ION LABS QUALITY FIRST	Standard Operating Procedure Material Review Board	SOP Number C-202	Revision 5
		Effective Date 11/13/19	Page Page 1 of 3
Written by/ Date KBurris 10/07/19	Reviewed by/ Date 10/07/19	Approved by/ Date 10-24-19	
Title: Quality Systems Manager	Title: CEO	Title: VP of Quality & Regulatory Affairs	

1.0 Purpose

The purpose of this procedure is to define the process for conducting a Material Review Board meeting.

2.0 Scope

This procedure applies to all members of the Material Review Board at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of the Vice President of Quality and Regulatory Affairs or designee to schedule an MRB meeting.

3.2 It is the responsibility of the MRB to determine the final disposition of materials, products, and equipment in a situation that has not been previously resolved during the deviation process. The MRB is also responsible for reviewing and approving deviations, reviewing and approving new products, discussing recall activities and audits/inspections, and for making plans to improve facility compliance.

4.0 Definitions

4.1 **MRB** – Material review Board; a group consisting of company leadership (with the responsibility of discussing and deciding the appropriate outcome for any issues that may affect product quality, regulatory status, or GMP compliance. The MRB consists of the following employees:

4.1.1 CEO

4.1.2 Vice President of Quality and Regulatory Affairs

4.1.3 Production Director and/or Manager

4.1.4 R&D Manager

4.1.5 QC Laboratory Director and/or Analytical Development Manager

4.1.6 Quality Systems Manager

4.1.7 Quality Assurance Manager

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

4.3 **CAPA** – Corrective and Preventative Action

4.4 **QA** – Quality Assurance

5.0 References

5.1 C-201, SOP, Deviation and Investigation Procedure

5.2 C-403, SOP, Change Control Procedure

5.3 B-108, SOP, Reprocessing/Rework Procedure

5.4 E-801, SOP, Return of Materials and Destruction of Non-Hazardous Waste Materials

6.0 Procedure

6.1 An MRB meeting is necessary if the root cause for a deviation has not been identified, or if product quality is in question. Refer to SOP C-201 Deviation and Investigation Procedure.

6.2 The MRB will review for accuracy the deviation and any attached documentation.

6.3 The MRB will determine a disposition and/or other actions that are necessary. The disposition will be either approved or rejected.

6.3.1 Should the deviation pose a threat to employees and/or consumers, the deviated product, material, or equipment will be rejected.

6.3.2 Should the deviation undermine the integrity and quality of a product, material, or equipment, it will be rejected.

6.3.3 If a procedure or specification can be changed by change control to accommodate the deviation, it will be accepted. Refer to SOP C-403 Change Control Procedure.

6.3.4 If the MRB determines that a deviated product is capable of being reworked, it will be accepted. The product must be reworked following SOP B-108 Reprocessing/Rework Procedure.

6.3.4.1 Once a product has been reworked and undergone inspection that verifies conformance to the specifications, the product can be released.

6.3.5 If the MRB determines that a raw material must be rejected, the raw material will be returned to the supplier following SOP E-801 Return of Materials and Destruction of Non-Hazardous Waste Materials.

6.3.6 If deviated equipment can be made compliant, it will be accepted.

6.3.6.1 The activity must be completed no later than thirty days after the MRB determines the appropriate action, unless justification is provided.

6.4 The MRB is responsible for approving new products.

6.5 The members of the MRB will print, sign, and date all related forms.

Note: At least three members of the MRB must approve the MRB related documents in order for the documents to be considered effective.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	03/16/13	New	-	-
2	10/09/13	Updated procedure	13-870	V. Iltcheva
3	09/10/14	Removed reference to recalls. Redefined MRB.	14-0707	S. Millar
4	08/23/16	Biennial review: Redefined MRB.	16-0772	K. Burris
5	10/07/19	Scheduled review: added MRB member requirements.	19-0728	K. Burris