



## Standard Practice for Validation of Process Stream Analyzer Systems<sup>1</sup>

This standard is issued under the fixed designation D 3764; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

### INTRODUCTION

Operation of a process stream analyzer system typically involves four sequential activities. (1) **Analyzer Calibration**—When an analyzer is initially installed, or after major maintenance has been performed, diagnostic testing is performed to demonstrate that the analyzer meets the manufacturer's specifications and historical performance standards. These diagnostic tests may require that the analyzer be adjusted so as to provide predetermined output levels for certain reference materials. (2) **Correlation**—Once the diagnostic testing is completed, process stream samples are analyzed using both the analyzer system and the corresponding primary test method. A mathematical function is derived that relates the analyzer output to the primary test method (PTM). The application of this mathematical function to an analyzer output produces a predicted PTM result. (3) **Initial Validation**—Once the relationship between the analyzer output and primary test method results has been established, an initial validation is performed to demonstrate that the predicted PTM results agree with those from the primary test method within the tolerances established from the correlation activities and with no statistically observable systemic bias. (4) **Continual Validation**—During normal operation of the process analyzer system, quality assurance testing is conducted to demonstrate that the agreement between the analyzer and primary test method results during the initial validation is maintained. This practice deals primarily with the third and fourth of these activities.

### 1. Scope

1.1 This practice describes procedures and recommendations for the validation of a total process analyzer system or its subsystems, or both, used in the direct measurement of physical or chemical characteristics of petroleum and petrochemical products. Procedures for initial validation and subsequent continuous quality assurance of system performance are described.

1.2 Validation is achieved by statistical assessment of results generated for common materials by the total analyzer system or its subsystem versus results generated by an ASTM or other established primary test method (PTM).

1.2.1 For analyzers used in product certification, the analyzer system precision determined by the statistical assessment is typically compared to the site precision for the PTM.

1.2.2 For other analyzer applications, analyzer system precision determined by the statistical assessment is compared to prespecified performance criteria based on the intended use.

1.3 Two procedures for validation are described: the line sample procedure and the validation reference material (VRM) injection procedure.

1.4 Only the analyzer system or subsystem downstream of the VRM injection point or the line sample extraction point is being validated by this practice.

1.5 The line sample procedure is limited to applications where material can be safely withdrawn from the sampling point of the analyzer unit without significantly altering the property of interest.

1.6 Validation information obtained in the application of this practice is applicable only to the type and property range of the materials used to perform the validation.

1.7 Procedures for conducting an initial validation are described. These procedures are typically conducted at installation or after major maintenance once the system mechanical fitness-for-use has been established.

1.8 Procedures for the continual validation of system performance are described. These procedures are typically applied at a frequency commensurate with the criticality of the application.

1.9 This practice applies if the process stream analyzer system and the primary test method are based on the same measurement principle(s), or, if the process stream analyzer

<sup>1</sup> This practice is under the jurisdiction of ASTM Committee D02 on Petroleum Products and Lubricants and is the direct responsibility of Subcommittee D02.25 on Validation of Process Analyzers.

Current edition approved Dec. 10, 2001. Published April 2002. Originally published as D 3764 - 80. Last previous edition D 3764 - 92 (1998).

