

# ISO 33406:2024-05 (E)

## Approaches for the production of reference materials with qualitative properties

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>1</b>
<b>4</b>	<b>Qualitative properties .....</b>	<b>1</b>
<b>5</b>	<b>Meeting technical and production requirements .....</b>	<b>2</b>
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
	<b>Annex A (informative) Guidance for DNA and protein reference materials .....</b>	<b>18</b>
	<b>Annex B (informative) Expressing confidence in qualitative values .....</b>	<b>21</b>
	<b>Annex C (informative) Statistical procedures .....</b>	<b>28</b>
	<b>Annex D (informative) Examples of homogeneity and stability studies of reference materials with qualitative properties .....</b>	<b>32</b>
	<b>Bibliography .....</b>	<b>37</b>