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

c. APPENDIX 3 – The USDA Guide 65 Program

2. REPLACEMENT HIGHLIGHTS

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

This directive is revised to:

a. remove the words “not written” from APPENDIX 2;

b. change the name of APPENDIX 3 to The USDA Guide 65 Program and remove the words “not written”; and

c. attach the completed APPENDICES

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:

(a) Original filed in FMD.

(b) Copies retained until the organization withdraws request for service.

(2) Audit reports and related approval documentation:

(a) Electronic version filed in FMD.

(b) One copy sent to organization with approval letter.

(c) Copies retained for at least 6 years.

(3) Approval letters:

(a) Signed original sent to organization.

(b) Electronic version filed in FMD.

(c) Copies retained for at least 6 years.

/s/ John C. Giler

John C. Giler, Acting Director
Field Management Division

THE PROCESS VERIFIED PROGRAM

1. INTRODUCTION

The Process Verified Program (PVP) is a voluntary, user-fee service available to producers, marketers, processors, and associated service providers of agricultural products. The program is designed to provide verification of an organization's quality management system where the organization:

a) Needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements,

b) Aims to enhance customer satisfaction through the effective application of its management system, and

c) Identifies specific processing or marketing claims to be used in conjunction with the USDA Process Verified term and logo.

The program will use a "USDA Process Verified" label to enhance buyers' confidence in the product that they receive, whether they are domestic or foreign.

Following in Sections 2 through 9 are the general and specific requirements that must be addressed in the organization's quality management system. The documentation provided for verification must be in sufficient detail that the activities performed can be audited against the requirements.

2. APPLICABILITY OF THIS APPENDIX

a) The scope of this program ranges from seed purchase to a final product on grocery shelves or any segment in between.

b) All requirements are generic and are intended to be applied to all organizations providing a product or service within the grain industry regardless of type, size, and product provided.

c) Applicants must maintain a quality management system and submit their quality system documentation, commonly referred to as a "Quality Manual," for approval. Documentation submitted in writing to FMD will be reviewed in an adequacy audit as described in Section 6 of Directive 9180.79. An organization will be approved when it has successfully passed an onsite audit conducted according to procedures outlined in Section 7 of Directive 9180.79.

d) In these requirements, wherever the term "product" occurs, it can also mean "service," and the term "product" applies only to the product intended for, or required by, a customer.

3. REFERENCES

a) AMS Industry Services Audit and Accreditation Program: *USDA Process Verified Program*

b) ISO 9000:2000 Quality Management Systems - Requirements

4. QUALITY MANAGEMENT SYSTEM

4.1 General Requirements. The organization must:

a) identify the processes needed for the quality management system and their application throughout the organization;

b) determine the sequence and interaction of these processes;

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

d) ensure the availability of resources and information necessary to support the operation and monitor these processes;

e) monitor, measure, and analyze these processes;

f) implement actions necessary to achieve planned results and continual improvement of these processes; and

g) establish substantive, verifiable processes that add value to their product or service and substantiate marketing claims (Verification Points).

4.2 Documentation Requirements.

4.2.1 General documentation required. The quality management system documentation must include:

a) a quality manual;

b) documented statements of a quality policy and quality objectives;

c) documented procedures required by this document;

d) documents needed by the organization to ensure the effective planning, operation, and control of its processes; and

e) records required by this document.

Note 1: The term "documented procedure" means that a procedure must be established, documented, implemented, and maintained.

Note 2: The extent of the quality management system documentation can differ from one organization to another due to the size of the organization and type of activities, the complexity of the processes and their interactions, and the competence of personnel.

Note 3: The documentation can be in any form or type of medium.

4.2.2 Quality manual. The organization must establish and maintain a quality manual that includes:

a) the scope of the process, including details of, and justification for, any exclusions;

b) the specified process verification points;

c) the documented procedures established for the quality management system or reference to them;

d) a description of the interaction between the processes of the quality management system; and

e) other documents as required by the quality management system.

4.2.3 Control of documents. Documents required by the quality management system must be controlled. Records are a special type of document and must be controlled according to the requirements given in 4.2.4.

A master document list must be established that shows the most current issue of the quality management system procedures, work instructions, forms, tags, and labels used to track a product or demonstrate conformance.

A documented procedure must be established to define the controls needed to:

a) approve documents for adequacy prior to being issued;

b) review and update, as necessary, and re-approve documents;

c) ensure that changes and the current revision status of documents are identified on all pages;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified and their distribution controlled; and

g) prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records. Records must be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records must remain legible, readily identifiable, and retrievable. A documented procedure must be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Commitment. Top management must provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) communicating to the organization the importance of meeting customer, as well as statutory and regulatory, requirements;

b) establishing the quality policy;

c) ensuring that quality objectives are established;

d) conducting management reviews; and

e) ensuring the availability of resources.

5.2 Customer Focus. Top management must ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality Policy. Top management must ensure that the quality policy:

a) is appropriate to the purpose of the organization;

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;

c) provides a framework for establishing and reviewing quality objectives;

d) is communicated and understood within the organization; and

e) is reviewed for continuing suitability.

5.4 Planning.

5.4.1 Quality objectives. Top management must ensure that quality objectives, including those needed to meet requirements for product (see 7.1.1 a), are established at relevant functions and levels within the organization. The quality objectives must be measurable and consistent with the quality policy.

5.4.2 Quality management system planning. Top management must ensure that:

a) the planning of the quality management system is carried out in order to meet the general requirements stated in section 4, as well as the quality objectives; and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.4.3 Process Verified Points Top management must ensure that the process verified points:

a) are established and stated in the quality manual and included as part of the overall quality management system; and

b) must add value to the product or service; be substantive, verifiable, repeatable; and be within the scope of GIPSA's authority.

NOTE: Process verified points may not be requirements of regulations, the USDA Process Verified Program Requirements, or standards under which organizations in the same industry generally operate.

5.5 Responsibility, Authority and Communication.

5.5.1 Responsibility and authority. Top management must ensure that responsibilities and authorities are defined and communicated within the organization.

The quality manual must include an organization chart or similar document listing all personnel assigned to managerial positions within the organization, including each person's responsibilities and authorities.

5.5.2 Management representative. Top management must appoint a member of management who, irrespective of other responsibilities, must have responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented, and maintained;

b) reporting to top management on the performance of the quality management system and any need for improvement; and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication. Top management must ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review.

5.6.1 General. Top management must review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. This review must include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy, quality objectives, and the process verified points.

Records from management reviews must be maintained (see 4.2.4).

5.6.2 Review input. The input to management reviews must include information on:

a) results of audits;

b) customer feedback;

c) process performance and product conformity;

d) status of preventive and corrective actions;

e) follow up actions from previous management reviews;

f) changes that could affect the quality management system; and

g) recommendations for improvement.

5.6.3 Review output. The output from the management review must include any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes;

b) improvement of product related to customer requirements; and

c) resources needs.

6. RESOURCE MANAGEMENT

6.1 Provision of Resources. The organization must determine and provide the resources needed to implement and maintain the quality management system, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources.

6.2.1 General. Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, technical knowledge and experience.

6.2.2 Competence, awareness and training. The organization must document a procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the quality management system. The organization must:

a) determine the necessary competence stated in a position description or similar document for personnel performing work affecting product quality;

b) provide training or take other actions to satisfy these needs;

c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and

e) maintain appropriate records of education, training, skills, and experience.

6.3 Infrastructure. The organization must determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, buildings, workspace, associated utilities, process equipment (both hardware and software), and supporting services (such as transport or communication).

6.4 Work Environment. The organization must determine and manage the work environment needed to achieve conformity to product requirements.

7. PRODUCT REALIZATION

7.1 Planning of Product Realization. The organization must plan and develop the processes needed for product realization. Planning of product realization must be consistent with the other processes of the quality management system.

7.1.1 In planning product realization, the organization must determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance; and

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

7.1.2 The output of this planning must be in a form suitable for the organization's method of operations.

Note 1: If any requirements of this section (Section 7) cannot be applied due to the nature of an organization and its product, then these requirements may be considered for exclusion. Exclusions may not affect

the organization's ability to provide a conforming product nor do exclusions affect the organization's responsibility to provide a conforming product.
NOTE 2. The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-Related Processes.

7.2.1 Determination of requirements related to the product. The organization must determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for specified or intended use, where known;

c) statutory and regulatory requirements related to the product; and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product. The organization must review the requirements related to the product. This review must be conducted prior to the organization's commitment to supply the product to the customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensure that:

a) product requirements are defined;

b) contract or order requirements differing from those previously expressed are resolved; and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained (see 4.2.4).

Where the customer provides no documented statement of requirements, the customer requirements must be confirmed by the organization before acceptance.

Where product requirements are changed, the organization must ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internal sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as categories or advertising material.

7.2.3 Customer communication. The organization must determine and implement effective arrangements for communicating with customers in relation to:

a) product information;

b) inquiries, contracts or order handling, including amendments; and

c) customer feedback, including customer complaints.

7.3 Design and Development.

7.3.1 Design and development planning. The organization must plan and control the design and development of product.

During the design and development planning, the organization must determine:

a) the design and development stages;

b) the review, verification and validation that are appropriate to each design and development stage; and

c) the responsibilities and authorities for design and development.

The organization must manage the interfaces between the different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output must be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs. Inputs relating to product requirements must be determined and records maintained (see 4.2.4). These inputs must include:

a) functional and performance requirements;

b) applicable statutory and regulatory requirements;

c) where applicable, information derived from previous similar designs; and

d) other requirements essential for design and development.

These inputs must be reviewed for adequacy. Requirements must be complete, unambiguous, and not in conflict with each other.

7.3.3 Design and development outputs. The outputs of design and development must be provided in a form that enables verification against the design and development input and must be approved prior to release. Design and development outputs must:

a) meet input requirements for design development;

b) provide appropriate information for purchasing, production, and for service provision;

c) contain or reference product acceptance criteria; and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review. At suitable stages, systematic reviews of design and development must be performed in accordance with planned arrangements (see 7.3.1):

a) to evaluate the ability of the results of design and development to meet requirements; and

b) to identify any problems and propose necessary actions.

Participants in such reviews must include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions must be maintained (see 4.2.4).

7.3.5 Design and development verification. Verification must be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions must be maintained (see 4.2.4).

7.3.6 Design and development validation. Design and development validation must be performed in accordance with planned arrangements (see 7.3.1) to

ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation must be completed prior to delivery or implementation of the product. Records of the results of validation and any necessary actions must be maintained (see 4.2.4).

7.3.7 Control of design and development changes. Design and development changes must be identified and records maintained. The changes must be reviewed, verified, validated, as appropriate, and approved before implementation. The review of design and development changes must include evaluation of the effect of the changes on the constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions must be maintained (see 4.2.4).

7.4 Purchasing.

Where organization outsourcers any of their processes, supplies, ingredients, or services, it must identify them and specify how it plan to control the items or activities.

7.4.1 Purchasing process. The organization must ensure that purchased product or product received from an outside establishment for use in the product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product or received product must be dependent upon its effect on subsequent product realization or the final product.

The organization must evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation must be established and documented. Records of the results of evaluations and any necessary actions arising from the evaluation must be maintained (see 4.2.4).

7.4.2 Purchasing information. Purchasing information must describe the product to be purchased or received, including, where appropriate:

a) requirements for approval of product, procedures, processes, and equipment;

b) requirements for qualifications of personnel; and

c) quality system requirements.

The organization must ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased or received product. The organization must establish and implement the inspection or other activities necessary for ensuring that purchased or received product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization must state the intended verification arrangements and method of product release in the purchasing information.

7.4.4 Documented Procedure Requirements. The organization must have a documented procedure addressing the following:

a) all products or services received from outside establishments that affect the quality management system or the product;

b) the receiving requirements for approval of products to be used in the product;

c) the criteria and process for selection, evaluation and re-evaluation of the supplier; and

d) the process used to ensure that products or services purchased or received from outside establishments and used in the product conform to specific requirements.

7.5 Production and Service Provision.

7.5.1 Control of production and service provision. The organization must plan and carry out production and service provision under controlled conditions. Controlled conditions must include, as applicable:

a) the availability of information that describes the characteristics of the product;

b) the availability of work instructions, as necessary;

c) the use of suitable equipment;

d) the availability and use of monitoring and measuring devices;

e) the implementation of monitoring and measurement; and

f) the implementation of release, delivery, and post-delivery activities.

7.5.2 Validation of processes for production and service provision. The organization must validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation must demonstrate the ability of these processes to achieve planned results.

The organization must establish arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes;

b) approval of equipment and qualification of personnel;

c) use of specific methods and procedures;

d) requirements for records (see 4.2.4); and

e) revalidation.

7.5.3 Identification and traceability. The organization must have a documented procedure to:

a) identify the product by suitable means throughout the product realization, where appropriate;

b) identify the product status with respect to monitoring and measurement requirements;

c) control and record the unique identification of the product (see 4.2.4), when tracking is a requirement; and

d) control and record the use of the "USDA Process Verified" shield or the term "USDA Process Verified", if applicable.

The organization must maintain records of all products and/or ingredients as they are handled through out product realization.

7.5.4 Customer property. The organization must exercise care with customer property while it is under the organization's control or being used by the organization. The organization must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this must be reported to the customer and records maintained (see 4.2.4).

NOTE: Customer property can include intellectual property.

7.5.5 Preservation of product. The organization must preserve the conformity of product during internal processing and delivery to the intended destination. This preservation must include identification, handling, packaging, storage, and protection. Preservation must also apply to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Devices.

7.6.1 The organization must determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

7.6.2 The organization must establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

7.6.3 Where necessary to ensure valid results, measuring equipment must:

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification must be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement results; and

e) be protected from damage and deterioration during handling, maintenance, and storage.

7.6.4 In addition, the organization must assess and record the validity of the previous measuring results when the equipment is found not to conform to

requirements. The organization must take appropriate action on the equipment and any product affected. Records of the results of calibration and verification must be maintained (see 4.2.4).

7.6.5 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application must be confirmed. This must be undertaken prior to initial use and reconfirmed as necessary.

8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General. The organization must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

a) to demonstrate conformity of product;

b) to ensure conformity of the quality process system; and

c) to continually improve the effectiveness of the quality management system.

This must include determination of applicable methods, including statistical techniques and the extent of their use.

8.2 Monitoring and Measurement.

8.2.1 Customer satisfaction. As one of the measurements of the performance of the quality process system, the organization must monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information must be determined.

The organization must take appropriate actions to address customer complaints regarding conformance to the quality management system or the resulting products or service. Records of customer complaints and any actions taken to address them must be maintained.

8.2.2 Internal audits. The organization must conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements (see 7.1), to the general requirements of this document, and to the quality management system requirements established by the organization, and is effectively implemented and maintained.

The organization must have a documented procedure which addresses:

a) planning the audit program taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits;

b) the audit criteria, scope, frequency, and methods used;

c) selection of auditors and conduct of auditors to ensure objectivity and impartiality of the audit process (Auditors may not audit their own work.);

d) the responsibilities and requirements for planning and conducting audits;

e) reporting audit results;

f) following up on activities, including the verification of actions taken and the reporting of the verification results(see 8.5.2); and

g) maintaining records.

Management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Note: See ISO 19011:2002 for guidance.

8.2.3 Monitoring and measurement of processes. The organization must apply suitable methods for monitoring and, where applicable, measurement of quality management system processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product. The organization must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery must not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless

otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Nonconforming Product.

8.3.1 The organization must ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The identification of non-conforming product, the controls used to prevent the unintended use or delivery of non-conforming product, and the related responsibilities and authorities for dealing with nonconforming product must be defined in a documented procedure.

8.3.2 The organization must deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; and

c) by taking action to preclude its original intended use or application.

8.3.3 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, must be maintained (see 4.2.4).

8.3.4 When nonconforming product is corrected, it must be subject to re-verification to demonstrate conformity to the requirements.

8.3.5 When nonconforming product is detected after delivery or use has started, the organization must take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data. The organization must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This must include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data must provide information relating to:

a) customer satisfaction (see 8.2.1);

b) conformity to product requirements (see 7.2.1);

c) characteristics and trends of processes and products including opportunities for preventive action; and

d) suppliers.

8.5 Improvement.

8.5.1 Continual improvement. The organization must continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.2 Corrective action. The organization must take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions must be appropriate to the effects of the nonconformities encountered.

A documented procedure must be established to define requirements for:

a) reviewing nonconformities (including customer complaints);

b) determining the causes of nonconformities;

c) evaluating the need for action to ensure that nonconformities do not recur;

d) determining and implementing action needed;

e) records of the results of actions taken (see 4.2.4); and

f) reviewing corrective action taken.

8.5.3 Preventive action. The organization must determine action to eliminate causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

A documented procedure must be established to define requirements for:

a) determining potential nonconformities and their causes;

b) evaluating the need for action to prevent occurrence of nonconformities;

c) determining and implementing action needed;

d) records of results of action taken (see 4.2.4); and

e) reviewing preventive action taken.

9. CONTROL OF THE USDA PROCESS VERIFIED TERM AND SHIELD

9.1 Use of Term and Shield. The organization may use the term "USDA Process Verified" and the USDA Process Verified Shield in promotional and advertising materials which include labels, packaging, websites, brochures, and other marketing materials.

The organization must request the use of the term and shield.

A documented procedure for the use of promotional materials must be established to:

a) identify a person or persons with responsibility for the development, review, distribution approval and control of promotional materials;

b) ensure that the specified process verification points are accurately represented in the materials;

c) ensure that the USDA Process Verified shield and the term "USDA Process Verified" are placed on product labels, promotional material, or advertising in a manner directly associated with a clear description of the specified process verification points;

d) ensures the use of the term and shield are not misrepresented and are not used in association with any company claims;

e) ensures that promotional materials reference the GIPSA Process Verified Program website, when possible; and

f) provides for the proper control and use of the term and shield on materials by:

(1) ensuring that promotional materials are supplied to and used only by approved entities;

(2) providing for a system of surveillance to prevent unauthorized use of process verification points, the term "USDA Process Verified" or the USDA Process Verified shield; and

(3) ensuring that materials are submitted to the Process Verified Program Manager for approval prior to use.

Records of all approved materials must be maintained to show conformance to the documented procedure.

9.2 Placement of the "USDA Process Verified" Term and Shield. Placement of the USDA Process Verified term and shield must meet one of the following conditions:

a) the specified process verified points are printed immediately adjacent to the USDA Process Verified Shield; or

b) an asterisk referring the consumer to the information panel for further information about the specified process verified points is printed with the USDA Process Verified Shield; or

c) an asterisk referring the consumer to point of sale information is printed with the USDA Process Verified Shield. In this situation, the organization must ensure that the point of sale information is readily available and within close proximity of the display counter containing the product.

THE MULTI-SITE VERIFICATION PROGRAM

1. INTRODUCTION

The USDA Multi-site Verification Program (MSVP) expands the existing USDA Process Verified Program (PVP) by facilitating the approval of a company that has extended its quality management system (QMS) to a network of operations in different locations. The MSVP provides confidence that all parties conform to the PVP while being practical and feasible in economic and operative terms.

2. DEFINITIONS

2.1 Primary Company.

The central location or headquarters of the company; the source of the central function; the location where activities are planned, controlled, or managed.

2.2 Secondary Operation.

The locations or companies that form the network of the Primary Company. They are the locations where the planned activities are fully or partially carried out.

2.3 Tertiary Company.

As the suppliers of ingredients or services to the Primary Company or the Secondary operations, they are initially reviewed by the Primary Company to ensure that required specifications for the product or service can be met. They are continually monitored by the Primary Company and the Secondary operations to ensure that product or service delivered meets the requirements.

2.4 Sampling, Attachment 1.

Sampling is a method of reducing the number of audits performed on a multi-site organization. The formulas used in this document to determine the number of sites visited are taken from the International Accreditation Forum, Inc. as cited in Section 4, References.

2.4.1 Adequacy Audit.

The size of the sample is the square root of the number of Secondaryoperations ($y=\sqrt{x}$), rounded to the upper whole number.

2.4.2 On-site Visit.

The size of the annual sample is the square root of the number of Secondary operations with 0.6 as a coefficient ($y=0.6 \sqrt{x}$), rounded to the upper whole number. Some of the sample sites are planned and some are randomly selected.

2.4.3 Reassessment.

The size of the sample is the same as an on-site audit. If the QMS has proved effective over a period of three years, the size of the sample is reduced by a factor 0.8, i.e.: ($y=0.8 \sqrt{x}$), rounded to the upper whole number.

2.4.4 Additional Audits.

The size of the sample is increased when an analysis of the activity covered by the QMS indicates special circumstances regarding factors such as:

a. The size of the sites and number of employees,

b. The complexity of the activity and of the QMS,

c. Variations in working practices,

d. Variations in activities undertaken,

e. Records of complaints and other relevant aspects of corrective and preventive action, and

f. Results of internal audits.

Example: *A company that allows the use of its name on products produced in multiple plants or mills and provides oversight to ensure that its QMS is implemented according to planned results could use this program to extend PVP verification to each plant or mill. During a normal audit cycle, the Primary Company is audited annually and a sample number of the Secondary operations are audited based on the formula stated in section 2.4 and as noted in Attachment 1. A company with 50 sites can expect 8 Secondary sites audited in the adequacy audit and 5 sites audited in subsequent on-site audits.*

3. APPLICABILITY

3.1 Eligibility.

Only companies meeting Section 5, Program Requirements, are eligible for reducing the number of adequacy, on-site and reassessment audits through the sampling process.

If all sites are not ready to be submitted for assessment, the Primary Company may notify the GIPSA Verification Programs Manager of the Secondary operations it wishes to include in the MSVP. Additional sites may be added at a later date.

3.2 Primary Company.

Under this program, the Primary Company is responsible for:

a. The quality management system (QMS) and its implementation in each of the Secondary operations, and

b. Ensuring that appropriate Tertiary companies supply specified ingredients or services to itself and to the Secondary operations for use in products manufactured for or services provided on behalf of the Primary Company.

3.3 Secondary Operations.

The Secondary operations:

a. Are listed on the Primary Company's certificate,

b. Are allowed use of the Process Verified term and shield for products produced in accordance with the QMS of the Primary Company, and

c. Receive their own certificate explaining their relationship to the Primary Company.

3.4 Tertiary Companies.

Tertiary companies are:

a. Considered suppliers to the Primary Company and/or the Secondary operations,

b. Not eligible to use the PVP term or shield, and

c. Not listed on, nor do they receive a certificate.

4. REFERENCES

a. ISO 9000:2000 Quality Management Systems - Requirements

b. International Accreditation Forum, Inc.; *Guidance on the Application of ISO/IEC Guide 62:1996;* Appendix 3.

c. International Accreditation Forum, Inc.; *Guidance on the Application of ISO/IEC Guide 66;* pages 26 – 33.

5. PROGRAM REQUIREMENTS

5.1 The Primary Company.

The Primary Company's QMS must:

a. Meet all applicable requirements of Federal Grain Inspection Service Directive 9081.79 the Process Verified Program as stated in Appendix 1.

b. Ensure that the Secondary operations also meet the applicable requirements of Directive 9081.79 and the Process Verified Program as stated in Appendix 1.

c. Demonstrate the ability to collect and analyze data from all sites, including the central office, regarding, but not limited to:

(1) System documentation and system changes,

(2) Management review,

(3) Complaints,

(4) Evaluation of corrective and preventive actions, and

(5) Internal audit planning and evaluation of the results.

5.2 Operation of the Primary Company.

The Primary Company must:

a. Demonstrate the authority and ability to initiate organizational change if required,

b. Ensure that all applicable Federal, State and Local regulations are met by itself and by Secondary operations,

c. Have a legal or contractual link with the Secondary operations, and

d. Ensure that the products or services provided by Secondary operations are substantially of the same kind, and that they are produced fundamentally according to the same methods and procedures.

5.4 The Secondary Operation.

The Secondary Operations QMS must:

a. Meet the all applicable requirements of Federal Grain Inspection Service Directive 9081.79 and the Process Verified Program as stated in Appendix 1,

b. Demonstrate the ability to collect and analyze data and provide data to the Primary Company upon request,

c. Be administered according to the centrally controlled plan and accept actions of the Primary Company that result from a central management review, and

d. Be subject to the Primary Company's internal audit program and be audited in accordance with that program prior to submitting an application.

5.3 Operation of Secondary Operations

The Secondary Operation must:

a. Make organizational changes if required by the Primary Company,

b. Ensure that all applicable Federal, State and Local regulations are met,

c. Have a legal or contractual link with the Primary Company, and

d. Ensure that the products or services included within the scope of the Primary Company are substantially of the same kind, and that they are produced fundamentally according to the same methods and procedures.

6. MULTI-SITE APPROVAL

6.1 Nonconformance.

In addition to the requirements stated in Directive 9180.79, sections 8, 10, 11 and 16, the following will apply to the MSVP:

a. A multi-site organization is not approved if any site has a major nonconformance. Approval is granted pending satisfactory corrective action.

b. When a nonconformance is noted during an internal or external audit, the Primary Company must determine whether the other sites are affected. If the findings indicate a systemic deficiency, corrective action is required both at the Primary Company's site and at the Secondary operations' sites.

c. An organization may not change the scope of the multi-site program to eliminate a "problematic" Secondary operation. Corrective action is required.

6.2 Certificates.

6.2.1 Primary Company Certificate, Attachment 2a.

A single certificate is issued to the Primary Company listing the location's name and address. A list of all the sites related to the certificate is issued as an appendix. The scope on the certificate makes it clear that the approved activities are performed by a network of sites in the list. The Primary Company is listed on the GIPSA Verification Program website. See Attachment 2a.

6.2.2 Secondary Operation Certificates, Attachment 2b.

A certificate is issued to the secondary operations covered by the Primary Company's QMS. It contains the same scope and includes a clear reference to the main certificate. Secondary operations are listed under the Primary Company's name on the GIPSA Verification Program website. See Attachment 2b.

6.2.3 Withdrawal of Approval and Certificates.

Approval, certificates, and postings on the GIPSA website are withdrawn if the central office or any of the Secondary operations fail to fulfill the necessary requirements for maintaining approval.

6.2.4 Voluntary Withdrawal.

The Primary Company must inform the GIPSA Verification Programs Manager about the closure or removal of any Secondary operation from the scope of its QMS. Failure to provide such information is considered misuse of the approval and subject to Suspension, as noted in Section 16 of Directive 9180.79.

6.2.5 Additional Secondary Operations.

The Primary Company may add Secondary operations to the scope of the Primary Company's approval upon notification of the GIPSA Verification Programs Manager. The new operation will be added to the appendix of the Primary Company's certificate, will receive its own sub-certificate, and will be included in the GIPSA Verification Program website. The new operation will be included in the planned sample of Secondary operations during the next on-site auditing cycle.

7. VERIFICATION POINTS, the USDA SHIELD, and the PROCESS VERIFIED TERM

7.1 Verification Points.

Verification points must:

a. Meet the requirements of PVP Procedure 015, *Process Verified Points: Use of the USDA Process Verified Shield and the Term "USDA Process Verified";*

b. Be determined by the Primary Company;

c. Be implemented and auditable at all Secondary Operations; and

d. Not be exclusive, additional points in Secondary operations.

7.2 Use of the USDA Shield and the Process Verified Term

a. The Primary Company is responsible for control of all promotional material, advertising and labeling that uses the USDA Shield and the term "Process Verified" that reference its verification points.

b. The USDA Shield and the term "Process Verified" may be used by both the Primary Company and the Secondary operations under the following conditions:

(1) Use by a Secondary operation is approved by the Primary Company and

(2) Use by the Primary Company or a Secondary operation is approved by the GIPSA Verification Programs Manager.

John C. Giler, Acting Director
Field Management Division

Attachment 1 - Multi-site Verification Program Sampling Size Requirements

Number of Sites	Sampling Size Initial Audit	Sampling Size Surveillance Audit	Sampling Size Reassessment Audit
1	1	1	1
2	2	1	2
3	2	2	2
4	2	2	2
5	3	2	2
6	3	2	2
7	3	2	3
8	3	2	3
9	3	2	3
10	4	2	3
11	4	2	3
12	4	3	3
13	4	3	3
14	4	3	3
15	4	3	4
16	4	3	4
17	5	3	4
18	5	3	4
19	5	3	4
20 – 25	5	3	4
26 – 26	6	4	5
37 – 39	7	4	5
40 – 44	7	4	6
45 – 49	7	5	6
50 – 56	8	5	6
57 – 64	8	5	7
65 – 69	9	5	7
70 – 76	9	6	7
77 – 81	9	6	8
82 – 100	10	6	8
101 – 121	11	7	9
122 – up	**	**	**

CERTIFICATE OF CONFORMANCE

United States Department of Agriculture

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

FEDERAL GRAIN INSPECTION SERVICE

MULTI-SITE VERIFICATION PROGRAM

Primary Company: **ABC Corporation**
123 Main Street
Hometown, USA

Secondary Operation: **See Attached List**

Scope:

Meets Requirements Prescribed by the Federal Grain Inspection Service Directive 9180.79, Appendix 2: Multi-Site Verification Program

This certificate is receivable by all officers of all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the U.S. Department of Agriculture.

Certificate No: PV5213MMA Issue Date: September 2, 2005 Renewal Date: March 2, 2006

_____

Beth Hayden, Manager
GIPSA Verification Program

CERTIFICATE OF CONFORMANCE

United States Department of Agriculture

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

FEDERAL GRAIN INSPECTION SERVICE

MULTI-SITE VERIFICATION PROGRAM

Primary Company: **ABC Corporation**
123 Main Street
Hometown, USA

Secondary Operation: **ZYX Mill**
Anywhere in Iowa
Corn City, Iowa

Scope:

Meets Requirements Prescribed by the Federal Grain Inspection Service Directive 9180.79, Appendix 2: Multi-Site Verification Program

This certificate is receivable by all officers of all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the U.S. Department of Agriculture.

Certificate No: PV5213MMA **Issue Date: September 2, 2005** **Renewal Date: March 2, 2006**

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Beth Hayden, Manager
GIPSA Verification Program

THE USDA ISO GUIDE 65 PROGRAM

1. INTRODUCTION

The USDA ISO Guide 65 Program provides the means for a large number of businesses, such as farms or processors, to receive certification of conformance to an industry created or adopted standard from a certifying agent accredited by the GIPSA Verification Services Program (GVSP). Certified businesses realize a savings under this program because they are audited and approved directly by the certifying agent rather than by GVSP. The certifying agent incurs the cost for GSVP accreditation (approval). The certified businesses benefit directly, however, by linking their certification to the USDA accredited agent. Their names and product information will be posted on the GIPSA website in conjunction with the certifying agent's information. An identification logo created by the certifying agent for use by the certified business also may reference USDA accreditation.

An applicant for accreditation must meet the requirements of ISO Guide 65 – General requirements for bodies operating product certification systems. Certified operations must meet the requirements of the industry adopted standard as verified by the certifying agent and its inspectors. Inspectors who do desk audits and onsite inspections for the certifying agent must meet the agent's criteria for education, experience and training. Minimum qualifications are stated below in section 5 e).

The USDA Guide 65 Program operates under the requirements of FGIS Directive 9180.79. Exceptions and additional requirements follow in Section 5. The USDA Guide 65 Program is a voluntary conformity assessment program provided to certification bodies in the grain, oilseed, or pulse industries and associated agribusinesses.

2. DEFINITIONS

2.1 Accreditation Body.

GVSP is the accreditation body and third-party auditing service that verifies a certifying agent's ability to meet the requirements of ISO Guide 65 and ensures that the agent's customers meet the requirements of an approved standard. GVSP must meet the requirements of ISO 10017, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.*

2.2 Certifying Agent or Conformity Assessment Body.

The organization that provides third-party auditing services to businesses and ensures that they meet a designated standard, such as an industry created or adopted standard. In this APPENDIX, a certifying agent must meet the requirements of ISO Guide 65 - *The General requirements for bodies operating product certification systems*, prior to receiving accreditation from GVSP.

2.3 Certified Operation.

The organization that meets the requirements of an approved standard based on a third-party audit from an accredited certifying agent.

2.4 Approved Standard.

An approved standard must include:

a. Nationally accepted standards or standards used by marketing sectors in other countries, or

b. Industry developed and adopted standard that meets a specific need and has been accepted by GVSP as a credible method of describing a quality management or quality assurance system.

3. APPLICABILITY

The USDA Guide 65 Program is a voluntary conformity assessment and accreditation program provided to certification bodies in the grain, oilseed, or pulse industries and associated agribusinesses. Applicants for accreditation may already be in operation, providing certification to a recognized standard, or they may be a new company using a newly approved standard.

4. REFERENCES

a. ISO Guide 65 - *The General requirements for bodies operating product certification systems.*

b. USDA Agricultural Marketing Service, Audit Review and Compliance Branch Procedure 1012.

c. GVSP procedures and forms for Committee Meetings and Recommendations

5. PROGRAM REQUIREMENTS, EXCEPTIONS, ADDITIONS AND CLARIFICATIONS TO DIRECTIVE 9180.79

5.1 Requirements.

a. Certifying agents must meet all requirements of ISO Guide 65 "*The General requirements for bodies operating product certification systems"*.

b. Certification is limited to 1 year. Certifying agents must conduct annual certification reviews including an on-site inspection.

5.2 Exceptions.

a. FGIS Directive 9180.79, Sections 6, 7, and 9, describe an auditing and approval process in which an adequacy audit (sometimes referred to as a desk audit) is performed to ensure that the applicant organization is capable of conforming to program requirements. The adequacy audit is followed by an on-site audit to assess the way in which the applicant has implemented its documented program. After passing the on-site audit, approval is either granted or denied. This procedure does not change for certifying agents already in existence performing conformity assessment audits to an existing standard.

Under the USDA Guide 65 Program, applicants that are a new certifying agent are accredited (approved) based upon the adequacy audit. Once accredited, they may begin certifying applicants. Certification documents must be sent to GVSP for review. An on-site audit will be conducted after the applicant has performed several certifications and has an opportunity to establish a track record for review.

b. FGIS Directive 9180.79, Section 9 mentions that the names of approved operations are listed on the GVSP page of the GIPSA website. Under the USDA Guide 65 Program, the name and contact information of accredited certifying agents will be listed on the GVSP webpage, including the names of the operations certified by each agent.

5.3 Additions.

a. ISO Guide 65 requires the certifying agent to provide a certificate of conformance to a certified operation. In addition to the items stated in Guide 65, a certifying agent may place other pertinent information on the certificate including the following or a similar statement: "[Name of the Certifier] is accredited under ISO Guide 65 by the U.S. Department of Agriculture." Certificate formats are approved during the adequacy audit.

Certifying agents also may use the statement in company brochures, advertisements, and official documents, provided remarks or references are complete and not misleading. Such use must be approved by GVSP prior to publication.

b. ISO Guide 65 allows certifying agents to use its logo or another symbol of identification on certified products or in advertising and promotional material. The logo or symbol must be appropriate for the certifying agent and may not mimic the USDA logo; however, it may be accompanied by the statement "Accredited by the U.S. Department of Agriculture", or by a similar statement. The certifying agent's logo must be approved prior to accreditation.

c. Inspectors hired by accredited certifying agents must meet the certifying agent's requirements for education, experience, and training. The basic qualifications must include at least:

(1) Educational levels sufficient to ensure the reading, writing and mathematical skills necessary to interpret the standard, write reports, and determine fees and other charges by the certifying agent.

(2) Experience working in the agricultural sector being audited to ensure an accurate evaluation based on the standard being used.

(3) Attendance at a training session or sessions that cover the standard to which the inspector will be auditing, the audit protocol required in ISO Guide 65, and the certifying agent's auditing, reporting, and billing requirements. Training may be provided directly by the certifying agent.

5.4 Clarification.

FGIS Directive 9180.79 at section 19 addresses appeals, complaints and disputes from applicants for accreditation or accredited certifying agents directed toward GVSP regarding pending accreditation or accreditation matters.

Section 7 in ISO Guide 65 addresses appeals, complaints, and disputes from applicants for certification or certified operations directed toward the certifying agent regarding pending certification or certification matters.

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