

Summary of Changes to V1 M2 – M7

Items underlined and in italics are those that were modified/revised from the previous version.

Global Changes:

Change “parameter” to “analyte”

Converted “notes” added by TNI to requirements (if applicable)

V1M2

Change ISO citation from ISO/IEC 17025:2005(E) to ISO/IEC 17025:2005

Add language specifically excluding all notes as requirements

Definitions

Analyte (revised)

Data Integrity (revised)

Parameter (deleted)

Physical parameter (added)

Reference Method (revised)

5.4.4 Non Standard Methods – added ISO Text

5.4.5 Validation of Methods – added ISO Text

5.4.5.4 (TNI additional requirements) – revised for clarity

V1M3

1.4 Method Selection – deleted majority of text and referred to Module 2

1.5 Method Validation – deleted majority of text and referred to Module 2

Specified requirements for non-standard and reference methods as separate items.

1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.

1.6.3 Revised for clarity – on-going DOC are meant to be continuous rather than singular events.

V1M4

Removed proposed definition for Physical Parameter and placed it Module 2

1.4 Method Selection – deleted majority of text and referred to Module 2

1.5 Method Validation – deleted majority of text and referred to Module 2

Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.

1.5.2.1 LOD

Removed “etc.” as suggested.

a) through e) reordered for clarity

1.5.2.2 LOQ

Substituted the word “determine(d)” for “establish(ed)” to clarify how LOQs are ascertained.

Removed “etc.” as suggested.

Clarified that LOQs are verified on each instrument used for a specific test.

Reordered b) through d) for clarity

1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.

1.6.3.1 Revised for clarity – on-going DOC are meant to be continuous rather than singular events.

V1M5

Added Definition for “**Source Water**”

1.4 Method Selection – deleted majority of text and referred to Module 2

1.5 Method Validation – deleted majority of text and referred to Module 2

Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.

1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.

1.6.2.2 a) "sterile" added to further characterize and quality system matrix.

1.7.3.1 b) Sterility Checks reordered for clarity

1.7.5 b) Removed multiple uses of "source" in the paragraph

The use of sterile buffered water or peptone was modified with the statement "When required by method, the diluents". Removed the perceived inconsistency between a quality system matrix and the use of sterile diluents.

1.6.3.1 Revised for clarity – on-going DOC are meant to be continuous rather than singular events.

V1M6

1.4 Method Selection – deleted majority of text and referred to Module 2

1.5 Method Validation – deleted majority of text and referred to Module 2

Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.

1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.

1.6.3.1 Revised for clarity – on-going DOC are meant to be continuous rather than singular events.

1.7.1 c)

Added language to distinguish background measurements from short-term contamination checks.

c) iii) Changed "weekly" to "quarterly" for consistency with the ASTM standard.

V1M 7

1.4 Method Selection – deleted majority of text and referred to Module 2

1.5 Method Validation – deleted majority of text and referred to Module 2

Specific requirements for reference and non-standard methods are stated.

1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.

1.6.3 Revised for clarity – on-going DOC are meant to be continuous rather than singular events.