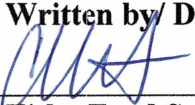
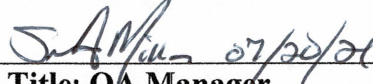

	Standard Operating Procedure Control of Glass, Brittle Plastics, Ceramics and Wood	SOP Number F-508	Revision 3
		Effective Date 09/16/21	Page Page 1 of 8
Written by/ Date  07/20/21	Reviewed by/ Date  07/20/21	Approved by/ Date  08-04-21	
Title: Food Safety & Training Supervisor	Title: QA Manager	Title: VP of Quality & Regulatory Affairs	

1.0 Purpose

The purpose of this procedure is to define and establish a Glass, Brittle Plastics, Ceramics and Wood Control Program to ensure compliance and safety of all products manufactured and distributed by Ion Labs, Inc.

2.0 Scope

This procedure applies to all manufacturing and warehouse areas at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of the Production, Facility, and Maintenance Management to implement and maintain this procedure.
- 3.2 It is the responsibility of all personnel to ensure that this program is followed and that all glass, brittle plastics, ceramics and wood are controlled and disposed of in an appropriate manner.
- 3.3 It is the responsibility of the Facility Manager or designee to oversee and aid in the cleanup of all broken glass, brittle plastics, ceramics and/or wood; to ensure proper disposal and handling. This will reduce the chance for contamination and injury.
- 3.4 It is the responsibility of the Maintenance Manager to ensure that all machinery and equipment where glass, brittle plastic or ceramic may be present are well maintained and secure.
- 3.5 It is the responsibility of the QS Manager or designee to review the affected area and perform an appropriate area clearance. The QS Manager or designee will also ensure that all associated documentation is reviewed with proper accountability.
- 3.6 It is the responsibility of the QA Manager or designee to ensure that random areas are audited on a monthly basis.

4.0 Definitions

- 4.1 **Contamination** – the presence of an undesirable substance or material rendering that

material/product harmful or unsuitable for use.

- 4.2 **QC** – Quality Control
- 4.3 **QA** – Quality Assurance
- 4.4 **HACCP**- Hazard Analysis Critical Control Point
- 4.5 **HARPC**- Hazard Analysis Risk-based Preventative Control

5.0 References

- 5.1 C-502, SOP, Record Storage, Retention, and Destruction
- 5.2 QS-105, SOP, Food Safety Plan
- 5.3 F-508-F1, Form, Glass, Brittle Plastic or Ceramic Breakage Form
- 5.4 F-508-F2, Form, Glass/Brittle Plastic/Ceramics/Wood Audit Checklist
- 5.5 Glass, Brittle Plastic, Ceramics and Wood Policy Statement
- 5.6 HACCP/HARPC Plan
- 5.7 GMP and Sanitation Monthly Audit
- 5.8 21 CFR 111 and 117

6.0 Procedure

- 6.1 Ion Labs has implemented a Glass, Brittle Plastic, Ceramics and Wood Policy in order to assist in reducing the risk of contamination to our products.
- 6.2 Glass, Brittle Plastic, and Ceramics
 - 6.2.1 Glass, Brittle Plastics and Ceramics are physical hazards and considered a significant food safety risk. To ensure the safety of the product, the following procedures are implemented.
 - 6.2.1.1 All lights must be protected to effectively contain broken glass. To avoid contaminating food/product/packaging with glass materials, all fluorescent tubes and light fixtures are required to be fitted with diffusers, safety covers/shields, or shatterproof bulbs.

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6.2.1.2 Lights should only be replaced during non-production hours when there is no exposed product.

6.2.1.3 If a light MUST be replaced during production hours: All product, packaging, and equipment must be covered or moved to a designated hold area that is a sufficient distance from the fixture to prevent accidental contamination (this area may be designated by the Production, Facility, or Maintenance management or designee).

6.2.2 In the event of a breakage in the production or warehouse area, the following corrective actions are to be followed:

6.2.2.1 All glass, brittle plastic or ceramic breakage must be reported immediately to the area supervisor or manager.

6.2.2.2 Stop production where contamination of the product is possible. Stop operations and attempt to locate the source of the glass, brittle plastic or ceramic fragments.

Note: Uncovered/exposed product/packaging material in the immediate area will require a risk assessment to ensure that there is no contamination of product. Product that is contaminated and needs to be disposed will be at the discretion of VP of Quality/RA or designee. Affected product should be moved to a designated area for proper disposal. Facility maintenance will orchestrate this activity, ensuring containment. The QS Manager or designee will review and modify/approve all associated product documentation to ensure proper accountability.

6.2.2.3 If removal of large pieces of glass, brittle plastics, or ceramic is to be by hand, appropriate gloves must be worn and pieces must be placed in a designated sharps container or proper disposal container.

6.2.2.4 Carefully sweep up the glass/other fragments into a dustpan and transfer to a lined cardboard box to be marked “Broken Glass” or appropriate sharps container. Facility management or designee will dispose of glass/plastic properly and ensure tools used/uniforms worn (i.e. gloves, shoes/footwear covers, brooms, brushes, and dustpan) are cleaned/changed outside of the affected area to prevent further contamination.

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- 6.2.2.5 Ensure that the area is wiped clean with disposable wipes and an approved cleaner to further eliminate any residual fragments. Dispose of cleanup material properly.
- 6.2.2.6 Facility or Production management will make any needed modifications to the area or source to prevent any future introduction of glass, brittle plastic or ceramic fragments.
- 6.2.2.7 All equipment will be thoroughly cleaned should they be in the area of the breakage or become contaminated. This is at the discretion of the Maintenance Manager.
- 6.2.2.8 Resuming production/operations in the affected area will require a complete review of the area by the QS Manager or designee. This review will be documented on form F-508-F1 Glass, Brittle Plastic and Ceramic Breakage Form.

6.3 Wood

- 6.3.1 Wood is a physical hazard and considered a significant food safety risk. To ensure the safety of the product, the following procedures are implemented:
 - 6.3.1.1 As a general principle the use of wood should be avoided, however it is acknowledged that wood pallets maybe used for delivery and production areas.
 - 6.3.1.2 Wood pallets must not be in areas where product is exposed. When there is an exception, wood pallets that are used in production areas (primary packaging) near exposed product/product contact surfaces, must be wrapped properly to prevent a risk of contamination.
 - 6.3.1.3 Pallets within the warehouse must be maintained in good condition: dry, clean, free from damage and contamination.
 - 6.3.1.4 Pallets that are unacceptable to use are removed from the production/warehouse area and place in a designated location.
 - 6.3.1.5 Pallets that are acceptable to use are stored in the Warehouse.
 - 6.3.1.6 Pallets must not have, loose, damaged or missing boards or blocks.
 - 6.3.1.7 Pallets condition must be subject to regular inspections.

- 6.3.1.8 Wood pallets must not be treated with tainted chemicals.
- 6.3.1.9 Pallets must not have any protruding nails.
- 6.3.1.10 Pallets must not have any large or protruding splinters or sharp edges.
- 6.3.1.11 Pallets must not have any off odors or physical contamination.
- 6.3.1.12 All loose, trailing shrink/stretch wrap must be removed, when applicable.
- 6.3.1.13 After handling wood pallets, hands should be washed prior to touching any product or product contact surfaces.
- 6.3.1.14 Wood utensils are not permitted in the warehouse and manufacturing facility areas (as they cannot be properly cleaned/sanitized and may be a source of foreign materials contamination).

6.4 Inventory, Internal Audits, and Hazard Analysis

- 6.4.1 An internal audit for Glass, Brittle Plastic, Ceramics and Wood will be conducted monthly using Form F-508-F2 Glass/ Brittle Plastic/Ceramic/Wood Audit Checklist (including internal Glass, Brittle Plastic, and Ceramic Register). The internal audit assesses random areas, ensuring that there is no risk for contamination from glass, brittle plastics, ceramic or wood. The QA Manager or designee will notify Production, Maintenance, and/or Facility Management or designee (as applicable) of any noted failure during the audit.
 - 6.4.1.1 Any action that is required as a result of a failure will necessitate immediate attention/correction, depending on the situation or risk. The corrective action will be documented on Form F-508-F2 Glass, Brittle Plastic, Ceramic or Wood Audit Checklist. A work order will be generated, if necessary.
 - 6.4.1.2 Once the corrective action has been completed, the Quality Manager or designee will be notified to reassess the area. The reassessment will also be documented on the form. If the corrective action is not completed satisfactorily, a plan must be obtained by the respected department management; including a time frame for completion.
- 6.4.2 Random checks are conducted during the GMP and Sanitation Audit. These checks ensure items (may contain/are glass, brittle plastic, ceramic and/or wood

pallet) are designed, constructed, and stored properly so they do not pose a risk to contaminating the product/product contact surfaces. These checks also ensure the surrounding areas near product/product contact surfaces are not at risk of being contaminated.

6.4.2.1 Any action that is required as a result of a failure will necessitate immediate attention/correction, depending on the situation or risk. Corrective action will be documented on the GMP and Sanitation Audit Observation Report. The QA Manager or designee will notify the Production Manager, Maintenance Manager, or Facility Manager (as applicable) of any noted failure during the audit.

6.4.2.2 Once the corrective action has been complete, the Quality Manager or designee will assess and verify. If the corrective action is not completed satisfactorily, a plan must be obtained by the respected department management; including a time frame for completion.

6.4.3 A hazard analysis was performed and is documented in the HACCP/HARPC Plan. Each process step was assessed based off risk for physical hazards such as glass, brittle plastic, ceramics, and wood. Preventative Controls are in place to eliminate cross contamination. (see HACCP/HARPC Plan for details)

6.5 Record Keeping

6.5.1 In the event of a breakage, complete form F-508-F1 Glass, Brittle Plastic, and Ceramic Breakage Form. The form will then be place in the batch record. Quality may hold a copy at their discretion.

6.5.2 Documents will be maintained following SOP C-502 Record Storage, Retention, and Destruction.

6.5.3 Internal Audits are maintained by the QA department.

6.5.4 A reassessment of the HACCP/HARPC Plan is conducted annually and maintained by the QA department.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/09/15	New	15-0396	S. Millar
1	01/25/16	Changed and added responsibilities; added reference to equipment	15-0994	S. Millar

2	04/27/18	Added reference to ceramics. Updated titles. Revised audit checklist.	18-0148	S. Millar
3	07/13/21	Added reference 21 CFR 111 and 117, HACCP/HARPC, GMP and Sanitation Audit, Glass, Brittle Plastic, Ceramic and Wood Policy Statement, and QS-105 Food Safety Plan. Added a Glass, Brittle Plastic, Ceramic and Wood Policy Statement. Revised procedure to add wood and current practices. Compliant to requirements.	CC-21-0249	C. Horelle

8.0 Attachments

8.1 Attachment 1 - Glass, Brittle Plastics, Ceramics and Wood Policy Statement

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Attachment 1 - Glass, Brittle Plastics, Ceramics and Wood Policy Statement

Ion Labs operates to the highest possible quality standards. Glass, Brittle Plastic, Ceramics, and Wood are a significant physical food safety risk. To safeguard our products we have adopted the following policy to assist in reducing the risk of contamination of our products from glass, brittle plastics, ceramics and wood.

- By this commitment, Ion Labs minimizes the risk of potential product contaminations by glass, brittle plastics, ceramics and/or wood.
- Wherever possible, items constructed of glass, brittle plastics, ceramics and/or wood are avoided in the Production Areas. When no satisfactory alternatives can be found, such articles shall be protected in a manner which can be prevented from being shattered, broken or source of contamination. When in an emergency situation, shattered or broken fragments can be contained in a manner that would eliminate or prevent potential cross contamination.
- Exceptions to this policy include Laboratory, Breakroom and Office Areas. These areas are separate from Contact Areas/Manufacturing Area. The Laboratory Area has a policy for broken glass. Glassware/blades/cutting instruments are disposed of in a separate waste disposal container.
- It is Ion Labs policy to provide continual monitoring of glass, brittle plastics, ceramics, and wood articles within the manufacturing facility. This shall be accomplished by monthly self-inspection/audits to assess random areas, ensuring that there is no risk for contamination from glass, brittle plastics, ceramics, and wood.
- A Glass, Brittle Plastics, Ceramics, and Wood register has been established with assigned risk. The register identifies examples of glass, brittle plastic, ceramics, and wood in immediate contact areas/production.
- Lights and light fixtures suspended over product contact or product contact surfaces in any stage of process or exposed packaging material must be protected to prevent contamination of product in case of breakage.
- **Other Foreign Body Control Policy:** Illness and Injury are covered under the Good Manufacturing Practices and Personal Hygiene Procedure. Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts must be covered with colored bandages containing a metal strip or an alternative suitable waterproof and colored dressing. Gloves must be worn over bandages.
- Glass, Brittle Plastic, Ceramics, and Wood Policy will be applicable regardless if production is taking place or not.



Glass, Brittle Plastic, and Ceramic Breakage Form

Form: F-508-F1

CCR No. CC-21-0249

Revision: 3

This form must be completed whenever glass, brittle plastic or ceramic material is found broken in the warehouse or manufacturing areas.

Date of Incident:	
Batch Number:	
Person Performing Cleanup: (Ensure proper gloves are worn to reduce the chance of injury)	
Broken Item:	
Material Type (Glass, Brittle Plastic, Ceramic)	
Area Found:	
Product Affected (if applicable):	

Cleanup Procedure:

- Report all glass, brittle plastic or ceramic breakage immediately to the area Supervisor or Manager.
- Stop production where contamination of the product is possible. Stop operations and attempt to locate the source of the glass, brittle plastic and/or ceramic fragments.
- Uncovered/Exposed Product/Packaging Material in the immediate area will require a risk assessment to ensure that there is no contamination of product. Product that is contaminated and needs to be disposed will be at the discretion of VP of Quality/RA or designee. Affected product must be moved to a designated area for proper disposal. Facility maintenance will orchestrate this activity to ensure containment. The QS Manager or designee will review and modify/approve all associated product documentation to ensure proper accountability.
- If removal of large pieces of glass, brittle plastic or ceramic material is by hand, appropriate gloves must be worn and pieces must be placed in a designated sharps container or proper disposal container.
- Carefully sweep the glass or brittle plastic fragments into a dustpan and transfer to a lined cardboard box to marked 'Broken Glass/Brittle Plastic/Ceramic' or an appropriate sharps container. Facility maintenance will dispose of glass/plastic/ceramic properly and ensure tools used/uniforms worn (i.e. shoes, brooms, brushes, and dustpan) are cleaned/changed outside of the affected area to prevent further contamination. This area will be designated by the Director of Operations.
- Ensure that the area is wiped clean with disposable wipes and approved cleaner to further eliminate any residual fragments. Dispose of cleanup material properly.
- Resuming production/operations in the affected area will require a complete review of the area by the QS Manager or designee.

Facility Management/Operations: _____ Date: _____

Comments:

Area Clearance: Area is free of contaminants and is acceptable

Quality: _____ Date: _____

