

International Serum Industry Association

Traceability Policy and Procedure

The following policy and procedures are effective as of **April 2008**.

Purpose – The purpose of this policy and procedure is to provide International Serum Industry Association (ISIA)-sanctioned standards for the proper control of geographic origin and type of products produced by its member companies. ISIA members who elect to follow these guidelines including implementation of the auditing procedure are free to use their compliance with these standards in any marketing communications.

ISIA Traceability Standard – Any customer or auditor, whether government regulatory agents or ISIA-approved inspectors, reviewing traceability-standard-compliant-members are assured that the geographic origin represented on the product is, in fact, accurate, true, and traceable to the abattoir(s) or donor farm(s) from whence the raw blood was collected and that the type of serum (species and age) represented is correct. Each compliant member is responsible for keeping proper records which demonstrate traceability and serum type accuracy from the abattoir(s) or donor farms(s) through one step forward of their position in the supply chain. The integrity of the document chain is to be tested by third-party, independent audit.

Supporting References – This document is not intended to be all inclusive. It is designed to provide the minimum requirements for meeting the ISIA traceability standard. Other relevant reference documents regarding traceability are listed in Annex 1. You are encouraged to review these references.

Document Retention - All documents are to be maintained on file for a minimum of five years from the date of blood collection or the date of primary process pooling or date of final processing, depending on the date to which you have earliest access.

Policies and Procedures for Slaughter Sourced Material

I. Blood Collection

- A. An abattoir log is to be maintained at each primary processing center for abattoirs contributing blood supply to that center, and a master list of all supplying abattoirs must be maintained at the member's headquarters.

For each abattoir from which blood is received the log must contain:

1. Abattoir name

2. Physical address
 3. Telephone and fax numbers
 4. Name of the member's primary abattoir contact person
 5. A unique identifying number. The number assigned by the National Agriculture Authority (NAA) is preferred. Where unique numbers are not provided by the NAA, the member must assign the unique numbers.
- B. Each collection bag (refer to glossary of terms) is to be labeled with the blood type. The types of blood permitted are: (1) fetal, (2) newborn, (3) calf (lamb), (4) adult, (5) donor plus the species for each (bovine, equine, ovine etc.)
- C. The invoice received from the abattoir is to include:
1. Name of the collecting company
 2. Number of liters or weight of blood collected
 3. Price per liter
 4. Delivery docket number if dockets are used
 5. Type of blood
 6. The time period represented by the invoice

II. Transfer – Abattoir to Primary Processing Plant

1. Remote Locations
 - a. The container(s) used to transport the blood bags are to be labeled with the abattoir number and the date of collection.
 - b. A transfer document accompanies the shipment which certifies
 - The type of blood
 - Number of bags
 - Number of liters or weight
 - Signature of (in order of preference) a NAA official; or an abattoir representative; or the collecting company representative.
2. In-abattoir Locations
 - Every bag must be properly labeled (see I.B.)
 - Description of other documents is described below under Primary Processing Plant.

III. Primary Processing Plant

- A. A daily receiving log is to be maintained and must contain:
 - 1. Number of blood bags received
 - 2. Date of receipt
 - 3. Date of collection
 - 4. Volume or weight of each bag with the conversion factor used to calculate volume
 - 5. Abattoir number(s)
 - 6. The receiving log must reconcile with (1) the transfer documents, (2) the invoices received, and (3) the payments made.
 - 7. Type of blood
- B. A daily processing log is to be maintained and must contain for each type of blood
 - 1. Volume of blood processed
 - 2. Volume of serum produced
 - 3. Abattoir identification numbers clearly linked to each pool or jug number
 - 4. The numbering system implemented must allow seamless, easy linkage between pool numbers and the abattoir identification number(s) contributing to the pool
 - 5. Jugs into which the serum is pooled for freezing must be labeled with:
 - a. Type of serum
 - b. Date of pooling
 - c. Unique batch number. This number must allow seamless, easy linkage between it, all intermediate pools, if any, and the abattoir identification number(s) of those abattoirs contributing blood to the batch or jug.
 - d. Unique jug numbers that are continuous for all the jugs filled at a particular plant. It is suggested that the jug numbers be continuous for each day, month or year and renewed with the annotation of each succeeding day, month or year.
 - e. Country of origin

IV. Transfer - Primary Processing Plant to Final Processing (Filtration) Plant

- A. Each jug shipped is to be labeled with:
 - 1. Type of Serum
 - 2. Date of pooling
 - 3. Unique pool/batch number which allows seamless, easy linkage between it and the abattoir identification number(s) contributing to the batch.
 - 4. Country of Origin

- B. Each shipment must be accompanied by a packing list which contains:
 - 1. Type of serum
 - 2. Shipping Date
 - 3. Number of boxes
 - 4. Batch number(s)
 - 5. Number of jugs with a list of all the unique jug numbers
 - 6. Volume of each jug
 - 7. Country of origin

- C. In addition, for contract manufacturing customers (sale or transfer of raw serum to third parties) each unique batch number must be accompanied by a Certificate of Origin certifying the country of origin. The batch number must appear on the Certificate and link seamlessly and easily to the abattoir identification number(s). The Certificate is to be signed by a designated company representative. In addition, a certificate identifying country of origin issued by the NAA should accompany each shipment if the NAA will provide such certification.
 - 1. The invoice sent to the customer must contain by individual batch:
 - a. Number of liters
 - b. Price per liter
 - c. Type of serum
 - d. Number of containers
 - e. Volume of each container

V. Final Processing (Filtration) Plant

- A. A receiving log recording for each shipment received and containing or referencing
 - 1. Packing list(s) accompanying the shipment(s) or packing list number(s)
 - 2. Number of boxes
 - 3. Number of jugs
 - 4. Volume of each jug
 - 5. Shippers name
 - 6. Date received
 - 7. Type of serum
 - 8. Batch number

- B. A daily processing log is to be maintained which contains for each batch
 - 1. Type of serum
 - 2. Batch number(s) of finished product produced
 - 3. Name of the supplier(s) of unfiltered product
 - 4. Country of Origin
 - 5. Batch volume

- C. A batch history record is to be maintained for each batch produced and must contain:
 - 1. The unique batch number
 - 2. Type of serum
 - 3. Unfiltered, raw serum list containing:
 - a. Number of containers used
 - b. Volume of each container
 - c. Batch number(s)
 - d. Country of Origin including Certificate(s) of Origin accompanying the product
 - e. Name of the supplier(s)
 - 4. Certificate of Analysis showing the results of the quality control tests and the country of origin
 - 5. Certificate of Origin showing:
 - a. Unique batch number
 - b. Country of origin
 - Each batch should contain serum from only one country of origin, or
 - Occasionally multiple origins may be blended into a single batch. In such cases the Certificate of Origin and the

Certificate of Analysis must state clearly "Mixed Origin" and the countries of origin are to be listed with the percent by volume of the finished batch represented by each origin.

6. Copies of the finished product labels. The labels must be clearly printed with:
 - a. Unique batch number
 - b. Container volume
 - c. Name of the manufacturer
 - d. Manufacturer contact information
 - e. Type of serum

7. Labels are to be applied at the time of sterile filling. In rare occasions, filling into bottles with only the batch number may be permitted. The batch number must appear on the bottles. No other coding system is permitted to replace use of the batch number.

VI. Transfer - Final Processing (Filtration) Plant to Other Locations (Export or In-country)

A. Contract manufacture customers

1. Documents in addition to those required by regulations (customer forms, NAA Certifications) shall include:
 - a. A Certificate of Origin prepared by the final processing company for each batch certifying country of origin and linked to the batch by the unique batch number.
 - b. A packing lists which contains:
 - Type of serum
 - Shipping Date
 - Number of boxes
 - Batch number(s)
 - Number of jugs in each batch
 - Volume of each jug

Policies and Procedures for Donor Sourced Material

1. Either – Member Receives Blood From Donor Farm
Substitute “Abattoir” with “Donor Farm” in the Policies and Procedures for Slaughtered Source Animals and comply with the requirements. The “Donor Farm Log” must, in addition to the requirements listed contain a copy of the Certificate or Registry Number of the Donor Farm provided by the NAA.
- II. Or – Member Receives Serum from the Donor Farm
 - A. A donor farm log is to be maintained which lists for each donor farm contributing serum supply. The log contains for each donor farm from which serum is received:
 - g. Donor Farm Name
 - h. Physical Address
 - i. Telephone and fax numbers
 - j. Name of the member’s primary contact person at the farm
 - k. A unique identifying number
 - l. A copy of the Certificate or Registration of the farm from the NAA
 - B. Substitute “Abattoir” with “Donor Farm” in the Policies and Procedures for Slaughtered Source Animals and comply with the requirement beginning at III. Transfer – Primary Processing Plan to Final Processing (Filtration) Plant

The ISIA Board of Directors may, at any time, revise, modify or change the foregoing procedures and standards and will notify its members within a reasonable time after any such revision, modification or change is made. If any member needs further clarification with regard to the foregoing, they should contact the CEO of ISIA.

Annex 1

1. EC 1774/2002
 - a. Article 7
 - b. Article 10
 - c. Article 11
 - d. Article 18
 - e. Article 25
 - f. Article 26
 - g. Annex II
 - i. Chapter I
 - ii. Chapter III
 - iii. Chapter IV
 - iv. Chapter V
 - v. Chapter VIII
 - vi. Chapter X
 - h. Annex VIII
2. EC 178/2002 This reference relates to FOOD regulations and is listed for information only
 1. Article 18
 2. Article 27
 3. Article 50
3. EC 2007/2006
 1. Article 3
 2. Article 6
 3. Article 7
 4. Annex I
4. EP 5.0; 5.2.8 Minimizing Risk of TSE
5. SANCO 10542/2006
6. FDA – Docket Number 2005N-0373 pages 1582 - 1619 – Federal Register/Vol. 72, No.8/ January 12, 2007