

# 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>
<b>5.1</b>	<b>Characterization .....</b>	<b>2</b>
<b>5.1.1</b>	<b>General considerations .....</b>	<b>2</b>
<b>5.1.2</b>	<b>Materials characterized based on provenance .....</b>	<b>2</b>
<b>5.1.3</b>	<b>Materials characterized for identity based on measurements .....</b>	<b>2</b>
<b>5.1.4</b>	<b>Characterization by a combination of methods .....</b>	<b>3</b>
<b>5.2</b>	<b>Application of metrological traceability to qualitative determinations .....</b>	<b>4</b>
<b>5.2.1</b>	<b>General .....</b>	<b>4</b>
<b>5.2.2</b>	<b>Metrological traceability .....</b>	<b>5</b>
<b>5.2.3</b>	<b>Reference data and reference materials for qualitative determinations .....</b>	<b>5</b>
<b>5.2.4</b>	<b>Qualitative value assigned based on provenance .....</b>	<b>5</b>
<b>5.3</b>	<b>Measurement uncertainty and confidence in qualitative values .....</b>	<b>6</b>
<b>5.3.1</b>	<b>General considerations .....</b>	<b>6</b>
<b>5.3.2</b>	<b>Measurement uncertainty .....</b>	<b>6</b>
<b>5.3.3</b>	<b>Confidence in qualitative values .....</b>	<b>7</b>
<b>5.4</b>	<b>General considerations for the selection of statistical approaches .....</b>	<b>8</b>
<b>5.5</b>	<b>Assessment of homogeneity .....</b>	<b>9</b>
<b>5.5.1</b>	<b>General considerations .....</b>	<b>9</b>
<b>5.5.2</b>	<b>Experimental designs for homogeneity assessment for qualitative values .....</b>	<b>9</b>
<b>5.5.3</b>	<b>Statistical approaches for homogeneity assessment for qualitative properties .....</b>	<b>10</b>
<b>5.6</b>	<b>Assessment of stability .....</b>	<b>12</b>
<b>5.6.1</b>	<b>General considerations for stability assessment .....</b>	<b>12</b>
<b>5.6.2</b>	<b>Designs for experimental stability studies for qualitative properties .....</b>	<b>13</b>
<b>5.7</b>	<b>Commutability assessment .....</b>	<b>15</b>
<b>5.7.1</b>	<b>General considerations .....</b>	<b>15</b>
<b>5.7.2</b>	<b>Commutability assessment for qualitative properties .....</b>	<b>16</b>
<b>5.7.3</b>	<b>Commutability statement .....</b>	<b>16</b>
	<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>