

ISO 33406:2024-05 (E)

Approaches for the production of reference materials with qualitative properties

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Qualitative properties	1
5	Meeting technical and production requirements	2
5.1	Characterization	2
5.1.1	General considerations	2
5.1.2	Materials characterized based on provenance	2
5.1.3	Materials characterized for identity based on measurements	2
5.1.4	Characterization by a combination of methods	3
5.2	Application of metrological traceability to qualitative determinations	4
5.2.1	General	4
5.2.2	Metrological traceability	5
5.2.3	Reference data and reference materials for qualitative determinations	5
5.2.4	Qualitative value assigned based on provenance	5
5.3	Measurement uncertainty and confidence in qualitative values	6
5.3.1	General considerations	6
5.3.2	Measurement uncertainty	6
5.3.3	Confidence in qualitative values	7
5.4	General considerations for the selection of statistical approaches	8
5.5	Assessment of homogeneity	9
5.5.1	General considerations	9
5.5.2	Experimental designs for homogeneity assessment for qualitative values	9
5.5.3	Statistical approaches for homogeneity assessment for qualitative properties	10
5.6	Assessment of stability	12
5.6.1	General considerations for stability assessment	12
5.6.2	Designs for experimental stability studies for qualitative properties	13
5.7	Commutability assessment	15
5.7.1	General considerations	15
5.7.2	Commutability assessment for qualitative properties	16
5.7.3	Commutability statement	16
Annex A (informative) Guidance for DNA and protein reference materials		18
Annex B (informative) Expressing confidence in qualitative values		21
Annex C (informative) Statistical procedures		28
Annex D (informative) Examples of homogeneity and stability studies of reference materials with qualitative properties		32
Bibliography		37