VERIFICATION SERVICE

1. PURPOSE

This directive establishes official procedures for obtaining and performing verification services for all products assigned to the Grain Inspection, Packers and Stockyards Administration (GIPSA) and services associated with marketing of these products.

GIPSA verification services are voluntary, user-fee services available to producers, marketers, processors, and associated service providers of agricultural products. The services are provided under the authority of the Agricultural Marketing Act of 1946 (AMA), as amended, and the Code of Federal Regulations (CFR) 7, Part 868, and this directive.

Services are performed as prescribed in this directive by GIPSA authorized employees. Interested parties wanting official services should contact the Field Management Division (FMD). See Section 4 for details. See the Appendices for specific verification program requirements:

a. APPENDIX 1 – The Process Verified Program

b. APPENDIX 2 – Multi-Site Verification Program (not written)

c. APPENDIX 3 – Farmer/Handler Certification Program (not written)

2. REPLACEMENT HIGHLIGHTS

This Directive replaces FGIS Directive 9180.79, Process Verification Service, dated 1-31-05.

This directive is revised to:

a. change the title to “Verification Service” from “Process Verification Service;”

b. replace Data and Information Analysis Branch, which has been abolished, with the FMD for authority and responsibility;

c. substitute the term “applicant” with “organization” where appropriate, the term “certified” for “approved”, because not all applicants will be certified although they may be approved;

d. clarify the term “program” by substituting “quality system” when referencing customer activities, and adding the word “verification” when referencing GIPSA activities (verification program);

e. change the scope of the directive from the Process Verified Program to an umbrella requirements document for several verification programs;

f. remove all direct references to, and information about the Process Verified Program (PVP), and moved them to APPENDIX 1, as appropriate;

g. delete section 25 that addressed auditors because it was redundant and unnecessary;

h. establish the use of appendices to provide specific program information; for example, APPENDIX 1 addresses the Process Verified Program;

i. add to the PVP requirements in APPENDIX 1

   (1) two additional documented procedures,

   (2) a requirement for a Master Document List,

   (3) requirements for verification points, and

   (4) additional requirements for the control of promotional material;

j. changed “shall” to “must”, in keeping with “plain language” requirements;

k. changed the numbering system in APPENDIX 1 to be consistent with ISO 9001:2000; and

l. include minor editorial changes.

3. BACKGROUND

One mission of GIPSA is to facilitate the marketing of grains, oilseeds, pulses, rice, and related agricultural commodities. Traditionally, GIPSA accomplished this mission by offering various testing services and establishing official grading standards. Today, these services and standards still play an important role in marketing, but do not adequately address emerging practices used to market US agricultural products.

In response to changing consumer demands, the market is adopting a variety of new marketing mechanisms, such as identity preservation, to augment traditional marketing approaches. GIPSA's goal is to add value in this evolving marketplace by augmenting, not supplanting, existing marketing practices.

To this end, GIPSA, on behalf of the US Department of Agriculture (USDA), published an Advance Notice of Proposed Rulemaking in the *Federal Register* (Vol. 67, No.151, August 6, 2002, pg. 50853) seeking public comment on USDA's roles in facilitating the marketing of grains, oilseeds, fruits, vegetables, and nuts. Respondents recommended USDA (1) continue existing programs to standardize testing methodology and component testing, and (2) build on the success of its process verification programs for fruits, vegetables, and livestock by developing similar programs for grains, oilseeds, and related agricultural commodities.

Verification services provide producers, marketers, processors, and associated service providers of agricultural products the opportunity to market attributes that are expensive or impossible to test for in their final product. The program embraces the theory that it is more efficient to build quality into American agricultural products by focusing on the "process" of producing and delivering the product to assure it meets customers' expectations. Organizations have found that it is more efficient to build quality into their product at every step than it is to test only their final product to determine if it can be sold as intended.

The verification procedures verify the process by which a product or service is produced, handled, and processed rather than verifying the contents of the final product. The scope of a process may range from seed purchase to a final product on grocery shelves or a segment in between. However, more extensive processes create a greater need for other technical experts to assist GIPSA. Therefore, GIPSA will seek opportunities to partner with other organizations already performing such services.

The verification services are based on internationally recognized quality management standards with lead auditors who have been thoroughly trained.

The programs offered will not seek to compete with or duplicate programs already existing in the private sector. Rather, they are intended to complement those programs by offering an independent, internationally respected source of verification activities. At the same time, the programs will have sufficient safeguards to ensure the integrity of their results.

4. REQUESTING AND CANCELING SERVICE

a. Any person with a financial interest in agricultural products or related services may apply for service under this program. Interested parties must submit an application that includes:

(1) Form FGIS-907, Application for Inspection and Weighing Services, under the AMA of 1946. The form is available at: http://ingipsa.usda.gov:8010/gipsaforms/fgis907_f.pdf. Applicants may also receive the form by calling the FMD office at (202) 720-0228.

(2) A cover letter sent with the application indicating the quality system and scope of the verification requested. The letter should give a full description of the applicant, the product or service to be verified, and contact information for the individual responsible for the quality system.

(3) A complete copy of the applicant's quality system documentation as described in the applicable APPENDIX for the verification sought. In addition to a quality manual and the required documented procedures, applicants may be requested to provide copies of forms taken from actual records, identification markers, and copies of letters from suppliers and customers, as appropriate.

(4) Other information required by the specified quality system.

b. Send above request, application, and documentation to the following address:

Verification Programs Manager
USDA, GIPSA, FMD
Room 2409 – S, Stop 3630
1400 Independence Avenue, SW
Washington, DC 20250-3630

c. All proprietary information must be identified as such when it is submitted to GIPSA. Identified information will be protected from disclosure to the extent possible under the existing Freedom of Information Act (FOIA) regulations.

d. Applicants for service and approved operations may cancel service at any time by notifying FMD in writing. Applicants who withdraw from the program and cancel their application will be charged an hourly fee for services rendered.

e. Approved operations canceling service are responsible for all accrued fees. Upon cancellation, the organization's name will be removed from the list of approved operations. The organization must reapply and be approved through an audit before being returned to the list.

5. RECEIVING APPLICATIONS

a. FMD will receive and review applications for completeness and store a copy of the information in the applicant's file. If any information is missing, FMD will contact the applicant to request any additional information necessary and will withhold the application from further review until the necessary information is received.

b. Once FMD has determined that the application is complete, the request for service and accompanying quality system documentation will be forwarded to the assigned auditor and the applicant will be notified of the status of the application.

6. ADEQUACY AUDIT (DOCUMENT REVIEW)

All audits will be conducted in conformance to ISO 19011, Guidelines for quality and/or environmental management systems auditing.

a. The assigned auditor will conduct a complete adequacy audit of the applicant's quality system documentation to ensure that each element of the specific quality system description has been fully addressed and conforms to the specified program requirements. These requirements provide the basis for an audit checklist which will be used to conduct the document review and subsequent audits.

b. If the documentation is adequate, the auditor will arrange to conduct an on-site audit. If any element of the documentation requires clarification that can be easily obtained by working directly with the applicant, the auditor will contact the applicant and request any additional information necessary.

c. If the applicant's information is seriously deficient, the auditor will prepare and submit a report itemizing the deficiencies to FMD. FMD will determine whether to return the application to the applicant for further development or to notify the applicant of the deficiencies and retain the application in anticipation of receiving revised or additional information.

7. ON-SITE AUDITS

The objective of an on-site audit is to verify an operation's conformance to the audit criteria.

a. After the operation has been notified that the quality system documentation is adequate, the Lead Auditor will notify the applicant of the following information:

(1) Proposed date(s) and itinerary of the on-site audit.

(2) Projected cost of the audit, including hourly fees, per diem, and travel expenses.

(3) Names of the audit team members. Applicants will be provided an opportunity to request different auditors if there is a valid reason for not using the assigned auditors.

b. Auditors will travel to each location and conduct a detailed audit. At each location, the Lead Auditor will:

(1) Interview management personnel and employees with specific responsibilities relative to the quality system to verify their knowledge of quality system requirements, their role in the system, and the roles and responsibilities of other persons involved in the system.

(2) Determine, during the on-site audit, whether additional on-site audits may be required to validate procedures.

(3) Review written procedures and supporting documentation.

(4) Establish positive tracking of products on hand, as appropriate.

(5) Conduct reviews of applicant's supporting businesses, as applicable for the specified quality system, to ensure conformance.

c. In order to reduce travel expenses and time required on-site, the Lead Auditor may elect to conduct phone interviews and request fax or e-mail copies of specific quality system documentation or records prior to arrival on-site as part of the official audit.

d. Checklists based on the requirements will be used to document the audit results.

8. AUDIT REPORTS

a. Upon completion of the on-site audit, the auditor will prepare a detailed report of the audit observations, findings, and recommendations to FMD. The report will include, at a minimum:

(1) The name, address, and the organizational structure of the business.

(2) The name, phone number and email address of the contact person for the business.

(3) Scope of the audit including any exclusions.

(4) Identification of audit team members, their role, and the audit dates.

(5) Identification of the referenced documents against which the audit was conducted.

(6) A description of the audit activities, including locations evaluated.

(7) Product identity, segregation, and tracking procedures, as applicable.

(8) Involvement of other parties such as suppliers, handlers, processors, seed providers, harvesters, outside auditors, and subcontractors.

(9) Audit team's judgment of the extent of the applicant's conformance to the applicable requirements and related documentation, including the observation of nonconformities and a conclusion regarding approval.

(10) An evaluation of the system's ability to achieve defined verification points.

b. Auditors will itemize any significant findings of nonconformance in the finding section of the audit report and assign a tracking number to each nonconformance. Auditors will classify each itemized nonconformance as a *continuous improvement point, a minor nonconformance, or a major nonconformance* according to the following definitions:

(1) *Continuous improvement point (CIP)*: An observation made by an auditor that is not a nonconformance, but an area where the operation might improve.

(2) *Minor Nonconformance:* A nonconformance that, although it needs to be corrected in a timely manner, does not compromise the integrity of the product or the quality system.

(3) *Major Nonconformance*: A nonconformance that compromises the integrity of the quality system to the extent that approval should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown in a required element will be considered a major nonconformance. An accumulation of minor nonconformances also may result in the assignment of a major nonconformance for an audit.

c. All audit findings to be sent forward to FMD, including the auditors' conclusions, will be discussed with the applicant during the closing meeting of the audit. Auditors will then submit a complete report of the audit to FMD for final review and disposition. In the event that the audit findings must be changed, FMD will notify the applicant prior to changing the report.

d. Applicants will be provided a draft copy of the audit report when the report is changed (paragraph c. above). They will be given sufficient time to rebut any findings prior to the report becoming final.

9. APPROVAL

a. In most verification programs, approval decisions will be made by the Verification Programs (VP) Manager after a Review Committee, comprised of qualified USDA personnel, has reviewed the applicable audit reports and made a recommendation to grant or deny approval. An auditor may not participate in the Review Committee for an operation that he or she has audited. In the event that the VP Manager participates in the audit of an operation, the approval decision will be made by qualified USDA personnel.

b. Organizations meeting all verification program requirements will be issued a certificate of conformance valid for 1 year from the date of the on-site audit. FMD will ensure that information regarding the organization's status will be posted on the GIPSA website.

c. FMD will issue a letter to the organization's management representative regarding the decision to approve, conditionally approve, or deny approval, stating any terms and conditions, as appropriate. The letter will include references to all audit reports or other information on which the approval decision was based. Approved organizations should retain the approval letter for their records.

10. CONDITIONAL APPROVAL

a. FMD may issue conditional approval when:

(1) The operation was not fully functioning during the initial on-site audit.

(2) Minor nonconformances were identified during an on-site audit.

(3) Minor nonconformances are identified during a review of corrective actions.

b. Corrective action must be taken by the organization within the time period specified in the approval letter to address minor nonconformance and provide documentation of the actions for FMD to review. At the conclusion of the specified time period, FMD will perform a corrective actions audit of the documentation provided to determine whether all verification program requirements are met. An additional on-site audit may be required to observe the implementation of corrective actions. The decision by the VP Manager to continue approval will be made as follows:

(1) If the follow-up audit finds all nonconformances have been adequately addressed and no new nonconformances are identified, approval will continue from the date the certificate was issued.

(2) If the follow-up audit finds all previously identified nonconformances have been adequately addressed, but new minor nonconformances are identified, FMD may continue the conditional approval as described in this section with opportunity to address the new nonconformances.

(3) If the follow-up audit finds previously identified nonconformances have not been corrected, the organization will be allowed no more than 5 days to address the nonconformance. If it is not addressed, the operation's name will be removed from the list of approve operations until corrective actions are completed and confirmed by an additional audit.

c. Conditional approval is granted for a period of 6 months from the date of the on-site audit.

11. DENIED APPROVAL

FMD may deny approval for any of the following reasons:

a. Failure to adequately address any documentation requirement.

b. Failure to demonstrate capability to meet any requirement during the on-site audit.

c. Denying access to organization's facilities and records within the scope of the requested approval.

d. Presenting false or misleading information to any GIPSA official at any point in the review or approval process.

e. Finding of any objective evidence of major nonconformance within the scope of the requested approval.

Organizations whose approval has been denied may reapply at any time. Nonconformances identified during the initial audit must be addressed with effective corrective/preventive actions.

12. PUBLICATION OF APPROVED STATUS

Information about the approved status of an organization's operation will be posted on the list of approved process verification operations at *http://www.gipsa.usda.gov*. The posting will include the following information:

a. Name and contact information for each approved verification program participant.

b. The approved verification points.

c. Certificate number.

d. Effective date of approval.

e. Renewal date.

13. MAINTAINING APPROVAL

Approved operations are required to maintain their quality systems as described in their approved documentation. Any changes to the organization's approved system that may potentially affect the quality or integrity of verified services or products must be submitted in writing to FMD and approved prior to implementation. Depending upon the nature and extent of the changes, FMD may require a complete or partial onsite audit of the system prior to approval. In situations where an additional on-site audit is required, a new approval will be issued for the appropriate time period based on the findings of the audit.

14. SURVEILLANCE

All approved operations are subject to unannounced audits by FMD representatives. In an official memorandum to FMD, the auditor will document the findings of unannounced reviews. Findings of unannounced audits will be considered when determining conformance to the verification program for ongoing approval or renewal or may provide the basis for suspension or revocation.

15. RENEWAL OF APPROVAL

FMD will notify organizations 120 days before expiration of their approval to determine if they wish to renew. Organizations should contact the FMD office in Washington, DC, at least 90 days before the expiration of their approval to request renewal. Upon request,

FMD will arrange for a document review and on-site audit to be conducted at a time as near the renewal date as possible while coordinating the audit with other audits in the area. Each organization must submit any revised copies of quality system documentation and be reassessed as described in this directive to maintain approval.

16. SUSPENDING APPROVAL

a. FMD may suspend approval and remove an operation's name from the list of approved operations at *http://www.gipsa.usda.gov* for any of the following reasons:

(1) Failure to follow the approved quality management system, policies, or procedures resulting in a major nonconformance;

(2) Implementing significant changes to an approved system without prior written notification to FMD;

(3) Confirmed finding of violations as described in appropriate regulatory authority requirements. Upon confirming the violation, GIPSA will suspend all approvals for operations in the product's chain of custody pending a complete investigation in cooperation with appropriate regulatory agencies;

(4) Denying access to operation's facilities and records within the scope of the requested approval;

(5) Failure to pay fees; or

(6) Failure to respond to corrective actions in the timeframe provided.

b. FMD will notify the organization in writing of the suspension and the details of actions required to regain approved status. Information provided will not include specific remedies to barriers for approval.

17. REINSTATEMENT OF SUSPENDED APPROVAL

a. Approval suspended for implementing changes to the organization's system without the required advance notifications will be reinstated immediately upon receipt of appropriate corrective action.

b. FMD will reinstate approval for organizations whose systems are within the chain of custody of products identified as failing to meet regulatory requirements only upon revalidation of the integrity of their quality system, in cooperation with appropriate regulatory agencies.

c. Approval for organizations found to be responsible for violation of regulatory actions associated with verified products or services will be suspended until such time as the organization provides objective evidence that their system has been completely purged of all potentially affected products or services and an on-site audit verifies that effective corrective action has been taken. Final decisions on the suitability of corrective action and the organization's eligibility for reinstatement are at the discretion of FMD.

d. Approval for organizations suspended for failure to pay fees will be reinstated upon notification that all outstanding fees and interest have been paid in full.

18. REVOKING APPROVAL

a. FMD may revoke approval and remove an organization's name from the list of approved organizations at *http://www.gipsa.usda.gov* for any of the following reasons:

(1) Repeated failure to maintain its system in conformance with the requirements of this directive and the approved quality system;

(2) Failure of a suspended operation to meet conditions for reinstatement within the required timeframe;

(3) Willful violation of Federal or State regulations;

(4) Deliberate misrepresentation of the eligibility of products or services distributed under an approved system; or

(5) Fraudulent use of USDA labeling claims on labels or in advertising and promotional material.

b. FMD will notify organization in writing of the revocation.

c. Organizations whose approval has been revoked may reapply for approval after a period of 2 years.

19. APPEALS, COMPLAINTS, AND DISPUTES

Organizations have the right to question or appeal any adverse audit findings or decisions issued by FMD. Appeals and disputes must be submitted in writing to the FMD Director, Washington, DC, within 30 days of the date of the official report or letter rendering the findings or decisions. Appeals of decisions made by the FMD Director will be reviewed by the Deputy Administrator. Requests for appeals must include:

a. The basis for the appeal, complaint, or dispute.

b. The requested alternative decision or actions.

The FMD Director will review any request for action and notify the organization of the final decision within 30 working days of the receipt of the request. Any suspended or revoked approvals will remain in effect pending the outcome of the appeal.

Complaints regarding GIPSA auditing activities also may be sent to the FMD Director, Washington, DC.

20. FEES

The cost of document reviews, on-site audits, and any follow-up or surveillance audits, including auditing and travel time, per diem, and related expenses, are the responsibility of the party requesting the service.

a. Fees charged for service will be charged according to the approved hourly rate published in the *Federal Register* (Vo. 70; No. 195; October 11, 2005; pg. 58969). Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments and time required to complete all related travel.

b. Organizations will be billed for official time spent preparing for quality system audits performed on their behalf. Official preparation time will include review of approved quality manuals, records from previous audits, and preparation of checklists.

c. Organizations will be charged for travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide service to multiple organizations, charges will be prorated.

d. Hours of service to be charged to the organization will be documented on Form FGIS-992, Services Performed Report. Copies of the form will be maintained with the audit working papers.

e. Upon request, organizations will receive a cost estimate from GIPSA prior to service being performed.

21. DOCUMENT CONTROL AND RETENTION

a. GIPSA will notify organizations of any changes in the Verified Program Requirements or operating procedures by mail, email, and by a posting on the GIPSA Internet site.

b. Records relating to services provided are stored and maintained as follows:

(1) FGIS 907 - Application for Inspection under the AMA of 1946:

Original filed in FMD.
Copies retained until the organization withdraws request for service.

(2) Audit reports and related approval documentation:

Electronic version filed in FMD.
One copy sent to organization with approval letter.
Copies retained for at least 6 years.

(3) Approval letters:

Signed original sent to organization.
Electronic version filed in FMD.
Copies retained for at least 6 years.

/s/ John Giler, Acting Director
Field Management Division