Addendum
Quality Management Program:
Requirements for Official Service Providers
FGIS Directive 9180.81

QUALITY MANUAL TEMPLATE

All statements written in italics are for information. They explain the manual requirements which follow. Bracketed areas require a written explanation or description of OSPs policies or activities.

When establishing a Quality Management Program (QMP), an Official Service Provider (OSP) ***must document*** *its quality plan, including everything to do in support of a QMP prior to assigning responsibilities, resources, and processes. The type and extent of the documentation will depend on the size and complexity of the OSP's business operation as well as the nature of its products, services, and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.*

1. Official Service Provider Overview

a. [Official Service Provider name] is a [corporation, sole proprietorship, non-profit, state agency, FGIS Field Office]

1) Location
2) Telephone number
3) Fax number
4) Email address
5) Primary contact person

b. The scope of operations includes:

[Please describe the services your agency provides on behalf of GIPSA, for example, official inspection, weighing, Official Commercial Inspection Service (OCIS), customers served (e.g., producers, grain elevators, processors, feed mills, and other commercial entities), and other official activities. Describe all that you perform in a broad overview or "scope" statement, etc.]

c. This Quality Manual addresses all elements required by GIPSA's Quality Management Directive 9181.81, "Quality Management Program Requirements for Official Service Providers". Documented procedures are attached. All required records are kept and available on site.

2. General Legal Responsibilities

All activities performed on behalf of GIPSA must comply with the United States Grain Standards Act (7 U.S.C. 71-87.), regulations (7 CFR Part 800, 801, 802, 810, 868), the Agricultural Marketing Act of 1946 and associated regulations, instructions, methods, and policy and procedures, as applicable. A complete copy of all requirements can be found at www.gipsa.usda.gov.

a. [Official Service Provider's name] ("We" in the following statements) has the ability to provide all products or services, including official inspection services, as required by agreements, regulations, instructions, and handbooks. We have copies of the regulations, instructions, handbooks, and agreements (as appropriate). They are located in [please state the location(s)]. We verify that we have adequate staff and facilities to provide service in an accurate and timely manner. [Person's name or position title] has overall responsibility for our operation.

b. We will report to the responsible GIPSA contact person or office whenever we add or close service locations, or change the scope of official services provided at any service locations. [Person's name or position title] is responsible for reporting such matters to GIPSA.

c. We do not discriminate when charging fees. Records of all fees and billings are maintained in the [please state the location]. [Person's name or position title] is responsible for determining, billing, and collecting fees.

d. We will report to the responsible GIPSA contact person or office when we have information that shows or may show a violation of any provision of the U.S. Grain Standards Act and Agricultural Marketing Act of 1946 and associated regulations, or instructions that have been issued by GIPSA. [Person's name or position title] is responsible for reporting such matters to GIPSA.

e. We will provide sufficient security to ensure that official samples, records, equipment, forms, and GIPSA-owned property are reasonably secure from theft, alteration, or misuse. [Person's name or position title] is responsible for security. Security measures include [please list your security activities].

f. [Person's name or position title] is responsible for responding in a timely manner to non-compliances identified during GIPSA audits.

g. We will comply with all applicable Federal, State, and local regulations, including those related to the activity we are performing for GIPSA as well as those for safety and sanitation. [Person or job title] is responsible for conformance.

h. We will notify the appropriate GIPSA contact person or office of any changes that may affect the quality of the product or service being provided on behalf of GIPSA prior to the changes being made. [Person or job title] is responsible for providing the information.

i. We will allow GIPSA access to any structure, work area, records, and documents that are related to the performance of official services on behalf of GIPSA.

j. We will rotate personnel, **as required by GIPSA regulations and where feasible**, among elevators and other facilities as is necessary to preserve the integrity of the official inspection and weighing system. We have identified [Person or job title] as responsible for implementing the rotation plan. [Please briefly describe your plan]

k. We ensure that no officer, director, stockholder, employee, or other related entity has no conflict of interest related to commercial grain merchandizing, transporting, storage, or other related activity. Our plan to prevent conflicts of interest is: [Please describe your plan]

l. We **do not** perform unofficially any service that is the same as the official services covered by our official designation.

m. We maintain a certificate control system for all official certificates received, issued, voided, computer generated, or otherwise rendered useless. [Person or job title] is responsible for the control system which includes the following: [please describe your certificate control system]

n. We ensure that only personnel licensed by GIPSA perform official services. [Person or job title] is responsible for personnel and we have the following recordkeeping system of licensed personnel. [Please describe your recordkeeping system]

3. Management Responsibility

3.1 Management Commitment

This section should include a management statement establishing unity of purpose and directing the organization toward achieving goals by creating and defining the organization's policies and objectives, and ensuring that they are communicated to the entire organization.

3.2 Quality Coordinator

This section should specify the individual within the OSP responsible for implementing and maintaining the QMP. It is preferable that this responsibility not rest with the top manager, if at all possible.

[Insert name] is the Quality Coordinator for [OSP name]. Irrespective of other responsibilities, [he/she] has the responsibility and authority to do the following [Please describe the Quality Coordinator's activities to meet these requirements]:

a. Establish, implement, and maintain all processes and requirements specified in this quality manual to ensure that [name of agency] conforms with GIPSA's QMP.

b. Report to top management on the performance of [name of OSP] QMP and any need for improvement.

c. Promote awareness of customer requirements throughout the organization (e.g., by communicating customer expectations and seeking ideas for improvement.

d. Audit all internal processes addressed in this quality manual.

e. Develop, maintain, and implement documented procedures that describe the activities covered by the agency's local quality program for the eight core elements in section 4. (*A documented procedure describes an activity, who is responsible for the activity, where the activity occurs, and the frequency. It should provide information to carry out a process or activity in an orderly manner. The quality manual must establish documented procedures for each of the listed eight* ***core elements*** *noted in section 4****.*** *They can be either a written procedure or a reference a written instruction, policy bulletin, directive, or program notice issued by GIPSA.)*

4. Core Elements

4.1 Document Control

A document can be electronic or physical. There are many types of documents, such as equipment specifications, quality manuals, quality plans, forms, checklists, and inspection procedures. A document is dynamic because it changes over time. Management should list controlled documents (i.e., documents that contain proprietary and sensitive customer-related information) and where they are located. A document will be retained until changed or deemed obsolete.

a. Create a list of controlled documents that includes, at a minimum:

1) Dynamic documents (fee schedule, quality plan).
2) Certificate forms (paper or electronic).
3) Pan tickets, inspection logs, and other work forms.
4) Management review forms (checklists).
5) Employee training, licensing, and supervision forms (do not include records of a personal and confidential nature).

b. Describe the OSP processes for document management addressing several key areas:

1) Process for ensuring the accuracy and content of new documents.
2) Process for triggering revisions to existing documents.
3) System for identifying a document's current version, the date it was revised, and how it is made available at the point of use.
4) System to prevent the use of obsolete documents.
5) Process to prevent unauthorized use of documents.
6) System to review documents for legibility and current content of information.

4.2 Record Control and Accuracy

A record is a historical artifact that contains objective evidence showing conformance to the QMP. Records are always documents of what has happened in the past; typically a record is considered "static" since it cannot be changed. For example, a form that is completed is a record.

Management is responsible for retaining records for five (5) years and filing in a readily available manner.

a. Identify the types of records and where they are kept. These would include:

b. Required FGIS operation records such as "Authorization to Affix Signatures," any FDA notifications, "Letters of Fumigation," equipment records, records of official services requested and performed, and other official records.

c. Internal audit reports.

d. Corrective actions taken to resolve a non-compliant issue.

e. Billing statements.

f. Method of disposing of excess grain e.g., is the grain sold basis a contract with private individual, sold directly by the agency to a grain facility, or donated to a charitable organization or conservation effort, etc.

g. Certificates and pan tickets.

Management is responsible for evaluating the accuracy of records before they are released for use.

Describe your procedures addressing the following areas as well as the person(s) responsible for conducting these activities:

1) Ensuring certificate accuracy.
2) Ensuring billing accuracy.
3) Transferring correctly information from work record to the certificate.
4) Reviewing record accuracy on a periodic basis.
5) Correcting records when necessary.
6) Ensuring records of services performed are accurate and complete. This record should specify that date, time, and location of the service; the type of service requested and performed; the personnel assigned to perform the service; and fees charged for the service (e.g., mileage, labor, and lodging)

4.3 Communication Program

[Please describe how each of these activities are addressed]

Pertinent information is communicated to employees, including how OSP personnel are trained on accessing all computer-based information related to GIPSA handbooks, directives, and instructions.

Pertinent information is available onsite and up to date.

Pertinent information is obtained and updated.

4.4 Training, Licensing, and Supervision Program

Management must establish a written plan to create and maintain a documented workforce of highly trained professional people by training, licensing, supervising and monitoring all inspectors, technicians and samplers, as well as administrative and clerical personnel.

[Please describe your programs in the following areas:]

a. Employee training program

1) Orientation of new employees.
2) Training employees to become licensed to perform official services. Please list the person(s) primarily responsible for performing training. This section should include employee job descriptions relevant to license expectations, if applicable.
3) Educating employees on onsite elevator safety and GIPSA issuances and issuance changes.
4) Recording training activities.

5) Providing remedial or developmental training to employees, when necessary. Please include a description of the methods used to achieve these goals

b. Employee licensing program

1) The required and expected timeframe for achieving a license for each employee performing official inspection and weighing activities.
2) The actions employees are expected to take to achieve required license(s). This may include a checklist or other form to document completion of each action item.
3) The training materials and methods used to help employees meet licensing expectations. This should include both formal class room training and informal on-the-job training, where appropriate.

c. Employee supervision program

1) The person(s) primarily responsible for performing supervision of official services performed by the OSP.
2) The goals for the frequency of routine supervision of employee activities.
3) The plan for unannounced supervision.
4) The supervision forms used to document performance and identify problem areas for each type of licensing activity performed by the OSP.

4.5 Equipment

[Please address each of the items noted below]

a. Describe the type and location of all onsite and main laboratory equipment.

b. Denote whether equipment is agency or elevator owned.

c. Describe the procedure(s) followed to ensure that only GIPSA- approved equipment is purchased and utilized in official inspection activities, including sampling devices and diverter samplers.

d. Identify security measures followed for cross-utilized equipment.

e. Identify person(s) who makes decisions on purchasing of agency equipment.

f. Identify person(s) responsible for check testing equipment.

g. Explain the measures used to ensure timely check testing of all equipment per the GIPSA check test schedule.

h. Specify the location of all equipment check test records and where all other relevant information can be found for all equipment.

4.6 Facility Reviews

[Explain how you accomplish and verify the following requirements]

a. Providing customers with correct information regarding onsite facility requirements, e.g., lighting, floors, wall colors, and lab environment.

b. Using checklists to ensure compliance with all service-related processes provided at onsite labs, including approved equipment as well as safety procedures to be followed, and elevator policies.

c. Ensuring non-compliant situations are reported to elevator management and official agency management, and resolved immediately by the responsible party.

4.7 Local Quality Plan

Management is responsible for promoting improvement in the local quality plan by use of, but not limited to, internal audits and data analysis, and to make the necessary program adjustments.

[Please address the following items]

a. Identify the person(s) primarily responsible for implementing and monitoring compliance with activities specified in GIPSA's **Quality Handbook**, including the local quality program.

b. Identify the grains, oilseeds, and pulses that you inspect. Specify the factors or official criteria, as applicable, for each commodity.

c. Describe the process for correcting and aligning factor variances.

d. Describe the procedure to ensure that agency personnel are informed of OSP and GIPSA QA/QC processes and programs.

e. Identify the person(s) primarily responsible for analyzing data on the performance of the local quality program.

f. Describe how your local quality program meets GIPSA's QA/QC program in the following areas:

1) Sample Inspection Monitoring Samples (SIMS)
2) Subjective Testing and Evaluation Process (STEP)
3) Inspector calibration
4) Trainer opinion samples
5) Proficiency samples
6) Referee/survey samples
7) Test boxes
8) Site visits

4.8 Internal Audits

OSP management, in conjunction with the designated Quality Coordinator, designs and schedules an audit process to be followed by the OSP's audit team at least once a year.

[Describe how you accomplish the following:]

a. Examination of all processes, including human and physical resources.

b. Designating the members of the audit team and instructing the team not audit their own work. GIPSA encourages management to use current employees as auditors.

c. Determining the timeframe for completing annual audits taking into consideration the availability and workload of qualified employees.

d. Establishing the requirement that the audit team documents its findings and compares them to established GIPSA handbooks, directives, notices and instructions.

e. Developing and submitting a written report of the audit teams finding(s) to management.

f. Reviewing of audit findings and development of remedial actions by management to correct noncompliance items and prevent such items from reoccurring. This should include enhanced employee supervision and remedial training, where necessary.

5. Customer Focus

Organizations depend on their customers and must understand current and future customer needs, should meet customer requirements, and strive to exceed customer expectations.

We ensure customer requirements are determined and are met with the aim of enhancing customer satisfaction. We achieve these objections through the following outreach activities: [Please address each issue]:

a. Describe the scope of outreach activities and how customer satisfaction is assessed.

b. Describe how customer needs are anticipated, analyzed, and satisfied.

c. Describe how service complaints are handled and resolved.

6. Continual Improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

We strive for continual improvement in our quality program through a variety of proactive activities, including. We use a variety of activities to achieve this end:

[Please explain how you use the following activities o improve your QMP]

a. Customer feedback

b. Assessments of internal and external audit results to determine where improvements can be achieved.

c. Analyses of data and information relating to products and services to improve operating efficiency and customer satisfaction.

d. Preventive and corrective actions using the results of ongoing supervision and periodic audits of program performance.

e. Use of a customer satisfaction form to document concerns, complaints, service needs, and follow up action required to resolve any identified problems.