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Standard Guide for Development of an Independent Third-Party Verification of Reference Materials¹

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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;² 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

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.

¹ 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.

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