STANDARD OPERATING PROCEDURE

Title: Material Review Board

Effective Date: _____

Approvals (Signature and Date):

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC

1. PURPOSE

1.1 To describe the responsibilities of the Material Review Board (MRB).

1.2 To identify the individuals who are on the Material Review Board.

1.3 To identify what issues are brought before the Material Review Board.

2. SCOPE

2.1 This procedure applies to all purchased and manufactured products.

3. RESPONSIBILITY

3.1 Material Review Board is responsible for:

3.1.1 Discussing the failure of materials and products to meet quality specifications and to determine the disposition of these materials.

3.1.2 Making recommendations for corrective action to prevent similar incidents.

3.2 Quality Assurance is responsible for:

3.2.1 Notifying members of the need for an MRB meeting, providing the agenda, and conducting the meeting.

3.2.2 Ensuring that all available data are collected and prepared for distribution and review at the MRB meeting.

3.2.3 Periodically following-up to confirm that all corrective action decisions are carried out in a timely manner.

3.3 Materials Control is responsible for movement of materials in and out of MRB inventory locations.

3.4 Manufacturing or Quality Control, as appropriate, is responsible for filing the individual MRB Request and Report Forms in the appropriate batch record or in-coming material record.

4. REFERENCES AND APPLICABLE DOCUMENTS

4.1 09-0004-SOP-1.0 Discrepancy Report Procedure

4.2 09-0011-SOP-1.0 Customer Complaint Procedure

4.3 09-0217-SOP-1.0 Quality Improvement Project Monitoring System

4.4 09-0014-SOP-1.0 Product Recall, Domestic Market

4.5 09-0141-SOP-1.0 Product Recall, European Market

4.6 Company Quality Manual for references to applicable regulatory documents.

5. MATERIALS AND EQUIPMENT

5.1 MRB Notebook

6. HEALTH AND SAFETY CONSIDERATIONS

6.1 None

7. DOCUMENTATION REQUIREMENTS

7.1 MRB Request and Report Form (Attachment A)

8. MATERIAL REVIEW BOARD PROCEDURE

8.1 Bringing Issues Before the Material Review Board:

8.1.1 Discrepancy Reports (DRs) in accordance with 09-0004-SOP-1.0, Discrepancy Reports

8.1.2 Customer Action Reports (CARs) in accordance with 09-0011-SOP-1.0, Customer Complaint Procedure.

8.1.3 All Product Recalls.

8.1.4 Other matters which may have an impact on product quality such as vendor status, proposed changes, etc.

8.2 Identifying Individuals Who Serve on the Material Review Board.

8.2.1 The board consists of individuals designated on the MRB Matrix (Attachment B).

8.3 Organizating and Preparating the Material Review Board Meeting.

8.3.1 All issues brought before the MRB will have a completed MRB Request and Report Form (Attachment A). Supportive documentation such as a Discrepancy Report or Customer Action Report is attached to the MRB Request and Report Form, as appropriate.

8.3.2 The MRB meets whenever necessary to review issues/materials.

8.3.3 Quality Assurance notifies members of the need for an MRB meeting and provides the agenda.

8.3.4 Quality Assurance is responsible for ensuring that all available data are collected and prepared for distribution at the meeting. Summary sheets are prepared, if necessary, to reference related DRs or CARs, corrective action plans, or Quality Improvement Projects (QIPs).

8.4 Conducting and Documenting the Outcomes of an MRB Meeting

8.4.1 Quality Assurance chairs the MRB meeting.

8.4.2 The Material Review Board reviews the events/data, determines product disposition, recommends further investigation, reviews recommendations, and determines corrective action, or identifies Quality Improvement Projects, as appropriate.

8.4.3 The findings and recommendations of the MRB are indicated on the MRB Request and Report Form.

8.4.4 Unanimous approval of the board members is required for the disposition of a material and/or actions to be taken. Unanimous approval is documented by obtaining signatures on the completed MRB Request and Report Form.

8.4.5 Approval from Regulatory Affairs is required for the acceptance of non-conforming product on deviation.