1.0 Purpose

The purpose of this procedure is to provide a system to evaluate and verify that actions taken to correct and/or prevent an identified nonconformance or quality systems problem adequately mitigate the identified problem. .

2.0 Scope

This procedure applies to the evaluation of the effectiveness of Corrective Actions and Preventative Actions (CAPA). CAPA evaluated by this procedure include CAPA Quality Events given a CAPA Event Number, as well as CAPA referenced as actions already completed within other quality events.

3.0 Responsibility

3.1 It is the responsibility of all employees assigned to complete an EC to:

3.1.1 Sign form QS-113-F1 Effectiveness Check Assignment, accepting responsibility for the assignment.

3.1.2 Complete the assignment in a timely manner.

3.1.3 Provide progress updates as applicable.

3.1.4 Initiate form QS-113-F2 Effectiveness Check Closure when the EC is complete.

3.2 It is the responsibility of Quality to:

3.2.1 Determine if an EC is needed at the close of a quality event.

3.3 It is the responsibility of Document Control / Quality to:

3.3.1 Follow SOP QS-112 Core Quality Systems and Quality Events when assigning, logging, and managing EC Events.

3.3.2 Approve or reject EC Assignments and EC Closures.

4.0 Definitions

4.1 **Quality Event** – the issuance of an event number for a quality system subject to this procedure and as defined in the scope of specific procedures associated with that system

4.2 **cGMP** – Current Good Manufacturing Practices

4.3 **EC** – Effectiveness Check

4.4 **CAPA** – Corrective and Preventative Action

4.5 **DC** – Document Control

4.6 **CQS** – Core Quality System

5.0 References

5.1 QS-113-F1, Form, Effectiveness Check (EC) Assignment

5.2 QS-113-F2, Form, Effectiveness Check (EC) Closure

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

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

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

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

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

5.8 C-501, SOP, Document Control

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

6.0 Procedure

6.1 EC Source / Reference

6.1.1 The need for an EC is determined based on direction in other quality systems. For example, a CAPA may conclude that an effectiveness check is required. If that is the case, then reference the event number for the CAPA as the EC Source on form QS-113-F1 Effectiveness Check (EC) Assignment.

6.1.2 A CAPA event number is not required if the corrective or preventative action is already complete. In that case, other quality events reference the actions taken without a CAPA number. In the absence of a CAPA event number, reference the event that lists the action that the EC intends to check as applicable.

6.2 EC Applicability

6.2.1 Not all CAPA require an EC. Quality Management will determine if an EC is required. Reasons for assigning an EC include (1) building confidence that the solution will work, (2) validating that the solution did work, and (3) minimizing risk or potential problems that might cause reoccurrence. Verifying the effectiveness of a CAPA closes the loop between identifying a problem and completing the actions to solve a problem.

6.2.2 If the root cause and CAPA are apparent, then an EC is not required.

6.2.3 If there is uncertainty in the root cause, if there is uncertainty in the selected CAPA, or if there are changes in a procedure or test method then consider applying an EC.

6.2.4 Unless a quality system procedure indicates otherwise, Quality is responsible for making the determination of the need for assignment of an EC at the close or assignment of that quality event as applicable. Quality personnel may always escalate the decision for applicability of an EC assignment to upper level quality management.

6.3 EC Plan on QS-113-F1 Effectiveness Check (EC) Assignment

6.3.1 The EC Plan of form QS-113-F1 Effectiveness Check (EC) Assignment is a description of how to evaluate whether a CAPA accomplished the intended purpose. The person assigned to complete the EC must review and understand the source of the EC to understand the intent of the EC.

6.3.2 When determining the EC Action Plan be sure to include what is being measured, when it will be measured, and what is the acceptance standard of this measurement.

6.3.3 Common tools and principles used to make an EC successful may include trend analysis, periodic checks, surprise audits, and sampling. Table 1 below provides example EC Action Plans.

Table 1

EC Source Situation / CAPA	Possible EC Plan
Laboratory OOS created CAPA of method change.	Evaluate next Y tests, or testing for next X months to see if the problem occurs again.
An SOP is not followed. CAPA revised the SOP to make it easier to understand and retraining completed.	Evaluate the use of the SOP for the next X months to see if the problem occurs again.
Finished product bottles failed leak test due to capper problem. Instrument serviced and repaired.	Evaluate leak test results of bottles passed through serviced capper for Y months to confirm repairs.

6.4 EC Closure Summary on QS-113-F2 Effectiveness Check (EC) Closure

6.4.1 The Closure Summary on form QS-113-F2 Effectiveness Check (EC) Closure is a description of how and when the actions described in the EC Plan were completed and verify whether the corrective or preventative action was implemented, documented, and had accomplished the intended purpose.

6.5 Effectiveness Check Assignment / Closure

6.5.1 Initiate/assign an effectiveness check by submitting form QS-113-F1 Effectiveness Check (EC) Assignment to DC.

6.5.2 Close an effectiveness check by submitting form QS-113-F2 Effectiveness Check (EC) Closure to DC.

6.6 Additional Requirements from QS-112 Core Quality Systems and Quality Events

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

6.6.2 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. "effectiveness check" here).

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

6.6.3.1 Assignment of unique event numbers (i.e. Effectiveness Check numbers)

6.6.3.2 Logging of events with Document Control

6.6.3.3 Assignment of event due dates

6.6.3.4 Event due date extensions

6.6.3.5 Event cancellation

6.6.3.6 Event Revision / Amendment

6.6.3.7 Monitoring of open events

6.6.3.8 Record management and retention instructions

6.7 Documentation Maintenance

6.7.1 All completed risk assessment forms will be maintained as outlined in SOP C-501 Document Control and SOP C-502 Record Storage, Retention, and Destruction.

6.7.2 When applicable, completed risk assessment forms will be filed with the related subject source document (i.e. deviation, OOS, complaint).

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	12/30/19	New procedure.	N/A	K. Burris
1	09/19/23	Scheduled review: updated document format. Added document maintenance requirements and references.	CC-23-0471	K. Burris

ION Nutritional Labs	Effectiveness Check (EC) Assignment		
	Form: QS-113-F1	CCR No. CC-23-0472	Revision: 1

EVENT INFORMATION

Effectiveness Check Number	
Effectiveness Check Title / Description	
EC Source / Reference (i.e. CAPA #, DEV #, INV#, Etc.)	

DATE INFORMATION

Open Date | | Due Date | |

EFFECTIVENESS CHECK – OWNER (I.E. ASSIGNED TO)

EFFECTIVENESS CHECK PLAN / COMMENTS

☐ N/A	☐

Approval Signatures

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

ION Nutritional Labs	Effectiveness Check (EC) Closure		
	Form: QS-113-F2	CCR No. CC-23-0472	Revision: 1

EVENT INFORMATION

Effectiveness Check Number		Revision #	
Effectiveness Check Title / Description			

DATE INFORMATION

Closed Date	

CLOSURE SUMMARY

Include as applicable: Evidence and/or statement of closure, cross references to supporting documentation, general conclusions / outcome, etc.

EC FINAL STATUS

☐ Found as EFFECTIVE	No further Action Required
☐ Found as NOT EFFECTIVE	Issue additional events here (i.e. New CAPA, EC, etc.)
☐ Found as INCOMPLETE	Issue additional events here (i.e. New CAPA, EC, etc.)

Approval Signatures

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