

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

User Guide for Manufacturers

(Revision 1)

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United States Department of Agriculture
Agricultural Marketing Service
Federal Grain Inspection Service
Technology and Science Division

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

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Note: In accordance with 7 CFR 1.901(e), the contents of this document do not have the force and effect of law and are not meant to bind the public in any way, and the document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

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

1. Purpose and Scope

Inspection Technology Evaluation (ITE) is the internal process the Agricultural Marketing Service's (AMS) Federal Grain Inspection Service (FGIS) uses for the evaluation 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 does not apply to the research and development effort before the technology is deemed fit-for-purpose; that is, the instrument or method has already been developed so that it generates factor-specific results with sufficient accuracy for official grain inspection. The ITE process encompasses instrument, equipment, and methodology approvals for official grain inspection.

2. Authority

FGIS 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 may submit it to FGIS for evaluation. The initial evaluation of the submission focuses on the need and benefits of the technology for official grain inspection. If FGIS accepts the submission after initial evaluation, the submission enters a detailed evaluation sequence to validate the technology against FGIS' specific performance criteria. The manufacturer's validation data is compared with FGIS' criteria, and if met, FGIS performs a verification. 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 for 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.

Near-Infrared Analyzers: Prior to submission to the ITE process, you must obtain a 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>.

Moisture Meters: Prior to submission to the ITE process, you must obtain 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>.

Scales, Diverter-type Samplers, Dockage Testers, Hand Sieves, Lighting, Manual Sampling Devices, and Test Weight Devices: This technology is approved by a separate process using device dimensions and

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specifications as documented in the FGIS Equipment and Mechanical Sampling Handbooks. Scales must also hold an NTEP Certificate of Conformance.

Mycotoxin and Biotechnology Test Kits: This technology is approved by a separate process defined in 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>. Novel technology that does not fit the pre-defined criteria for this program should be submitted through the ITE process.

5. Contact Information

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

6. Definitions

FGIS program definitions

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.*

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

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

Equivalent Technologies: *Instrumentation, equipment, and/or 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.*

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

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

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.*

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

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.*

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

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

Repeatability: *Precision under conditions where independent test results are obtained with one technology 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 one technology on identical test items in different laboratories with different operators using different equipment.*

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.*

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

Quality Control: *Measures taken to ensure that data produced by the laboratory are fit-for-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 provide an overview of the technology for which they seek approval. This overview should describe the technology solution, indicate to which grains and inspection factor or factors the technology applies, and the steps the technology uses to analyze a sample.

The proposal should address the following six criteria:

- Need
- Accuracy
- Quality Control
- Automation
- Testing Time
- Testing Cost

Note: *Confidential business information (CBI), as defined under section (b) (4) of the FOIA, is protected from public disclosure and must be identified and justified by the manufacturer. Both CBI and CBI-deleted versions of the submission should be provided (see Appendix C). The submission of proposals and associated information for the evaluation of new technology for use in the official grain inspection and weighing system may be posted on the USDA AMS FGIS website. FGIS may seek public input on the proposals either through the Grain Inspection Advisory Committee, or a Federal Register (FR) Notice. FGIS may post on its website the CBI-deleted version of the proposal for public input.*

An FGIS review team conducts an initial evaluation of the proposal to determine if it meets these criteria. When the review team completes the initial evaluation, FGIS decides whether to accept the

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proposal. This decision is documented and communicated to the manufacturer. If a proposal is not accepted, the manufacturer is informed of the specific deficiencies and the requirements for resubmission. If accepted, the proposal enters a queue, and the manufacturer is 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 FGIS' developed criteria or specifications 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. If not already established, FGIS develops performance criteria and specifications and determines whether a Federal Register notice is needed to finalize the criteria.

With established performance criteria and specifications, FGIS requests that the manufacturer provide information and data supporting the criteria and specifications. When all requested information has been submitted and accepted, FGIS conducts an independent verification that focuses on trueness, repeatability, and reproducibility. FGIS will also determine if the submitted technology delivers results that are equivalent to currently approved technology. If this process shows that the technology passes the equivalence test, FGIS notifies stakeholders and provides them with the implementation plan. If FGIS is unable to verify trueness, repeatability, and reproducibility or the technology is not equivalent, the manufacturer is notified of the deficiencies and the 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 assesses the need through a review of the manufacturer provided information, input from stakeholders including official service providers, the Grain Inspection Advisory Committee, and from internal information.

- **Demand** – FGIS evaluates the demand for the testing technology from FGIS customers and stakeholders and compares the demand to the costs of providing the testing service, including standardization, calibration, and quality control efforts. FGIS recommends that manufacturers provide information from a market assessment of the technology that supports this demand.
- **Compatibility** – For existing inspection factors, a successful technology should 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, a successful new instrument should offer an added benefit to official inspection. Benefits include, but may not be limited to increased accuracy, total cost of ownership, time savings, easier to use, or better serviceability.
- **Equivalence** – For a test factor with an existing single approved instrument model, the new instrument should provide results in terms of accuracy that are equivalent to, or better than the currently approved instrument model.

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- **Regulatory Requirements** – If pertinent, manufacturers should provide national or international regulatory requirements the technology addresses. This may include, but is not limited to, maximum levels for toxic substances.

8.2 Accuracy

For a successful application, manufacturers should 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. Manufacturers should 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 should be sufficient in number and kind to fully cover the scope claimed by the manufacturer. If the submission is for an existing factor, manufacturers should provide relevant data demonstrating equivalent or better performance compared to existing technology in terms of trueness and precision in addition to the FGIS reference method data.¹ If the submission is for a factor new to FGIS, the manufacturer should 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.² The trueness, repeatability, and reproducibility data should 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

Manufacturers should provide recommended working instructions and quality control procedures necessary to ensure that the technology is delivering results within established tolerances. Successful working instructions 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 should provide the recommended procedures for updating and developing calibrations on their instrument. A successful application also includes recommended procedures for standardization to accomplish alignment of a network of instruments in different laboratories. FGIS' assessment reviews 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 should provide procedures for automatic data capture and the method to modify the output.

¹ Trueness and precision of new technology compared to the existing technology is equally as important as that compared to the FGIS reference method.

² 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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8.5 Testing Time

Manufacturers should 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 should be justified by providing a significant advantage over existing technology.

8.6 Testing Cost

The manufacturer should provide itemized cost estimates for the technology, maintenance, consumables, and all materials and equipment needed to perform the test. FGIS evaluates the estimated costs of the recommended quality control, calibration, and standardization procedures. The testing cost is compared to existing or similar technologies. Higher testing costs should provide significant advantages over existing technologies.

9. Submission Recommendations and Manufacturer Validation Study

Successful submission documents 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. FGIS recommends that the document include six sections with each section addressing one of the review criteria. In addition, the submission should include the completed form given in Appendix A.

To address accuracy, the manufacturer should perform a validation study 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 FGIS approves the technology according to the review of the information in sections 7 and 8, an FGIS certificate of conformance (COC) is issued that allows for use in official grain inspection. If any alterations to the technology are made that could affect measurement results, the manufacturer should inform FGIS in writing to determine the significance. In addition, if the manufacturer finds that the technology is not meeting FGIS performance criteria, they should immediately inform FGIS. Failure to inform FGIS, may result in cancellation of the COC. As a contingency for issuing a COC, manufacturers agree to 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

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Appendix C: Confidential Business Information

All documents submitted to FGIS are subject to the Freedom of Information Act (FOIA) 5 U.S.C. § 552, which requires federal agencies to provide the public with access to information. FGIS considers Section (b)(4) of the FOIA, which exempts from disclosure certain types of information related to trade secrets and commercial or financial information that are customarily kept as confidential by the business submitter and are collectively referred to as confidential business information (CBI). AMS follows USDA regulations (7 CFR § 1.8) and Executive Order 12600 in ensuring submitters have the opportunity to claim CBI, consistent with federal law. Documents submitted to FGIS that contain CBI require special handling.

What is CBI?

Section (b)(4) of the FOIA (also known as Exemption 4) protects (or exempts) from disclosure information that comprises “trade secrets and commercial or financial information obtained from a person that is privileged or confidential.” FGIS refers to this type of information as CBI. AMS follows Department of Justice [guidance](#) and relevant case law when analyzing CBI claims.

When a submitter provides FGIS with information and seeks to claim CBI, the submitter must demonstrate the information is customarily kept private or closely held, in the context of industry practices concerning the information.

A trade secret is information relating to the research and development of the technology design, calibration algorithms, production processes, and internal quality control tests and data. Such information must be (1) commercially valuable, (2) used in one’s business and (3) maintained in secrecy.

Information is protected as confidential under Exemption 4 if it is not ordinarily released by the submitter. Commercial or financial information may be deemed confidential if review establishes that the manufacturer faces active competition in the area to which the information relates.

Information which is published or otherwise publicly available may not be claimed as CBI. FGIS reserves the right to accept, challenge, or request further information on each claim of CBI.

If a manufacturer believes a document to be submitted to FGIS contains confidential business information, the submitter must include three documents in their submission:

- A CBI Justification - A detailed letter justifying any CBI claims found in the document.
- A CBI Copy – The document containing the CBI.
- A CBI-Deleted Copy – A CBI document with all CBI deleted.

If the manufacturer does not intend to claim confidential business information in a document to be submitted to FGIS, the submitter is only required to provide one copy of the material. These documents should be clearly marked “No CBI” in the upper right corner of the page.

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CBI Justification

All claims of CBI must include a CBI justification and such claims expire 10 years after the date of the submission unless the submitter requests and provides justification that supports a longer designation period.

If a submitter believes that a document to be submitted to FGIS contains confidential business information, the submitter must include a CBI Justification document justifying all claims of CBI. The CBI Justification must be detailed enough to demonstrate that each piece of information claimed as CBI is customarily kept private or closely held, in the context of industry practices concerning the information. Claims of CBI may be justified in terms related to potential competitive harm due to its release. The language used to prepare your CBI justification should be in non-technical terms when possible and should not reveal any information marked as confidential.

Please note that while some information is not eligible for withholding as CBI, it may be properly withheld under a different FOIA exemption. For example, personal privacy information may be withheld under Exemption 6 of the FOIA.

Preparation and Submission of Documents

If a document intended for submission to FGIS **does not contain CBI**, only submit **one copy**. These documents should be **clearly marked “No CBI” in the upper right corner of the page**.

If a document intended for submission to FGIS contains information that the manufacturer claims as CBI, the manufacturer must **submit two versions** of the document along with the justification: **a complete version containing CBI** (the “CBI Copy”), and an **edited version with the CBI redacted** (the “CBI-deleted Copy”).

Use the following guidelines to prepare these two versions of the document:

- Each page of a document containing CBI must have “CBI Copy” marked in the upper right corner.
- Each page of a CBI-redacted document must have “CBI-deleted Copy” marked in the upper right corner.

In a document containing CBI, mark with square brackets (“[]”) only the specific words or phrases claimed as CBI, and in the right margin for each set of brackets write “CBI.” In the CBI-deleted version, replace the words or phrases marked in the CBI version with blank spaces, mark the spaces with square brackets, and in the right margin for each set of brackets write “CBI-deleted.”

The CBI-deleted version should be identical to the CBI version, except 1) blank spaces surrounded by square brackets occurring in the text where the CBI text has been redacted and 2) “CBI-deleted Copy” should appear in the upper right corner of each page instead of “CBI Copy.”

The CBI-deleted version must be paginated identically to the CBI copy. The CBI-deleted version should be made directly from the same document which originally contained CBI. Do not insert additional text (transitions, paraphrasing, or generic substitutions, etc.) into the spaces of the CBI-deleted version.

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All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy.

How to Find More Information

If you would like more information about confidential business information in AMS submissions, please contact:

FOIA Officer USDA AMS
1400 Independence Avenue, SW
South Building, Rm. 1671
Stop 0203
Washington, DC 20250
Tel. (202) 302-0650
E-Mail – AMS.FOIA@usda.gov

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Appendix D: Revision History

Revision 0 – (07/05/2022)

Initial document as referenced in 87 FR 41096, “Process for the Evaluation of Technology for Official Grain Inspection,” on July 11, 2022.

Revision 1 – (10/19/2022)

- Statement added to the cover page, “Printed copies are uncontrolled and may contain incorrect information.”
- Clarification to “Equivalent Technologies” was made by adding “(instruments and/or methods)” to the definition.
- “Official service providers,” was added to the Initial Review Criteria section under “Need.”
- Clarification made to the Initial Review Criteria under “Benefit to the Official System” by adding, “A benefit includes, but may not be limited to increased accuracy, cost, or time savings, easier to use, more serviceable, and better support.”
- Clarification to the definition of Accuracy was made by adding footnote 1, “Trueness and precision of new technology compared to the existing technology (instruments) is equally as important as that compared to the FGIS reference method.”