

<b>Oregon</b> Department of Agriculture	<b>GENERAL REQUIREMENTS FOR THE CERTIFICATION OF          IDENTITY PRESERVED</b>	Program: Identity Preserved ODA.IP. PD.1 Revision: 3.0 Issue Date: 4/04
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## 1 INTRODUCTION

- 1.1 Identity Preserved (IP) is methodology established to assure that the operation and processes of an organization can achieve desired results specifically relating to product characteristics that constitute an “Identity” that has added value to interested parties. Within IP methodology, identification and segregation assures that the traceability of the product, and the verification/certification of compliance associated with the product, is maintained through the marketing channels.
- 1.2 The general requirements are intended to be broadly applicable to agricultural commodity production and the manufacturing of agricultural products. The framework within the general requirements provides a method to systematically incorporate and verify compliance to supplemental customer specifications, statutes, national and international standards, and other certifications schemes that contribute to the value added “Identity” of a product.
- 1.3 The foundation of this document is based on the concept that specified inputs managed through a controlled process consistently yield desired and planned results.

## 2 SCOPE

This document provides the criteria for IP certification and the basis to objectively evaluate Identity Preserved methods within the processes of the production of agricultural commodities and the manufacturing of agricultural commodity products.

## 3 GENERAL

- 3.1 The applicant shall always comply with the relevant provisions of the IP certification program
- 3.2 The applicant shall make all necessary arrangements for the conduct of the evaluation, including provisions for examining documentation and access to all areas, records and personnel for the purposes of evaluation (e.g. sampling, testing, inspection, audits, and reassessment) and resolution of complaints.

## 4 ORGANIZATION

- 4.1 The applicant shall be an entity with a business name and legal status.
- 4.2 The applicant shall be responsible for the operations and administration of the products within the scope of IP certification.
- 4.3 When the applicant decides to use subcontract work or a portion of the operations has been assigned to another organization or person the applicant shall:
  - a) Take full responsibility for such subcontracted work.
  - b) Ensure that the subcontracted body or person is competent and complies with the applicable provisions of this standard and other standards relevant to IP certification.

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c) Have a properly documented agreement covering the arrangements including a provision to comply with the standards and provisions of IP certification.

4.4 The applicant shall designate one person with the authority to act on behalf of the organization at locations where program activities are conducted. This IP contact/coordinator shall have access to the highest levels of management and influence operation in the IP product realization processes.

4.5 The applicant shall define and communicate responsibilities for the key activities in IP operations

## 5 TRACEABILITY

5.1 The applicant shall have implemented and maintained a traceability system for IP products that includes an IP product identification system. The product identification marks/numbers shall be unique to products within the scope of IP certification.

5.2 Finished/Packed Product shall be traceable to:

- a) Processing/Packing plant
- b) Production/Packing date
- c) Sources and locations of operations that have complied with the relevant provisions of the IP certification program
- d) Date raw product is received for processing/packing

5.3 Raw products shall be traceable to locations that has complied with the relevant provisions of the IP certification program

5.4 The applicant shall practice a “mock recall” to measure the effectiveness of their traceability program. The “mock recall” shall include:

- a) Determination of the scope of product involved in the mock recall and an accounting of product within that scope
- b) A trace-back that establishes the origin of the raw product to the field(s) of production
- c) A trace-forward that determines the distribution of the product
- d) Records of the results

## 6 APPLICATION

6.1 The applicant shall fill out an official IP application form signed by a duly authorized representative that contains the following:

- a) Corporate entity, name, address, legal status, and necessary contact/billing information
- b) Mission statement of IP program
- c) Measurable objectives of IP program
- d) Definition of the products to be certified
- e) Scope of desired certification

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- f) Standards against which the applicant is assessed (if known by the applicant)
- g) Designated IP contact/coordinator
- h) A statement that the applicant agrees to comply with the requirements for IP certification and to supply any information for evaluation of products/processes to be certified

## 7 LOCATION REGISTRATION

7.1 The applicant shall provide location registration that provides information to find locations and positive identify them within the scope of certification activities. The information shall include:

- a) Location name
- b) Location identifier
- c) One of the following:
  - ◆ Address
  - ◆ GPS coordinates
  - ◆ Township Range Section (TRS)
- d) Person responsible for the IP operations at the location including contact information
- e) Type of location
- f) Size of location
- g) If necessary: description, directions, and special instructions

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## 8 INPUTS

- 8.1 Seed sources, raw materials and ingredients shall be adequate to achieve the mission and objectives of the IP program.
- 8.2 Specifications for inputs shall be consistent with the mission and objectives.
- 8.3 Records of an inputs source, specifications, and verification results shall be available for review.

## 9 SAMPLING AND TESTING

- 9.1 Qualified/Authorized personnel shall perform sampling of inputs or products in a manner that conforms to documented methods approved by the ODA.
- 9.2 An ODA approved laboratory shall perform official testing.

## 10 PROCESS CONTROL

- 10.1 IP processes/products shall be segregated from non-IP processes/products and methods shall be documented and implemented to mitigate commingling of IP product.
- 10.2 The applicant shall perform an evaluation of their product realization process to indicate where further controls are needed to assure the applicant's ability achieve their IP program objectives.
- 10.3 This evaluation or "risk assessment" shall include:
  - a) Identification of the hazards that could potentially negatively effect the applicant's ability to accomplish the IP program mission or meet the applicant's stated objectives of the IP program.
  - b) Correlating the hazard to point of operation it is likely to occur.
- 10.4 Risks to the mission or objectives of the program shall be identified and designated by the ODA as, low, medium, high, or extremely high. The evaluation shall be based on the level of probability in relationship with the severity of the negative impact on the ability to accomplish the IP program mission or meet the objectives of the IP program.
- 10.5 The applicant shall identify methods to mitigate the risks that have been identified as medium, high, or extremely high. Methods for mitigating risks may include one or more of the following:
  - a) Standard Operating Procedures
  - b) Sampling and Testing
  - c) Supplemental Standards
  - d) Policies for Operation
  - e) Other Approved Certification Programs

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- 10.6 The ODA shall evaluate the control methods of the applicant and determine the residual risks as acceptable or unacceptable.
- 10.7 The applicant and ODA shall work to resolve any differences in understanding concerning the risk assessment and control methods.
- 10.8 The applicant shall incorporate the methods of risk mitigation into the quality system and implement the controls necessary to reduce the residual risk to a level accepted by the ODA.
- 10.9 The applicant shall maintain records demonstrating compliance with program requirements, policies and procedures.
- 10.10 The ODA shall officially verify compliance with program policies, procedures, and the effective implementation of risk mitigation methods.
- 10.11 Official verification that identifies noncompliance with the IP requirements, applicable standards, or the quality manual will result in the issue of a “Non-Conformity Report”.
- 10.12 The ODA shall assess the negative impact of non-conformities on the applicant’s ability to meet the objectives of the program.
- 10.13 The applicant shall implement corrective action to non-conformities in a timely and appropriate manner.
- 10.14 The ODA shall approve and verify corrective action.

## **11 DOCUMENTATION**

- 11.1 The applicant shall implement and maintain a documented IP Program.
- 11.2 The IP documentation shall be available for review and use by the ODA.
- 11.3 After the initial approval any significant changes to the IP documentation, control measures, or processes that may affect the IP mission and objectives shall be approved by the ODA prior to implementation.
- 11.4 IP procedures and instructions shall be available to people responsible for the appropriate activities.
- 11.5 The applicant’s IP program shall include the following documents:
  - a) Mission statement of the IP program describing the intent of the program, the requirements that will be met, and the intended end result.
  - b) Measurable IP objectives that establish the product or process identity and/or a definition of the value added specifications of the processes or product.
  - c) Customer specifications, certification program requirements/checklists, or other requirements referred to in the mission statement or IP objectives.
  - d) An organization chart showing lines of authority and function, including subcontractors, stemming from the senior executive.

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- e) A procedure for the control of documents and procedures that defines the methods to approve documents for adequacy prior to use and ensure that the current revision is identified and available at points of use.
- f) IP product identification and traceback plan.
- g) Recall Procedure.
- h) Policies, plans, procedures, and/or identification methods that are necessary to ensure the segregation of IP processes/products and mitigate commingling and contamination.
- i) Flow chart showing a step-by-step description of the key activities of the IP operation, including IP planning.
- j) The IP risk management plan that includes:
  - 1. The identified hazards to achieving the IP objectives. (Hazard Analysis)
  - 2. Evaluation of the hazards and a designation of the resulting risk as negligible, low, medium, high, or extremely high.(Risk assessment)
  - 3. Planned control measures and interventions to reduce the medium, high and extremely high risks to an acceptable level. (Risk management)
- k) Documents detailing the methods of control and intervention as part of the IP risk management plan such as policies, procedures, sampling plans, testing, training, or description of other techniques utilized to mitigate the risks.
- l) A control of nonconforming product procedure to assure that product that does not conform to the IP objectives is identified and controlled to prevent its unintended use and delivery.
- m) Additional procedures or instructions to assure the continuing stability and integrity of the IP activities. (As applicable) These may include:
  - 1. A control of records procedure to assure that records that provide evidence of conformity remain legible, readily identifiable, and retrievable.
  - 2. Education, skill, or experience requirements and training procedures to assure that employees and contractors that perform work affecting the IP objectives are competent to perform IP activities.
  - 3. A procedure to internally check (review or audit) that IP activities, procedures, and records conform to the planned arrangements and documented methods.
  - 4. A corrective action procedure to eliminate the cause of any nonconformity reports and assure that the nonconformity doesn't happen again.
- n) Examples of the forms utilized in the IP program. .

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- o) A procedure to control certification documents and certification marks on product to assure that the certification and labeling are accurate, not misrepresented, or applied to non-IP product.
- p) A procedure to record and resolve complaints concerning IP product.

11.6 The applicant shall maintain records of conformity to requirements and record to be able to verify effective implementation of policies and procedures.

**12 COMPLAINTS TO THE APPLICANT**

- 12.1 The applicant shall document and keep a record of all complaints made known to them relating to products associated with IP program certification and make these records available to the ODA on request.
- 12.2 The applicant shall immediately report to the ODA any complaints that indicate the “Identity” of the product has been adulterated or found to be inconsistent with the specifications of the applicant’s IP program.
- 12.3 The applicant shall take appropriate action with respect to such complaints and document the actions taken.

**13 CERTIFICATION DOCUMENTS**

- 13.1 The applicant shall make claims regarding IP certification only in respect of the scope for which certification has been granted.
- 13.2 The applicant shall not use IP certification in such a manner as to bring the ODA into disrepute and shall not make any statement regarding IP certification which the ODA may consider misleading or unauthorized.
- 13.3 Upon suspension or cancellation of certification the applicant shall discontinue its use of all advertising matter that contains any reference to the ODA IP certification program and any certification documents as required by the ODA.
- 13.4 The applicant shall endeavor to ensure that
  - a) IP certification is used only to indicate that products are certified as being in conformity with the standards and criteria of the IP program.
  - b) Any reference to IP certification in media such as documents, brochures or advertising complies with the requirements of the certification body.
  - c) Ensure that no certificate or report nor any part thereof is used in a misleading manner.