

**ASB 055: Standard for Breath Alcohol Measuring Instrument Calibration**  
**Summary of Changes to Draft Version 01**  
**06 November 2021**

During adjudication of initial public comments, many changes were made to the original standard and the reader should review Version 02 in its entirety (i.e., consider this as a new document). Comments will be considered for all portions of this version when commenters follow the ASB process of comment submission.

While substantive changes were few, significant reorganization occurred to provide clarity. Therefore, a 'red-line' version showing revisions from the original to the current version of the document will not be provided. Instead, a summary of changes has been provided to aid the reviewer.

Foreword:

- Minimal revisions were made to address public comment and incorporate some material previously contained in Annex A (Foundational Principles).

Section 1:

- No changes to the Scope.

Section 2:

- ANSI/ASB Standard 017, *Standard Practices for Measurement Traceability in Forensic Toxicology*, First Edition, 2018 was added as a normative reference.

Section 3:

- Definitions were revised:
  - Bias, lower limit of quantitation, masking, upper limit of quantitation
- Definitions were added to provide clarity to the document:
  - Calibrator, computer system, data, measured quantity value, nominal quantity value

Section 4:

- Content of this section limited to method development and optimization.
- Due to the nature of computer systems in breath alcohol instrumentation, select requirements and guidance previously covered in validation were moved to this section.
- Additional guidance added for process clarity:
  - Validation is to occur with a fully developed method.
  - Parameters for determining the upper and lower limits of quantitation.

Section 5:

- This is a new section (Elements of a Calibration Method); however, requirements were previously contained in the original version (Section 4.1).
- Expanded language to clarify the Consensus Body's intentions regarding reporting ranges (see 5.d).ii) and 5.f) in the revised document).
- Removed linear vs. non-linear calibration curve references.

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Section 6:

- Language revisions for clarity.
- Section 6.2 (Establishing a Validation Plan) appeared in Section 4.3 in the original version.
- Section 6.3.2 (Bias and Precision) appeared in Section 4.4.2 in the original version.
  - Precision formula updated to %CV.
  - Within and Between Run precision requirements added.
- Characteristics of reference material broadened in Section 6.3.5.

Section 7:

- This is a new section (Revalidation of Previously Validated Methods); however, requirements were previously contained in the original version (Section 4.5).

Section 8:

- This is a new section (Validation Documentation Requirements); however, requirements were previously contained in the original version (Section 4.6).

Section 9:

- Requirements were previously contained in the original version (Section 5).
- Revisions for clarity
- Additional requirement for instrument performance evaluation prior to adjustment.

Section 10:

- Requirements were previously contained in the original version (Section 6).
- Widening of document retention requirement (see Section 10.4).

Section 11:

- This is a new section (Elements of a Calibration Certificate); however, requirements were previously contained in the original version (Section 6.6.1).
- Minimal revisions to address public comment.

Section 12:

- This is a new section (Amended Certificates); however, requirements were previously contained in the original version (Section 6.6.2).

Annexes:

- Original Annex B became Annex A (Method Development Example). Revised formatting of tables.
- Original Annex C became Annex B (Method Validation Plan Example)
- Annex C is a new annex (calculations)

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- Revised Annex D to harmonize with changes to precision calculations and validation requirements.
- Annex E demonstration experiment acceptance criteria revised to bias and precision parameters used elsewhere in the document.
- Minor revisions to F, G, and H.

Removed from the original version:

- The term “interferences” was removed as it is no longer used in the document.
- Original version Annex A (Foundational Principles) removed as this is no longer an ASB requirement.
- Original version Section 6.2 (Personnel) removed in anticipation of ASB 173: *Standard for Education and Training of Forensic Toxicology Personnel* (unpublished at this time).