How Does the ISIA Traceability Program Differ from an ISO Audit ?

The ISIA Traceability Certification program is used internationally to certify companies to the ISIA traceability policy. The program emphasizes systems that ensure quality and traceability of animal serum from collection to the customer. ISIA certification differs from other certifications. ISO certification is the internationally recognized standard for Quality Management Systems (QMS). ISO 9001 provides a framework and sets principles to ensure consistently satisfying customers and has an emphasis on process improvement. ISO 13485 is a set of standards specific to the requirements of Medical Device Manufacturers. Serum collection and processing is unique and requires a certification program specifically designed for this specialized industry.

CATEGORY	ISIA	ISO 13485
Purpose	Certificate for serum traceability	Certificate for QMS compliance
Focus	Animal Serum/Plasma Industry specific	Medical Devices
Frequency	Audit every 3 years - initial certificaiton audit (review 1 year financials / inventory mass balance); subsequent audits every 3 years (review 3 years of financials / inventory mass balance)	Audit every year - initial certification audit followed by two annual surveillance audits; cycle repeats
Batch record review	Review batch records, processes, and documents for serum production	Review batch records and documents
Quality Management System (QMS)	Reviews some aspects of the QMS - depends on integration of business	Reviews all aspects of the QMS
Geographic testing	Required	Not required
Quality department	Quality unit typically in organization; present when producing finished product; maybe at a lessor extent for raw serum providers only	Requires Quality unit for continuity of QMS and adherence to ISO / regulatory requirements
Sample retention	Sample retention required	Batch / raw material samples may be retained
Yield review	Yields strictly monitored; % yield calculations reviewed and verified	Yields may be monitored
Record retention	5 years minimum	Variable
Traceability	Traceability requirement for blood/serum throughout the supply chain - including mass balance	Only requires general traceability for raw materials
Supplier audit requirements	Supplier audits for blood/serum suppliers more detailed - specific questions required	Supplier audits for raw materials are not as detailed as ISIA requirements
Financial mass balance review	Included	Not included
Additional regulatory Requirements	Based on country where member company resides and where product is shipped; e.g. EU / USDA / other country regulations	None - minimal USDA or other regulatory involvement
Auditors	ISIA approved auditors trained specifically on the serum industry	Auditors may not have knowledge of the serum industry