HBI Ion Labs	Standard Operating Procedure **Record Storage, Retention, and Destruction**	**SOP Number** **C-502**	**Revision** **6**
		Effective Date 06/02/25	**Page** **Page 1 of 5**

Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
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1.0 Purpose

The purpose of this procedure is to define the requirements for the storage of documents and files related to the manufacture, production, packaging, labeling, holding, and distribution of dietary supplements, pet products, and OTC drug products. This procedure details the types of records, responsible departments, locations for storage, minimum retention times, destruction methods, and conditions for storage.

2.0 Scope

This procedure applies to all quality, regulatory and related records/documents retained by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Quality to establish the system for identification, retention, retrieval, access, destruction, and control of quality records/documents.

3.2 It is the responsibility of DC to provide adequate and organized storage of quality records and documents associated with the manufacture, production, packaging, labeling, holding, and distribution of all products, and to maintain these documents for the retention period outlined in this procedure.

3.3 It is the responsibility of all involved departments to follow this procedure.

4.0 Definitions

4.1 **Quality Record** – A record that provides evidence of the conformity, implementation, and effective operation of the quality system.

4.2 **DC –** Document Control

4.3 **Electronic Record** – Information captured through electronic means

5.0 References

5.1 21 CFR Part 11

5.2 ISO 17025:2017

6.0 Procedure

6.1 Quality records/documents will be gathered and stored by the responsible departments as specified in Attachment 1 to provide documented evidence that quality processes have taken place and that products have been manufactured and distributed to applicable specifications. The records will be filed in a way that provides for expedient retrieval.

6.2 Transfer of records between Belcher Warehouse and Main buildings will be conducted to ensure that the integrity of the documents is maintained.

6.2.1 Batch records will be transferred while secured in Batch Record Binders.

6.2.2 Individual files and records that are not batch records that are secured in binders will be transferred between buildings in a document transfer container which will be securely closed during transit.

6.3 .Records to be retained may be defined in procedures and work instructions.

6.3.1 At a minimum, records will be retained for one year past the shelf life date, if shelf life dating is used, or two years beyond the date of distribution of the last batch of product associated with those respective records.

6.3.2 Employment/Training Records will be kept for the duration of employment plus an additional 2 years.

6.3.3 Medical exposure documents/records will be kept for the duration of employment plus an additional 30 years.

6.3.4 Laboratory records will be kept for the required retention period determined by customer requirements, accreditation body requirements, regulatory requirements, and decisions by Management. The longest period required is used. If record retention periods change to a longer retention period due to new requirements, the new retention length is noted. The retention period for laboratory records is currently set at 6 years.

6.3.4.1 Laboratory records associated with customer orders are made available to customers and/or regulatory authorities as required.

6.3.5 Financial records supporting the purchase and procurement of raw materials and packaging items used in production should be retained for 6 years.

6.3.6 Financial tax documents must be kept for a minimum of 4 years or as Federal, State, or Local regulations dictate.

6.3.7 Depreciable asset documents must be kept for the life of depreciation plus an additional 3 years.

6.3.8 Federal, State, or Local regulations may apply by department/document requirements.

6.3.9 Equipment qualification/validation records are retained for the life of the equipment.

6.4 Records will be archived on site in the DC department or respective departments as designated by management.

6.5 Record Storage

6.5.1 Management will ensure all quality records and documents associated with the manufacture, production, packaging, labeling, holding, and distribution of all products are legible, stored, and retained to be readily available, in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

6.5.2 Paper documents will be stored in a clean, dry area, away from direct sunlight. Clear and legible reference shall be made on the quality record as to which process or product it refers to.

6.5.3 Electronic records are backed up at regular intervals. Nightly on and offsite backups are performed. Onsite backups are retrievable via a local drive. The system is continually monitored to ensure recovery and may be audited as part of our internal audit process to ensure effectiveness.

6.5.4 Records deemed confidential will be reviewed for proprietary information or trade secrets and will be marked as "Confidential" when appropriate.

6.5.5 Records will be retained per established minimum record retention schedules. At the end of the retention time, record disposition will be handled by management and, if applicable, destruction handled by a reputable document destruction service, who may provide a certificate of destruction upon shredding.

6.6 The record/document storage chart (Attachment 1) lists the quality records, storage locations, and the minimum retention times for records for each responsible department.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/21/14	New	14-0407	S. Millar
1	07/23/14	Added section for electronic document retention and backup	14-0558	S. Millar
2	02/06/15	Generalized for all products	14-1065	D. Popp
3	07/25/17	Added requirements for equipment documentation.	17-0763	S. Millar
4	05/04/21	Scheduled review: removed Velocity as external IT support. Update attachment 1. Add CFR reference.	CC-21-0173	K. Burris
5	10/15/21	Updated to include ISO 17025:2017 requirements	CC-21-0413	J. Sassman
6	04/28/25	Added transfer of records between buildings	CC-25-0201	K. Markovic

8.0 Attachments

8.1 Attachment 1 – Records/Document Storage Chart

Attachment 1 – Records/Document Storage Chart

RECORD TYPE	RESPONSIBLE DEPARTMENT	LOCATION	RETENTION PERIOD
Document Change Records/Procedure/	Quality	Document Control	6 yrs.
Customer Complaints/ Adverse Event Files/ Non-Conforming Documentation/ Deviation/CAPA	Quality	Document Control	6 yrs.
Product Review/Batch Records	Quality	Document Control	6 yrs.
External/Internal Audits	Quality	Document Control	6 yrs.
Vendor Review/Assessment	Purchasing/Quality	Document Control	6 yrs.
Employee/Training	Quality/HR	Document Control/HR	Life of employment plus 2 years
Purchase Orders	Accounting	Accounting Office	6 yrs.
Recalls	Quality/RA	Document Control	6 yrs.
Corrective Actions	Quality/RA	Document Control	6 yrs.
Management Review/Quality Analysis/Plan	Quality/RA	Document Control	6 yrs.
Specifications	R&D/Production Control	Document Control	6 yrs.
Lab Testing/Records/Logs/ Calibration	QC Laboratory	Document Control	6 yrs.
Organizational Charts	HR	HR	6 yrs.
Vendor/Subcontractor Supplied Records/Reports	Purchasing/Accounting Quality/Purchasing	Purchasing/Accounting Document Control	6 yrs.
Shipping/Receiving Records	Accounting	Accounting	6 yrs.
Sales/Order Entry	Accounting	Accounting	6 yrs.
Labeling/Graphics/ Packaging Associated Records	Quality/Document Control	Document Control	6 yrs.
Medical/Exposure Documents	HR	HR	Duration of Employment plus 30 years per OSHA Requirements
Facility Records Equipment Maintenance	Operations	Maintenance/Facility	6 yrs.
Equipment Qualification/Validation Records	Operations	Document Control	Life of Equipment plus 6 years