

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Technical and production requirements	2
4.1 General	2
4.2 Production planning	2
4.3 Specification of the CRM and its measurand	2
4.3.1 General	2
4.3.2 Specification of purpose	2
4.3.3 Specification of the measurand	3
4.3.4 Definition of the metrological reference	3
4.3.5 Fitness for purpose	3
4.3.6 Safety considerations	4
4.3.7 Resources and approaches to purity analysis	4
4.4 Candidate material sourcing and assessment of suitability, including verification of PC identity and adequate purity	4
4.4.1 Material sourcing	4
4.4.2 Verification of PC identity	4
4.4.3 Material suitability	5
4.5 Product packaging and specification of conditions for storage and safe handling	5
4.5.1 General considerations	5
4.5.2 Selection and treatment of packaging materials	6
4.5.3 Storage and transportation issues	6
4.5.4 Label of containers	6
4.6 Determination of approaches to purity assessment of the CRM	7
4.7 Development and validation of procedures for characterization, including achieving target measurement uncertainty	8
4.7.1 General	8
4.7.2 Multiple methods for purity determination	8
4.7.3 Property value boundaries	9
4.8 Assessment of homogeneity	9
4.8.1 General	9
4.8.2 Preliminary assessment of homogeneity	9
4.8.3 Sampling strategy	9
4.8.4 Minimum sample size	10
4.8.5 Experimental method of homogeneity assessment	10
4.9 Assessment and monitoring of stability	10
4.9.1 General	10
4.9.2 Sources of instability	10
4.9.3 Repeated use stability	10
4.9.4 Stability monitoring	11
4.10 Characterization of the CRM	11
4.10.1 General	11
4.10.2 Direct determination	11
4.10.3 Indirect determination	11

4.10.4	Characterization for use in multi-component solutions	12
4.11	Metrological traceability of the certified property value	12
4.12	Preparation of certificates.....	12
Annex A (informative)	Examples of structure identification approaches.....	14
Annex B (informative)	Examples of measurement procedures for assessment of purity.....	16
Annex C (informative)	Examples of production of pure substance organic certified reference materials by reference material producers.....	20
Bibliography.....		41