocol, sets the acceptance criteria, selects the units, specifies the measurements for the subcontractor, evaluates the returned data, and reports the between-unit and within-unit contributions to the uncertainty budget.

1.2 Homogeneity is the property that different portions of a reference material, taken at random, carry the same value within stated limits. A reference material that is not adequately homogeneous cannot carry a single certified value, because the value would depend on which unit and which portion of a unit the user happened to measure. Assessment of homogeneity is therefore not a formality. It is one of the two experimental pillars, with stability under RMP-QP-24, on which a defensible certified value rests.

1.3 This procedure discharges the design, specification, criteria and evaluation elements of homogeneity assessment. All measurement is subcontracted. Section 4 states which activities are non-subcontractable and which are subcontracted, and section 5 states the point at which subcontractor data enter the process and the control applied to them before use.

2 Scope

2.1 This procedure applies to every batch of reference material produced by [Company Name] in every family of the production schedule RMP-FD-03: MX matrix solids, PF petroleum, fuel and gas materials, and BI biological, microbiological and in vitro diagnostic materials. It aligns with steps P10, P11 and P12 of the process map at QM-01 Annex B.

2.2 Homogeneity is assessed on the material in its FINAL PACKAGED FORM, for a stated property, and for a stated minimum sample size. It is never assessed in the abstract. A statement that a material is homogeneous, without naming the property, the packaged unit and the smallest test portion for which that statement holds, is not a valid homogeneity result and is not accepted at value assignment.

The homogeneity of a material is always qualified by three things	Because
The stated property	A material may be homogeneous for one measurand and inhomogeneous for another. A powder may be uniform in bulk composition yet segregated in a trace element. Clause 7.10.4 requires assessment for every property unless grouping is justified
The final packaged form	Homogeneity is a property of the unit the user receives, after filling, sealing, lyophilisation or ampouling. Assessment on bulk material before packaging does not demonstrate that the packaged units agree with one another
The minimum sample size	Within-unit homogeneity depends on the test portion. A value valid for a [500] mg portion may not hold for a [10] mg portion. The minimum sample size that supports the value is determined here and stated on the certificate

2.3 Two distinct contributions are assessed and are never conflated:

a) Between-unit homogeneity, the variation of the property value from one packaged unit to another across the batch. Its standard uncertainty is u_bb, estimated from an estimated between-unit standard deviation s_bb.

b) Within-unit homogeneity, the variation of the property value between test portions taken from a single unit, at the minimum sample size to be stated on the certificate. Its standard uncertainty is u_wb.

> **NOTE** For a non-certified reference material the position of clause 7.10.5 differs. Homogeneity need not be quantified as an uncertainty contribution, but it must still be assessed and the outcome stated. The non-certified position is set out in QM-01 Annex C. This procedure writes the certified path in full, because every material in the current schedule carries certified values.

3 References

Reference	Title	Use in this procedure
ISO 17034:2016	General requirements for the competence of reference material producers	Clauses 7.10.1 to 7.10.5 discharged. Clause 7.2.3 h) production plan content, and clause 7.13.6 b) uncertainty budget content, supported
ISO Guide 35	Reference materials, guidance for homogeneity and stability	One-way ANOVA model, the upper-limit estimate u*_bb, and the treatment of a non-significant among-unit term
RMP-QP-21	Statistical Procedures	Validation and control of TOOL-01 and TOOL-02
RMP-QP-09	Technical Evaluation of Subcontractor Data	Control gate for returned raw data, recorded on RMP-F-19
RMP-POL-08	Outliers, Anomalous Results and Robust Statistics	Cochran variance-outlier test and unit-mean outlier treatment
TOOL-01	Homogeneity ANOVA calculator	Computes MS_among, MS_within, F, u_bb and u*_bb from the returned data
TOOL-02	Minimum sample size calculator	Sets the number of units m for the batch size, and the within-unit portion for the certificate
RMP-F-35	Homogeneity Study Protocol	The design record issued for each study
RMP-F-36	Homogeneity Study Report	The evaluation record produced for each study

4 Responsibilities

4.1 Design of the study, the acceptance criteria, the selection of units and the evaluation of the returned data are non-subcontractable (NS). They are performed by the Metrology and Data Officer and approved by the Technical Manager. The measurement itself is subcontracted (SC) to an approved laboratory selected under RMP-QP-08. The determination codes are those of RMP-FD-02.

Activity	Det.	Tech Mgr	Metrology and Data	RM Production	Subcontract Off.	Lab
Fix batch, packaging form and properties (via TPL-01)	NS	A	C	R	I	-
Set m and the minimum sample size (TOOL-02)	NS	A	R	C	I	-
Design the study and write protocol RMP-F-35	NS	A	R	C	I	-
Set the acceptance criteria	NS	A	R	C	I	-
Select and label the units by stratified random selection	NS	C	R	R	I	-
Write the measurement plan RMP-F-40 into task spec RMP-F-18	NS	A	R	I	C	-
Place the subcontract order	SC	I	I	I	R	-
Perform the measurements under repeatability conditions	SC	I	I	I	C	R

Annex A Clause coverage of this procedure

ISO 17034:2016 clause	Requirement in brief	Where satisfied in this procedure
7.10.1	Assess homogeneity for the property values to be certified or specified	Sections 1.1, 2.2, 5.2 to 5.11
7.10.2	Where a value applies to more than one batch, demonstrate equivalence or assess each batch	Section 5.11
7.10.3	Measurement method of adequate precision and, where relevant, selectivity	Section 5.6
7.10.4	Assess every property unless grouping is scientifically justified	Section 5.2, with written justification on RMP-F-35
7.10.5	For a certified value, quantify the inhomogeneity contribution (u_bb, u_wb) or show it negligible	Sections 5.9, 5.10, 6.1, and the worked example in section 8
7.2.3 h)	Production plan to address homogeneity assessment	Sections 5.2 to 5.5, protocol RMP-F-35 derived from TPL-01
7.13.6 b)	Uncertainty budget to include the between-unit inhomogeneity contribution	Sections 5.9, 6.1, transfer to RMP-F-44
7.14	Statement of the minimum sample size on the certificate	Sections 5.3.2 and 5.10.2

NOTE For a non-certified reference material, clause 7.10.5 does not require the inhomogeneity to be expressed as an uncertainty contribution, but homogeneity must still be assessed and the result stated. See QM-01 Annex C.

[COMPANY LOGO]	[Company Name]	Form RMP-F-36

Homogeneity Study Report Template

Report of the evaluation of a homogeneity study, giving the between unit and within unit uncertainty contributions carried to the budget, per RMP-QP-23 and ISO 17034:2016 clause 7.10.5

Form number: RMP-F-36	Revision: 00	Retention: Life of the material plus 6 years	Owner: Metrology and Data Officer

Supports: RMP-QP-23, ISO 17034:2016 clauses 7.10.4, 7.10.5

> **NOTE** Evaluation of the returned data is non subcontractable (NS). The subcontractor raw data are first accepted on RMP-F-19 under RMP-QP-09. The one way ANOVA is computed with RMP-TOOL-01. This report records the inputs, the ANOVA outputs and the conclusion carried to the uncertainty budget RMP-F-44.

1 Study identification

Field	Entry
Report reference	[ ]
Protocol reference	RMP-F-35 no. [ ]
Reference material and code	[ ]
Family	MX / PF / BI (circle one)
Batch number	[ ]
Measurand	[ ]
Subcontractor and data acceptance	RMP-F-19 no. [ ]

2 Study inputs

Input	Symbol	Value
Number of units measured	m	[ ]
Test portions per unit	n	[ ]
Property mean over all portions		[ ]
Minimum sample size		[ ]
Single run confirmed		Yes / No

3 ANOVA outputs, from RMP-TOOL-01

Quantity	Symbol	Value
Mean square among units	MS_among	[ ]
Mean square within units	MS_within	[ ]
F ratio, MS_among / MS_within	F	[ ]
Estimated between unit standard deviation	s_bb	[ ]
Between unit standard uncertainty	u_bb	[ ]
Upper limit fallback where MS_among is not greater than MS_within	u*_bb	[ ]
Within unit standard uncertainty at the minimum sample size	u_wb	[ ]

FALLBACK RULE Where MS_among is greater than MS_within, report u_bb = sqrt((MS_among - MS_within)/n). Where MS_among is not greater than MS_within, u_bb cannot be estimated directly. Report the upper limit u*_bb = (MS_within/n)^0.5 times (2/(m*(n-1)))^0.25 and carry u*_bb to the budget, per POL-08 and RMP-QP-23.

4 Conclusion

Field	Entry
Material judged sufficiently homogeneous	Yes / No
Acceptance criterion met	Yes / No (per RMP-F-35 section 4)
Contribution carried to the budget	u_bb [ ] u_wb [ ] (or u*_bb [ ])
Carried to	RMP-F-44 uncertainty budget, clause 7.13.6 b)
Retest or further stratification required	Yes / No

NOTE MX-01 illustrative anchor. For the agricultural soil MX-01, aqua regia extractable cadmium, the study returns u_bb 0.030 mg/kg and u_wb 0.020 mg/kg at the minimum sample size of 0.5 g. These values are carried to the budget in RMP-F-44 alongside u_char 0.040, u_lts 0.025 and u_sts 0.015 mg/kg. The numbers are illustrative and do not relate to any actual batch.

Action	Name	Position	Signature	Date
Evaluated by	[ ]	Metrology and Data Officer		
Approved by	[ ]	Technical Manager		

This report supports RMP-QP-23 Homogeneity. The ANOVA is computed with RMP-TOOL-01. Contributions are carried to RMP-F-44.