



# Standard Guide for Development of an Independent Third-Party Verification of Reference Materials<sup>1</sup>

This standard is issued under the fixed designation F2717; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide covers the significance and use, planning, conduct and completion of an independent third-party verification of reference materials.

1.2 In this guide, independent third-party verification (ITPV) is defined as the evaluation of the conceptual and technical soundness a design or outcome being reviewed by one or more independent third party (ITPV) qualified by their education, training, and experience in the same discipline, or closely related field of science, to judge the worthiness of the design or assess the design's likelihood of achieving the intended objectives and anticipated outcomes.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

2.1 *U.S. Department of Environmental Protection:*<sup>2</sup>  
[EPA/100/B-06/002 EPA Peer Review Handbook](#)

## 3. Significance and Use

3.1 In this guide, the planning, conduct, and completion of the independent verification, and other related details are addressed.

3.2 The ITPV is intended to assist manufacturers, users, and regulating authorities in ensuring the accuracy of a reference material with a high level of confidence.

## 4. Standard Operating Procedures

4.1 *Overview*—Planning an ITPV is a critical first step to ensure a successful verification of a reference material. The

<sup>1</sup> This guide is under the jurisdiction of ASTM Committee F10 on Livestock, Meat, and Poultry Evaluation Systems and is the direct responsibility of Subcommittee F10.20 on Device Performance Criteria.

Current edition approved May 1, 2014. Published June 2014. Originally approved in 2008. Last previous edition approved in 2008 as F2717–08. DOI: 10.1520/F2717-14.

<sup>2</sup> Available from United States Environmental Protection Agency (EPA), Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460, <http://www.epa.gov>.

independent third party needs to create and document a standard operating procedure appropriate for verifying the accuracy of the reference material. This includes identification of needed resources (budget and personnel), schedule for completion, verification procedures, and verification of recorded results.

### 4.2 *Identification of Needed Resources:*

4.3 *Scheduling*—The stakeholder decides on the timing and frequency of the ITPV. At least one ITPV event must occur, beginning when the final draft work product becomes available. However, a review performed earlier in the work product development stages is a superior approach for some work products. There may be substantial incremental benefit to conducting more than one peer review during the whole process of work product development, particularly where it involves complex tasks or it could produce controversial findings.

4.4 *Mechanism for Verification*—An ITPV provides the greatest credibility when it involves well qualified independent third parties. An ITPV requires at least one qualified person or entity with the expertise to adequately verify a reference material. In some instances it may require more than one person or entity to conduct an ITPV. Arrangements for the most appropriate and feasible number of persons or entities forming an ITPV will involve good judgment and a willingness to consider substance, time, and resource tradeoffs.

### 4.5 *Selection of an Independent Third Party:*

4.5.1 Selection of an independent third party is crucial to an effective verification of the accuracy of a reference material. It is important that the independent third party be selected for independence and technical expertise. Therefore, the manufacturer or user will select a person or entity that does not have any real or perceived bias or conflict of interest and that is completely independent. Independent third parties should be able to demonstrate by documented education and experience, that they are competent to perform the requested verification.

NOTE 1—It is recommended that the independent third party is accredited from a number of organizations such as National Institute of Standards and Technology. Providing reasonable compensation to a reviewer or reviewing organization does not affect the independence of the reviewer.

4.5.2 The manufacturer or user of the electronic evaluation device must execute an appropriate agreement with the independent third party. The agreement statement of work should identify responsible individuals, the work to be performed, records retention, confidentiality, dispute resolution, and other related topics.

#### 4.6 *Review Record:*

4.6.1 It is the formal record (file) of the proceedings and decisions of the verification, the type of verification performed, and an explanation of how the results were addressed. The ITPV creates a separate, clearly marked verification record file, and once the verification is completed the manufacturer or user retains the file and stores it in a secure location.

4.6.2 The ITPV record should include all materials considered by the independent third parties, as well as their written comments and other input. Such materials include at a minimum:

4.6.2.1 Reference material submitted for verification;

4.6.2.2 Materials and information (including the charge) given to the independent third party;

4.6.2.3 Written comments, information, and materials received from the independent third party;

4.6.2.4 Information about the independent third party (such as independent third parties names, affiliations, resume of education and experience, statement of potential conflicts and their resolutions);

4.6.2.5 Logistical information about conduct of the verification (such as times and locations of meetings);

4.6.2.6 A written record, approved by the lead reviewer, specifying acceptance or where appropriate, non-acceptance; and

4.6.2.7 The final work product.

## 5. Conducting an ITPV

5.1 *Overview*—The success and usefulness of any ITPV depends on the quality of the reference material submitted for verification, the care given to the statement of issues or “charge,” and the scientific/technical expertise of the independent third party.

5.2 *ITPV Standard*—The manufacturer or user must inform the independent third party of the specific tolerances for precision and bias as set forth in the standard and supply the manufacturer’s manual. The essential elements of a standard operating procedure are as follows:

5.2.1 Brief overview or introduction (describe the reference material, how it was developed, and how it will be used or is currently being used);

5.2.2 A description or listing of materials supplied to the independent third party; and

5.2.3 The issues to be addressed by the independent third party, as follows:

5.2.3.1 The due date of independent third party comments,

5.2.3.2 The format of independent third party responses, and

5.2.3.3 The manufacturers or users point of contact in case the independent third parties have questions.

## 6. Completing an ITPV

6.1 *Overview*—The ITPV process closes with three major activities: evaluation of the end results, utilizing independent third party comments for a recommendation, and submission of an organized and comprehensive record.

6.2 *Final Work Product*—The independent third party must appraise the manufacturer, user, and any regulatory agency of the results of the ITPV. Including but not limited to comments and recommendations and how to address these comments and recommendations.

6.3 *Completing the ITPV Record*—Once the ITPV is completed and the final work product is approved by the ITPR, the review record is brought up to date and then indexed and maintained in a repository selected by the user or manufacturer. The location of the ITPR record needs to be readily identifiable and accessible so interested parties, with access rights, can locate and review the file.

## 7. Keywords

7.1 evaluation systems; independent third-party verification; ITPV; livestock; meat

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