

Procedure and Submission Guidelines for the Evaluation of Technology for Official Grain Inspection

User Guide for Manufacturers

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Procedure and Submission Guidelines for the Evaluation of Technology for Official Grain Inspection

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1. Purpose and Scope

Inspection Technology Evaluation (ITE) is the process the Agricultural Marketing Service's Federal Grain Inspection Service (FGIS) will utilize for the evaluation and approval of technology for use in official grain inspection. In this document, "technology," includes instrumentation, equipment, and the associated methods for measuring grain quality factors. Factor means a measurable grain quality attribute. This evaluation process is not applicable to research and development efforts necessary before the technology is deemed fit-for-purpose; that is, the instrument or method must have already been developed so that it generates factor-specific results with sufficient accuracy for official grain inspection. The ITE process encompasses all instrument, equipment, and methodology approvals for official grain inspection.

2. Authority

AMS provides inspection services under the authority of the United States Grain Standards Act (7 U.S.C. 71–87k) (USGSA), as amended, and the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended. Section 74 of the USGSA states that the primary objective of the United States standards for grain is to certify the quality of grain as accurately as practicable and to accommodate scientific advances in testing and new knowledge concerning factors related to, or highly correlated with, the end-use performance of grain. The primary focus of the ITE evaluation and approval process is on the need and suitability of the technology for official grain inspection.

3. ITE Process Summary

When a manufacturer develops technology for determining a specific grain factor, they have the option of submitting it to FGIS for evaluation and possible approval. The submission must first pass an initial evaluation that focuses on the need and benefits of the technology for official grain inspection. If the submission is accepted, it enters a more detailed evaluation sequence that provides a validation of the technology against specific performance criteria developed by FGIS. Validation data submitted by the manufacturer are compared with these criteria, and if met, a verification is performed by FGIS. If the technology is approved, it receives a certificate of conformance, which allows for its use in official grain inspection.

4. Additional Requirements for Specific Technologies

Specific technologies have additional or separate requirements that must be met as part of a submission to the ITE process. Examples include scales, moisture meters, near-infrared instruments, and mycotoxin and biotechnology test kits. The requirements for these technologies are listed below.

Diverter-type Samplers, Dockage Testers, Hand Sieves, Lighting, Manual Sampling Devices, and Test Weight Devices: These are examples of technology that are approved by device dimensions and specifications as documented in the FGIS Equipment and Mechanical Sampling Handbooks.

Scales and Near-Infrared Analyzers: Must hold an active National Conference on Weights and Measures, National Type Evaluation Program (NTEP) Certificate of Conformance. For information on how to apply for and obtain this certificate, please see <https://www.ncwm.com/ntep-faqs>.

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Moisture Meters: The process for approval of moisture meters is separate from this process. Moisture meters must have an NTEP Certificate of Conformance and meet the FGIS Unified Grain Moisture Algorithm requirements as specified in <https://www.ams.usda.gov/services/fgis/standardization/moisture-equipment>.

Mycotoxin and Biotechnology Test Kits: Approvals of rapid mycotoxin and biotechnology testing methods are performed through the FGIS Rapid Test Kit Evaluation Program. For more information on how to submit this technology, see <https://www.ams.usda.gov/services/fgis/standardization/tke>.

5. Contact Information

Please send submissions or questions to FGIS.ITE.Program@usda.gov.

6. Definitions

FGIS program definitions

Equivalent Technology: *A system of instruments and associated methods that can be used interchangeably and give results that are indistinguishable, taking into account measurement uncertainty.*

FGIS Reference Method: *The analytical method by which the accuracy of an alternate or new instrumental method will be measured or evaluated.*

Inspection Factor: *A measurable attribute of a specific grain type or class.*

Official Grain Inspection: *The process of examining and certifying grain according to the United States Grain Standards by, or under the supervision of, the Federal Grain Inspection Service.*

Standardization: *A process to align multiple instruments in order to increase overall system accuracy.*

Technology: *Instrumentation, equipment, and/or methods for measuring specific grain quality factors.*

Internationally-accepted definitions derived from references [1], [2], [3], [4].

Accuracy: *The closeness of agreement between a test result and an accepted reference value. When applied to test results, accuracy includes a combination of random and systematic errors. When applied to test methods, accuracy refers to a combination of trueness and precision.*

Calibration: *Act of determining the relationship between the observed analyte signal generated by an instrumental measuring system and the quantity of the analyte present in the sample measured to assure that the measurement is accurate.*

Fit-for-purpose: *Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.*

Measurement Range: *The interval over which the method generates results with acceptable accuracy.*

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Trueness: *Closeness of the agreement between the average value obtained from a large series of test results and an accepted reference value.*

Precision: *Closeness of agreement between independent test results obtained under prescribed conditions.*

Quality Control: *Measures taken to ensure that data produced by the laboratory are fit-for-purpose.*

Repeatability: *Precision under conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.*

Reproducibility: *Precision under conditions where independent test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.*

Validation: *Process of providing objective evidence that the method is fit for its intended purpose.*

7. ITE Process Description

The ITE process starts with the submission of a written proposal by a manufacturer of technology for a specific inspection factor. Manufacturers must provide an overview of the technology for which they are seeking approval. This overview should describe the technology solution, provide to which grains and inspection factor or factors it applies, and the steps required to analyze a sample.

The proposal must thoroughly address the following six criteria:

- Need
- Accuracy
- Quality Control, Calibration, and Standardization
- Automation
- Testing Time
- Testing Cost

Note: *All documents submitted to USDA AMS are subject to the Freedom of Information Act (FOIA), which requires that records submitted to federal agencies be made available to the public. Submissions should not contain any confidential business information as defined under section (b) (4) of the FOIA.*

An FGIS review team will provide an initial evaluation of the proposal to determine if it meets these criteria. When the review team completes the initial evaluation, a decision will be made to accept or not to accept the proposal. This decision will be documented and communicated to the manufacturer. If a proposal is not accepted, the manufacturer will be informed of the specific deficiencies and the requirements for resubmission. If accepted, the proposal will enter a queue, and the manufacturer will

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be notified and provided with an estimate for the start date along with various factors that may affect the length of the evaluation process.

The remaining steps of the evaluation process focus on validating the performance of the submitted technology using criteria and/or specifications developed by FGIS for the specific inspection factor. This allows for refinement of the initial review criteria to account for specific inspection needs and for a statistically-sound evaluation of accuracy of the technology. FGIS will develop performance criteria and specifications, if not already established, and determine whether a Federal Register notice is needed to finalize the criteria.

When the performance criteria and specifications are established, FGIS will request information and data from the manufacturer supporting them. When all requested information has been submitted and accepted, FGIS will conduct an independent verification that focuses on trueness, repeatability, and reproducibility. If all criteria are met and existing technology is already approved for official inspection, FGIS will perform a final assessment to determine if the submitted technology will deliver results that are equivalent to currently approved technology. If the equivalence test passes, all stakeholders will be notified and provided with the implementation plan. If either the verification or equivalence test fails, the manufacturer will be notified of the deficiencies and specific requirements for resubmission.

8. Initial Review Criteria

8.1 Need

Manufacturers should provide information and data that supports the need including the criteria listed below. FGIS will assess the need through a review of the manufacturer provided information, input from stakeholders including the Grain Inspection Advisory Committee, and from internal information.

- **Demand** – There must be sufficient demand for the testing technology from FGIS customers and stakeholders to offset the costs of providing the testing service, including standardization, calibration, and quality control efforts. Manufacturers should provide information from a market assessment of the technology that supports this demand.
- **Compatibility** – For existing inspection factors, the technology must be compatible with existing official procedures such as subsample size requirements. See FGIS Grain Inspection Handbooks.
- **Benefit to the Official System** – For a test factor with an existing single approved instrument model, the new instrument must offer an added benefit to official inspection.
- **Equivalence** – For a test factor with an existing single approved instrument model, there must be evidence that the new instrument can provide results in terms of accuracy that are equivalent to, or better than the currently approved instrument model.
- **Regulatory Requirements** – If pertinent, provide national or international regulatory requirements the technology addresses that may include, but are not limited to, maximum levels for toxic substances.

8.2 Accuracy

Manufacturers must provide relevant data detailing the accuracy of their submitted technology that includes measurement trueness and measurement precision compared with the existing FGIS reference method under reproducibility conditions and across the specified measurement range.

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Manufacturers must provide relevant data on the repeatability within and reproducibility between copies of the same model of their submitted technology. The samples included in the study data must be sufficient in number and kind to fully cover the scope claimed by the manufacturer. If the submission is for a factor new to FGIS, the manufacturer must provide data that demonstrates the technology is fit-for-purpose with measurement trueness and precision data based upon a collaboratively-studied reference method, preferably published by an international standards developing organization.* The trueness, repeatability, and reproducibility data must meet FGIS tolerances, where established. For technology meant to replace visual inspection factors, FGIS Grain Inspection Handbooks should be consulted to apply the appropriate trueness and precision requirements.

8.3 Quality Control, Calibration, and Standardization

Manufacturers must provide recommended working instructions and quality control procedures necessary to ensure that the technology is delivering results within established tolerances. Working instructions should include troubleshooting guidance to resolve problems when quality control measures are unacceptable. When calibrations are needed by the end-users to maintain accuracy over time, manufacturers must provide the recommended procedures for updating and/or developing calibrations on their instrument. Manufacturers must also provide recommended procedures for standardization to accomplish alignment of a network of instruments in different laboratories. The assessment will include the completeness, clarity, and validity of the working instructions, standardization, quality control, and calibration procedures.

8.4 Automation

If the technology generates an electronic result, the manufacturer must provide procedures for automatic data capture and the ability to modify the output.

8.5 Testing Time

Manufacturers must provide the estimated testing time required from sample receipt to the final result. The testing time will be assessed by comparison to existing or similar technologies. Longer testing times must be justified by providing a significant advantage over existing technology.

8.6 Testing Cost

The manufacturer must provide itemized cost estimates for the technology, maintenance, consumables, and all materials and equipment needed to perform the test. This criterion will also include the estimated costs of the recommended quality control, calibration, and standardization procedures. The testing cost will be assessed by comparing it to existing or similar technologies. Higher testing costs should provide significant advantages over existing technologies.

9. Submission Requirements and Manufacturer Validation Study

Submission documents must include an overview that describes the technology solution, the grains and inspection factor or factors to which it applies, and the steps required to analyze a sample. The

*Such as the Association of Analytical Collaboration International, the Cereals and Grains Association, the American Oil Chemists Society, or the International Organization for Standardization.

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document must also include six sections with each section addressing one of the review criteria. In addition, the submission must include the completed form given in Appendix A.

To address accuracy, a validation study must be performed that includes an assessment of the trueness and precision of the technology across the full range of the inspection factor being measured. For specific technologies such as near infrared, there may be a need to demonstrate accuracy over multiple crop years. The study should include a description of the scope of the method that includes the inspection factor and grain type, a description of the validation design including the number and type of samples, a description of the statistical analysis, a summary of results, and the conclusions supporting the study outcomes. The study should be of publication quality and follow the format and content of typical method validation studies as presented in peer-reviewed journals such as the Association of Official Analytical Collaboration International. For guidance on conducting validation studies, see references [1] and [5].

If the technology meets all requirements in sections 7 and 8, an FGIS certificate of conformance (COC) will be issued that allows for use in official grain inspection. If any alterations to the technology are made that could affect measurement results, the manufacturer must inform FGIS in writing to determine the significance. In addition, if the manufacturer finds that the technology is not meeting FGIS performance criteria, they must immediately inform FGIS. Failure to inform FGIS, in either case, could result in cancellation of the COC. If issued a COC, manufacturers must sign the statement given in Appendix B.

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References

- [1] M. Thompson, S. L. R. Ellison, and R. Wood, Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis, (IUPAC Technical Report), *Pure and Applied Chemistry*, vol. 74, pp. 835-855, 2002.
- [2] JCGM 200:2012, International Vocabulary of Metrology - Basic and General Concepts and Associated Terms, 2012. [Online]. Available: http://www.bipm.org/utis/common/documents/jcgm/JCGM_200_2012.pdf. [Accessed 07 01 2021].
- [3] Codex Alimentarius Commission, Guidelines on Analytical Terminology, Standard CAC/GL 72-2009, 2009. [Online]. Available: http://www.fao.org/input/download/standards/11357/cxg_072e.pdf. [Accessed 07 01 2021].
- [4] V. Barwick and E. Prichard, Eurachem, Terminology in Analytical Measurement - Introduction to VIM 3, 2011. [Online]. Available: <https://www.eurachem.org/index.php/publications/guides/terminology-in-analytical-measurement>. [Accessed 07 01 2021].
- [5] B. Magnusson and U. Ornemark (eds.), Eurachem Guide: The Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics (2nd ed.), 2014. [Online]. Available: https://www.eurachem.org/images/stories/Guides/pdf/MV_guide_2nd_ed_EN.pdf. [Accessed 2 February 2021].

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Appendix A: ITE Submission Form

Contact Information	
Company	
Primary Contact	
Primary Contact Email Address	
Primary Contact Telephone Number	
Street Address	
City, State, Zip Code	
Website (if applicable)	
Instrument or Device Information	
Name and Model Number	
Product or Catalog Number	
Measurement Technology or Description (NIR, NMR, Moisture Meter, Scale, etc.)	
National Type Evaluation Certificate Number (Applicable to NIR, Moisture Meters, and Scales)	
Operating Temperature Range (°C)	
Operating Humidity Range (%)	
Method Scope	
Applicable Grains or Commodities (barley, beans, buckwheat, canola, corn, flaxseed, hops, lentils, mustard seed, peas, rice, rye, safflower, sorghum, soybeans, sunflower seed, triticale, wheat, or processed-grain commodity)	
Type or Class of Grain or Commodity (six-row barley, two-row barley, malting barley, dent corn, flint corn, milled rice, paddy rice, hard red spring wheat, hard red winter wheat, hard white wheat, soft red winter wheat, soft white wheat, durum wheat, etc.)	
Inspection Factor	
Measurement Range (and units)	
Minimum Sample Size (g)	
Maximum Sample Size (g)	
Sample Preparation (whole grain, ground, etc.)	
Sample Temperature Range (°C)	

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Appendix B: Protocol and Notification Agreement Statement

This is to certify that I am an official representative of _____
that I fully understand the conditions that FGIS will use to determine if our technology marketed under
the trade name

_____ will be given a Certificate of
Conformance for use in the Official grain inspection system. **FGIS monitors the performance of all
approved technologies and reserves the right to check and verify its performance at any time.** I
understand that if the technology fails to meet FGIS performance criteria, the manufacturer will be
contacted to resolve the issue as soon as possible. If the issue cannot be resolved, the Certificate of
Conformance may be revoked. I further understand that any changes made to the technology that
could affect measurement results must be communicated to FGIS in writing. These changes may require
resubmission through the FGIS evaluation process. I accept these conditions and agree to abide by the
Manufacturer's Notification Responsibilities provided in this document.

Name

Date

Title