

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 Secondary operations ($y=\sqrt{x}$), 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

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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.

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