1.0 Purpose

The purpose of this procedure is to define the process for documentation of a nonconformance or deviation associated with any stage of manufacturing including, packaging, major processing equipment, instrument failure, discrepancies of controlled good manufacturing practice (GMP) documents and failure of facility support systems.

This procedure defines the process used for initiating, assessing, approving, executing, and closing formal investigations of nonconformities and unexpected deviations related but not limited to products, materials, equipment, processes, and quality systems.

These controls are intended to ensure that nonconforming products and materials are prevented from inadvertent use.

This procedure ensures that disposition decisions are made during management review at appropriate levels of the organization.

2.0 Scope

This procedure applies to any nonconformities and planned or unplanned deviations that may affect products manufactured and/or packaged by Ion Nutritional Labs.

3.0 Responsibility

3.1 All employees who identify a product, process, or equipment nonconformity or unexpected deviation, and/or who intend to deviate from an established process/procedure/specification, are responsible for informing the area supervisor of the need to initiate a deviation.

3.2 All departments are responsible for providing accurate and timely information, data, assessments, and other required input during the investigation. They are also responsible for active and cooperative participation in the investigation teams as requested by Quality.

3.2.1 The Initiator of the deviation is responsible for ensuring customer notification is executed as outlined in the Quality Agreement between HBI Ion Labs and the customer.

3.3 Quality is responsible for reviewing and approving all deviations, for determining if a deviation is required, for the final review and approval of all deviations, and for tracking and maintaining deviations.

4.0 Definitions

4.1 **Deviation** – A departure from an approved procedure, process or specification

4.1.1 An **unplanned deviation** is an unexpected departure from standard operating procedure, specification or process which requires investigation, root cause analysis, impact assessment and corrective actions. Typically discovered after the deviation has already occurred.

4.1.2 A **planned deviation** is a deviation identified and approved prior to the occurrence of the deviation. Typically, a temporary change which may or may not lead to a permanent change.

4.2 **Nonconformance** – The non-fulfillment of a requirement, failure to comply with requirements

4.3 **SOP** – Standard Operating Procedure

4.4 **BPR** – Batch Production Record

4.5 **QC** – Quality Control

4.6 **MRB** – Material Review Board

5.0 References

5.1 C-201-F1, Form, Unplanned Deviation Initiation Form

5.2 C-201-F2, Form, Unplanned Deviation Investigation Form

5.3 C-201-F3, Form, Unplanned Deviation Closure Form

5.4 C-201-F4, Form, Planned Deviation Initiation Form

5.5 C-210-F5, Form, Planned Deviation Closure Form

5.6 QS-112, SOP, Core Quality Systems and Quality Events

5.7 QS-112-F1, Form, Quality Event Extension Request

5.8 QS-112-F2, Form, Quality Event Cancellation Request

5.9 QS-112-F3, Form, Quality Event Amendment Request

5.10 C-202, SOP, Material Review Board

5.11 B-108, SOP, Reprocessing Procedure

5.12 C-403, SOP, Change Control Procedure

5.13 C-105, SOP, Protocol and Report Document Requirements

5.14 QS-108, SOP, Corrective and Preventative Action (CAPA)

5.15 QS-111, SOP, Root Cause Analysis (RCA)

5.16 QS-114, SOP, Quality Risk Management

5.17 C-502, SOP, Record Storage, Retention, and Destruction

5.18 C-501, SOP, Document Control Procedure

6.0 Procedure

6.1 General Deviation / Investigation Requirements

6.1.1 Impact Assessment and Scope

- Give careful consideration to what a deviation may affect and over what period of time the deviation may have influence. Consider more than just the specific activity.

6.1.2 Risk Assessment

- Quality will follow SOP QS-114 Quality Risk Management when conducting risk assessments.

6.1.3 Reprocessing

- When and investigation finds that a batch or material should or could be reprocessed, follow SOP B-108 Reprocessing Procedure.

6.1.4 Quality Review / Approval

- Forms associated with this procedure that require a quality signature imply Quality Management.

- In cases where there is no identified root cause of a deviation, material or product quality is in question, or when quality management is unsure of appropriate next steps, initiate an MRB meeting as indicated by SOP C-202 Material Review Board.

- Document MRB decisions on the applicable forms (C-201-F1 through F5) with MRB signatures as directed by SOP C-202 Material Review Board. Alternatively, summarize MRB decisions on one document

(e.g. a memorandum) with the necessary MRB signatures and attach that document to the deviation. Add a Quality management signature on the deviation forms with reference to the MRB document.

6.2 Unplanned Deviation

6.2.1 Anyone that identifies an unplanned deviation must inform management of the deviation. Use the forms listed below to document and control this process.

6.2.2 C-201 F1 - Unplanned Deviation Initiation Form

- The initiator will complete form C-201-F1 Unplanned Deviation Initiation Form.
- Take actions necessary to prevent further deviation, harm, or quality impact as necessary. If time is of the essence, take action before initiating the deviation upon management approval. Document actions taken on the deviation initiation form.
- Assign a lead investigator to complete form C-201-F2 Unplanned Deviation Investigation Form. The lead investigator does not have to be the same person that initiated the investigation. The lead investigator should be familiar with the circumstances and processes. For complicated investigations, use an investigation team. The lead investigator will coordinate the activities of the team and document findings.

6.2.3 C-201 F2 - Unplanned Deviation Investigation Form

- Investigate the circumstances of the deviation and identify causes of the deviation. Follow SOP QS-111 Root Cause Analysis when conducting this investigation.

- Continue the investigation until satisfied that all information needed to resolve the deviation is available.

- Document resolution of the deviation on form C-201-F3 Unplanned Deviation Closure Form.

6.2.4 C-201 F3 - Unplanned Deviation Closure Form

- Upon completion of forms C-201-F1 Unplanned Deviation Initiation Form and C-201-F2 Unplanned Deviation Investigation Form, Quality will complete C-201-F3 Unplanned Deviation Closure Form.

- If Quality finds that more information is needed to complete the closure form, Quality may request additional investigative work and have the previous forms amended.

7.1 Planned Deviation

7.1.3 Evaluate any planned deviation from a procedure, formula, process, or controlled document before proceeding. Use the forms listed below to document and control this process.

7.1.4 C-201-F4 – Planned Deviation Initiation Form

7.1.4.3 The initiator / requestor of the planned deviation will complete form C-201-F4 Planned Deviation Initiation Form.

7.1.4.4 If detailed instructions are required to execute and control the planned deviation, initiate a protocol with this detailed information. See SOP C-105 Protocol and Report Documentation Requirements for protocol documentation requirements. Attach applicable protocols to the planned deviation.

7.1.4.5 Conduct a risk assessment to justify the deviation as applicable. See SOP QS-114 Quality Risk Management for details about risk assessments and risk management.

7.1.4.6 Identify a planned deviation custodian to monitor the planned deviation. The custodian is responsible for closing the deviation using form C-201-F5 Planned Deviation Closure Form.

7.1.4.7 Document and log the planned deviation request as outlined in SOP QS-112 Core Quality Systems and Quality Events.

7.1.5 C-201-F5 – Planned Deviation Closure Form

7.1.5.3 The deviation custodian will initiate form C-201-F5 Planned Deviation Closure Form when the deviation is ready to close.

7.1.5.4 Quality will approve the closure form after confirmation that all necessary actions are complete.

7.2 Additional Requirements from QS-112 Core Quality Systems and Quality Events.

7.2.1 This procedure is a Core Quality System (CQS) that is also controlled by the CQS and Quality Events SOP QS-112.

7.2.2 The term "event" is a generic reference to any of the CQS covered by SOP QS-112 Core Quality Systems and Quality Events. The term "event" is used interchangeably with specific CQS events as applicable (i.e. "deviation" here).

7.2.3 SOP QS-112 Core Quality Systems and Quality Events provides instructions common to all Ion Nutritional Labs CQS, including the following topics which are not duplicated here:

7.2.3.1 Assignment of unique event numbers (i.e. deviation numbers)

7.2.3.2 Logging of events with Quality Assurance

7.2.3.3 Assignment of event due dates

7.2.3.4 Event due date extensions

7.2.3.5 Event cancellations

7.2.3.6 Event revisions / amendments

7.2.3.7 Monitoring of open events

7.2.3.8 Record management and retention instructions

7.3 Document Maintenance

7.3.1 Deviations will be maintained following SOPs C-501 Document Control Procedure and C-502 Record Storage, Retention, and Destruction.

7.3.2 When applicable, original completed deviations will be filed with the batch that it pertains to.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/07/10	New	-	-
1	11/29/12	Changed format. Added more definitions. Made SOP more detailed. Added a step to document whether or not previously released batches may be impacted. Added documentation of material disposition.	-	-
2	02/15/13	Clarified and organized SOP. Changed SOP title. Added sections 5.4, 5.5, 5.6, and 5.7.	-	-
3	06/13/13	Organized SOP. Changed forms.	-	-
4	10/15/13	Replaced Director of Quality and Regulatory Affairs with QA Manager. Replaced Management Committee with MRB. Added Form C-201-F3.	13-869	H. Peiser
5	12/29/14	Add customer notification; add reference to multiple SOPs; Revise for clarity.	14-1017	D. Popp
6	01/05/16	Remove manual logs and files; expand responsibilities to Quality Management or designee.	16-0029	D. Popp
7	03/01/17	Revise to clarify Raw Material Quarantine process; revise to clarify proper maintenance of closed deviations.	17-0214	D. Popp

8	01/14/20	Revise to align with new forms C-201-F1, C-201-F2, C-210-F3, C-201-F4, C-201-F5. Removed raw material quarantine form.	19-0600	K. Burris
9	09/18/23	Updated logo and format. Corrected typos. Added additional SOP references. Added documentation requirements. Added SOP and form names.	CC-23-0469	K. Burris
10	07/05/25	1.Update the Header and footer to HBI Ion Labs on each document 2. Update C-201 to specify responsibility for notification of customer per Quality Agreement 3. Update Definition of Deviations 4. Update C-201-F1 to include customer in notifications section and F2 to include date notified field and instruction to attach evidence. 5. Update C201-F3 to specify (Completed by the Deviation Custodian and/or Quality) for each section. 6. Update 7.2.3.2 to specify Quality Assurance	CC-25-0364	P. Christensen

HBI Health & Beauty Innovations	Unplanned Deviation Initiation Form		
	Form: C-201-F1	CCR No. CC-25-0364	Revision: 2

Deviation #

Section I – Unplanned Deviation Information

Deviation Overview (Completed by the Initiator)

Initiator's Name:		Department:	
Observer's Name:		Department:	
Deviation Title (Short description)			

Description of the Deviation: (Include details like who, what, when, where, and why associated with the deviation. As applicable include sequence of events, background information, cross references to protocols, etc. Include details like room numbers, lot numbers, material names and numbers, product names and numbers, etc.)

Deviation Details (Completed by the Initiator)

Date & Time (if known) deviation occurred:	
Date / Time deviation initiated:	
☐ N/A ☐ Reason for a delay between date of occurrence and initiation if greater than 2 business days	
Deviation Type: ☐ Deviation from Procedure ☐ Non-conforming material/product/result/data ☐ Deviation within facility/services/environment ☐ Deviation from regulations ☐ Adverse trend detected ☐ Other, Specify:	**Specify what was deviated from:** (procedure number, specification, standard, equipment function, etc.)

What may be affected by the deviation? (Completed by the Initiator)

HBI Health & Beauty Innovations	Unplanned Deviation Initiation Form		
	Form: C-201-F1	CCR No. CC-25-0364	Revision: 2

Deviation #

Item	Detail
☐ Equipment ID	
☐ Process/Specification	
☐ Product (SKU/Name/Batch#)	
☐ Material (Item#/R#)	
☐ Standard	
☐ Other	

Discuss potential impact of this deviation including process, products, materials, etc.
(Note: Impact may change after investigation is completed)

Initial Action(s) Taken (Completed by the Initiator)

Notifications (check all that apply)			*Quarantine / Tag Out / Hold*
☐ QA	☐ QC Lab	☐ Executive Management	☐ N/A
☐ QC Inspectors	☐ R&D	☐ Customer notification is required per Quality Agreement	☐ Yes (explain below)
☐ QC Doc Control	☐ Prod. Management		☐ No (explain below)

Describe immediate action taken to correct the deviation or nonconformance and to provide detail for boxes above.

Deviation Assignment (Completed by the Initiator and/or Quality)

Lead Investigator Role Assigned to		**Deviation Due Date**	

Approval Signatures

Name	Title	Signature	Date
Completed By: (Initiator)			
Assignment Accepted By: ☐ **N/A if same as completed by**			
Approved By: (Quality)			

Deviation #

Section II – Unplanned Deviation Investigation

Deviation Overview (Completed by the Investigator)

Deviation Title Short description	

Investigation Activities (Completed by the Investigator)

The following activities were used to conduct this investigation (check all that apply):

- ☐ Interviews (list interview personnel interviewed and key findings below)
- ☐ Document reviews (list documents reviewed and key findings below)
- ☐ Observations – (list observations and key findings below)
- ☐ Testing / Inspection (list activities and results below)
- ☐ Five (5) Whys review (list questions and answers below)
- ☐ Other (specify below)

Add detail information to the impact assessment selected above as applicable.

☐ Attached ☐ Discussed here

Deviation # | |

Causes and Root Cause Identified (Completed by the Investigator)

List likely causes of this deviation and identify the most likely root cause. See SOP QS-111 for Root Cause Analysis

☐ Attached ☐ Discussed here

Investigation Summary and Conclusions (Completed by the Investigator)

Summarize this deviation investigation and conclusions.

☐ Attached ☐ Discussed here

Approval Signatures

Note: Quality should not approve this investigation unless it is thorough enough for Quality to complete form C-201-F3 to close this investigation. Specifically, Quality will need to make Impact and Quality assessments as well as determine CAPA. This investigation must provide details necessary for these determinations.

Name	Title	Signature	Date
Completed By: (Investigator)			
Approved By: (Quality)			

HBI Ion Labs	Unplanned Deviation Closure Form			
	Form:	C-201-F3	CCR No. CC-25-0364	Revision: 2

Deviation #

Section III – Unplanned Deviation Closure

Deviation Overview (Completed by the Deviation Custodian and/or Quality)

Deviation Title Short description	

Impact Assessment (Completed by the Deviation Custodian and/or Quality)

Review the "What may be affected by the deviation?" section of form C-201-F1 for this investigation. Based on the investigation of the deviation completed on form C-201-F2, select impact statements listed below (check all that apply). NOTE: this is a scope assessment, not a quality or disposition assessment.

☐ All items identified at deviation initiation are still impacted by this deviation.

☐ Some items identified at deviation initiation are no longer impacted by this deviation. (list below)

☐ Some items are impacted by this deviation that were not identified at deviation initiation. (list below)

Add detail information to the impact assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Quality Assessment (Completed by the Deviation Custodian and/or Quality)

Based on the investigation of the deviation completed on form C-201-F2, select quality statements listed below (check all that apply):

☐ All items identified in the impact assessment above meet applicable quality standards and/or specifications and may be considered for release or continued use.

☐ Some items identified in the impact assessment above meet applicable quality standards and/or specifications and some do not. Describe findings and disposition decisions below:

☐ All items identified in the impact assessment above do not meet applicable quality standards and/or specifications and may be considered for release or continued use.

Add detail information to the quality assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Risk Assessment (Completed by the Deviation Custodian and/or Quality)

The impact assessment and/or quality assessment is based on the following risk assessment in addition to the information provided in the investigation of this deviation C-201-F1. The process of risk assessment is governed by SOP QS-114.

☐ The conclusions are not complicated and no additional risk assessment required.

☐ Additional risk assessment was performed (see below)

Add detail information to the risk assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

HBI Ion Labs	Unplanned Deviation Closure Form		
	Form: C-201-F3	CCR No. CC-25-0364	Revision: 2

Deviation #

Notifications / Additional Actions (Completed by the Deviation Custodian and/or Quality)

Are any notifications or additional actions required based on this Deviation

☐ No additional notification or action required.

☐ Customers notification, date notified (attach evidence)

☐ Additional action required.

Add detail information to the quality assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Attachments (– List all attachments applicable to this investigation. Include attachments from forms C-201-F1 and C-201-F2 as well as this closure form C-201-F3.

Title	Description	Pages

CAPA (Corrective Action(s) and Preventative Action(s) – (Completed by the Deviation Custodian and/or Quality)

Is there evidence of repeated observations or patterns?

☐ No – CAPA may be required – complete additional CAPA sections below as applicable. If at least one CAPA is not initiated, explain that decision in the space provided for CAPA below.

☐ Yes – CAPA is required – complete addition CAPA sections below.

List CAPA already completed and in place before closure of this form

List CAPA yet to be completed. These must have CAPA numbers and are managed by SOP QS-108

Approval Signatures

Name	Title	Signature	Date
Completed By:			
Approved By: (Quality)			

Deviation #

Section I – Planned Deviation Information

Deviation Overview (Completed by the Initiator)

Initiator's Name:		**Department:**	
Deviation Title Short description			

Description/Reason/Justification of the Planned Deviation: (Include details like who, what, when, where, and why associated with the planned deviation. As applicable include sequence of events, background information, cross references to protocols, etc. Include details like room numbers, lot numbers, material names and numbers, product names and numbers, etc.)

Deviation from what? (Completed by the Initiator) – check all that apply

☐ Deviation from Procedure(s)	
☐ Deviation within facility/services/environment	
☐ Deviation from regulations	
☐ Other (specify)	

Add detail information to the scope check boxes selected above as applicable.
☐ N/A ☐ Attached ☐ Discussed here

Deviation # | |

Deviation Scope (Completed by the Initiator and/or Quality) – check all that apply

Note: A due date (see custodian assignment) will be assigned to this planned deviation regardless of the scope identified below. The due date will create a mechanism to check on the progress toward closing this planned deviation.

☐ Specified Time Frame	Start		End	
☐ Specified Product(s) or Material(s)				
☐ Specified Locations Rooms or Areas				
☐ Specified Systems or Procedures				
☐ Until specified action is complete				
☐ Other (specify)				

Add detail information to the scope check boxes selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

What may be affected by the deviation? (Completed by the Initiator and/or Quality)

Item	Detail
☐ Same as deviation scope	
☐ Equipment ID	
☐ Process/Specification	
☐ Product / Material (Item # / Name / Batch#)	
☐ Other	

Discuss potential impact of this planned deviation including process, products, materials, etc.

☐ N/A ☐ Attached ☐ Discussed here

Notifications / Additional Actions (Completed by the Initiator and/or Quality)

Are any notifications or additional actions required based on this Deviation

☐ No additional notification or action required.

☐ Clients / Customers notification is required

☐ Additional action required.

Add detail information to the quality assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Deviation # | |

Planned Deviation Implementation Controls (Completed by the Initiator and/or Quality)

How will the planned deviation be implemented and processes controlled (check all that apply)

- ☐ Documented training on this planned deviation
- ☐ Issuance of hand corrected documentation and quarantine of currently approved documentation
- ☐ (Tags / Markers / Signs) on equipment, controls, rooms materials, product, documents, etc.
- ☐ Other

Add detail information to the quality assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

CAPA (Corrective Action(s) and Preventative Action(s) – Completed by the Initiator and/or Quality)

Is there evidence of need to make this deviation permanent?

- ☐ No – CAPA may be required – complete additional CAPA sections below as applicable.
- ☐ Yes – CAPA is required – complete addition CAPA sections below.

List CAPA already completed and in place before closure of this form

List CAPA yet to be completed. These must have CAPA numbers and are managed by SOP QS-108.

Deviation Custodian Assignment – (Completed by the Investigator and Quality)

The deviation custodian is responsible for monitoring and closing this planned deviation.

Deviation Custodian Role Assigned to		**Deviation Due Date**	

Approval Signatures

Name	Title	Signature	Date
Completed By: (Initiator)			
Assignment Accepted By: ☐ **N/A if same as completed by**			
Approved By: (Quality)			

HBI	Planned Deviation Closure Form			
	Form:	C-201-F5	CCR No. CC-25-0364	Revision: 2

Deviation #

Section II – Planned Deviation Closure

Deviation Overview (Completed by the Deviation Custodian and/or Quality)

Deviation Title (Short description)	

Deviation Scope Completion (Completed by the Deviation Custodian and/or Quality)

Was the deviation Scope defined on C-201-F4 met?

☐ Yes, all aspects of the deviation scope were met.

☐ No, all aspects of the deviation scope were not met. Discuss why the deviation is to be closed and impact of closure before the scope requirements are met.

Add detail information to the scope completion assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Deviation Implementation Controls Removal (Completed by the Deviation Custodian and/or Quality)

Review the planned deviation controls implemented in C-201-F4 and ensure that they are removed upon finalization of this closure form. (check all that apply)

☐ Implementation controls have been removed and previous procedure / process are in place.

☐ Implementation controls have been removed and new procedures / processes are in place.

☐ Other

Add detail information to the status of implementation controls selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Additional Actions (Completed by the Deviation Custodian and/or Quality)

Are any additional actions required before closing this planned deviation?

☐ No additional action required.

☐ Additional action required.

Add detail information to the quality assessment selected above as applicable.

☐ N/A ☐ Attached ☐ Discussed here

Approval Signatures

Name	Title	Signature	Date
Completed By: (Author)			
Approved By: (Quality)			