



Standard Practice for Validation of the Performance of Process Stream Analyzer Systems¹

This standard is issued under the fixed designation D3764; 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 the analyzer system. For application where the process analyzer system results are required to agree with results produced from an independent (primary) test method (PTM), a mathematical function is derived that relates the analyzer results to the primary test method results (PTMR). The application of this mathematical function to an analyzer result produces a predicted primary test method result (PPTMR). (3) **Probationary Validation**—After the correlation relationship between the analyzer results and primary test method results has been established, a probationary validation is performed using an independent but limited set of materials that were not part of the correlation activity. This probationary validation is intended to demonstrate that the PPTMRs agree with the PTMRs to within user-specified requirements for the analyzer system application. (4) **General and Continual Validation**—After an adequate amount of PPTMRs and PTMRs have been accrued on materials that were not part of the correlation activity, a comprehensive statistical assessment is performed to demonstrate that the PPTMRs agree with the PTMRs to within the tolerances established from the correlation activities. Subsequent to a successful general validation, quality assurance control chart monitoring of the differences between PPTMR and PTMR is conducted during normal operation of the process analyzer system to demonstrate that the agreement between the PPTMRs and PTMRs established in the General Validation is maintained. This practice deals with the third and fourth of these activities.

1. Scope

1.1 This practice describes procedures and methodologies based on the statistical principles of Practice D6708 to validate whether the degree of agreement between the results produced by a total analyzer system (or its subsystem), versus the results produced by an independent test method that purports to measure the same property, meets user-specified requirements. This is a performance-based validation, to be conducted using a set of materials that are not used a priori in the development of any correlation between the two measurement systems under

investigation. A result from the independent test method is herein referred to as a Primary Test Method Result (PTMR).

1.2 This practice assumes any correlation necessary to mitigate systemic biases between the analyzer system and PTM have been applied to the analyzer results.

1.3 This practice requires that both the primary method against which the analyzer is compared to, and the analyzer system under investigation, are in statistical control. Practices described in Practice D6299 should be used to ensure this condition is met.

1.4 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 system uses a direct and well-understood measurement principle that is similar to the measurement principle of the primary test method. This practice also applies if the process stream

¹ 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 Performance Assessment and Validation of Process Stream Analyzer Systems.

Current edition approved June 1, 2009. Published July 2009. Originally approved in 1980. Last previous edition approved in 2006 as D3764-06^{e1}. DOI: 10.1520/D3764-09.