Nonconforming Material System
Procedure
1.0 PURPOSE AND SCOPE

1.1 Purpose

a. To define the system for identifying, segregating and controlling, and disposing of material, identified as nonconforming, at our Company.

b. To establish the procedures, methods, and personnel responsible for evaluating nonconforming material data used to identify adverse trends of nonconformance.

c. To meet the ISO 9001 Quality System Requirements.

1.2 Scope

1.2.1 The scope of this procedure is applicable to all Customer orders.

2.0 APPLICABLE DOCUMENTS

The following documents are applicable as to the extent specified here in:

Industrial/Commercial/Government Documents
ISO 9001:2008 Quality Management System Requirements

Internal Document(s)
ATS-QAP-1004 Quality Records
ATS-QAP-1006 Corrective Action(s) System
ATS-QAP-1008 Internal Audits
ATS-QAP-1009 Management Review
ATS-QAP-1011 Analysis of Data
ATS-PGP-3001 Receiving Inspection
ATS-QAP-1406 Shipping Inspection
ATS-SOP-2101 Warehouse & Distribution Services
ATS-SOP-3101 Value-Added Assembly, Test & Inspection Services
ATS-SOP-4101 Calibration Services
ATS-SOP-5101 Microbial Lab Test Services; Enumeration & Identification

Form(s)
FORM 1251 Reject (red tag)
FORM 1069 Defect Report - Materials
FORM ATS11-1070 Defect Report - Documentation
FORM 1071 Defect Report - Documentation Continuation
FORM ATS11-1105 Customer Deviation Request
3.0 RESPONSIBILITIES

3.1 General
3.1.1 Quality Assurance - is responsible for ensuring that the requirements of this procedure are implemented, maintained and enforced.

3.1.2 Other Functions – shall support this process as defined herein.

4.0 REQUIREMENTS

4.1 General
   a. This document addresses nonconforming material and does not attempt to explain or define the corrective action system of our Company. The corrective action system is defined in ATS-QAP-1006, Corrective Action(s) System.

   b. Personnel performing inspection or test activities are authorized to generate and attach Non-conforming Material Documentation to Non-conforming Material (NCM).

   c. Only functions performing inspection or test activities have the authority to clear and remove documents that are used to identify Non-conforming Material (NCM). See Appendix B - MRB Approval List.

   d. A Defect Report (DR) then is prepared to record the nonconformance and to document the Material Review disposition. The Review/Disposition Status is recognizable by looking at the Defect Report. When deemed necessary, a Reject (red tag) is attached to the non-conforming material to prevent unauthorized usage.

   e. Non-conforming Material, which cannot be readily dispositioned by designated MRB Preliminary Review (PR) personnel shall be moved to an area, designated solely for the retention of NCM. If the NCM cannot be moved to a controlled area, it will be so identified to preclude its use in production.

   f. The Customer deviation request form shall be used to obtain Customer approval to ship products that do not conform to Customer order requirements.
4.2 Specific Requirements

4.2.1 Non-Conforming Material Identification, Documentation, and Segregation

4.2.1.1 When initially discovered, NCM shall be documented, identified and segregated in accordance with the following:

   a. **Defect Report - Documentation** – The Products are documentation packages reviewed and approved prior to filing and delivery to the customer. Our Production Operations and Quality Assurance Departments monitor and measure the characteristics of the product to verify that production requirements have been met. The standard Monitoring and Measurement processes used are as follows:

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATS-SOP-3101</td>
<td>Value-Added Assembly, Test &amp; Inspection Services</td>
</tr>
<tr>
<td>ATS-SOP-4101</td>
<td>Calibration Services</td>
</tr>
<tr>
<td>ATS-SOP-5101</td>
<td>Microbial Lab Test Services; Enumeration &amp; Identification</td>
</tr>
</tbody>
</table>

   These processes are carried out at appropriate stages of the product realization process in accordance with the planned arrangements. The initiators of this DR are the operators performing documentation Final Inspection activities.

   b. **Defect Report - Material** - The initiators of this DR are Production Operations, Receiving, In-Process, Final and Shipping Inspection personnel. The DR is used for the documentation of all fabrication/assembly, inspection and test related nonconformances (NCs). A Reject (red tag) may be attached to the material or the material container for material identification. If the material cannot be dispositioned "on the spot" by PR it shall be moved to the designated PR hold area to await disposition. The DR and/or Reject (red tag) form shall remain with the NCM until cleared by Inspection. See Appendix A - DR Form Completion Instructions. The standard Monitoring and Measurement processes used are as follows:

<table>
<thead>
<tr>
<th>Document Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>ATA-PGP-3001</td>
<td>Receiving Inspection</td>
</tr>
<tr>
<td>ATS-QAP-1406</td>
<td>Shipping Inspection</td>
</tr>
<tr>
<td>ATS-SOP-2101</td>
<td>Warehouse &amp; Distribution Services</td>
</tr>
</tbody>
</table>

4.2.1.2 Quality Assurance/Production Operations ensures timely reporting to Customers of non-conformances that may affect product already delivered. This typical cites the item's part number and description, Customer order number, quantity impacted, and description of nonconformance and recommend action. Typically, timely means within ten days of discovery of the nonconformance.
4.2.2 **Non-Conforming Material Hold Areas**

4.2.2.1 Quality Assurance/Production Operations shall clearly identify area(s) used for the retention of nonconforming material awaiting disposition. DR’s, that have a disposition recorded by InspectionQuality Assurance, are returned to the responsible department for resolution with the DR and are not retained in the designed nonconforming material area.

4.2.3 **Non-Conforming Material Records**

4.2.3.1 The Quality Assurance Department in accordance with ATS-QAP-1004, Quality Records, retains Nonconforming material records. Records of dispositions, assignable causes, corrective actions and effectiveness of corrective actions are stored physically and/or electronically. The records are organized to permit the summarization of the nonconforming material data. Summarization of the number of recurrences, quantity of nonconforming items, corrective action status, dispositions and causes of NC's are distributed as required by Quality Assurance to the Quality Council as required. The reports are used for trend analysis, to initiate Corrective Actions (CAs) and/or to verify the effectiveness of Corrective Action.

4.2.3.3 Once the DR is completed, the Inspector/Quality Assurance person closing the DR shall make a copy of the DR and place the DR Copy in a central “Defect Report Logbook” provided by QA at each facility location. The DR’s in this logbook are used by Quality Assurance to perform Analysis of Data as required by ATS-QAP-1011, Analysis of Data. The original DR is filed with the job documentation.

4.2.4 **Non-Conforming Material Documentation Requirements**

4.2.4.1 When used, the following information shall be recorded on the Defect Report (DR).

a. Initiator of the document
b. Date of initiation
c. The form assigned number
d. Specific identification of the item
e. Number of occurrences
f. Where in the Manufacturing process N/C was discovered
g. Detailed description of the N/C
h. Disposition of the N/C item
i. Identification of personnel responsible for the disposition of the NCM.

4.2.4.2 Additional documentation requirements are under the PR/MRB section of this procedure. Corrective Action documentation is addressed in ATS-QAP-1006, Corrective Action(s) System.
4.2.5 Preliminary Review (PR)
4.2.5.1 PR personnel are normally comprised of Quality Assurance or Receiving and Final Inspection personnel. This type of PR is responsible for the disposition of all manufacturing nonconformance.

4.2.5.2 Preliminary Review Dispositions
a. PR personnel are authorized to make all of the following dispositions.
   1. Scrap (Over $50 in value require Production Operations management approval)
   2. Rework
   3. Approved Standard Repair (Once approved by Customer in writing)
   4. Return to Vendor (RTV)
   5. No Defect

4.2.6 Material Review Board (MRB)
4.2.6.1 Material Review Board (MRB) members shall be selected on the basis of their technical competence. They shall know the requirements set forth in ISO 9001, the customer order or other documents that provide for the establishment of an MRB. When required by contract, a resume of the nominated MRB member shall be forwarded to the Customer for approval. Quality Assurance and the Customer shall approve all MRB members when required. See Appendix B - PR/MRB Member Approvals.

a. The Customer Representative is not a member of the MRB but retains the right to observe and disapprove any or all MRB functions.

4.2.6.2 MRB Dispositions
The MRB has authority to make all dispositions indicated in the Preliminary Review process. In addition, the MRB can recommend dispositions of:

1. Use As Is (*1)
2. Standard Repair (*1)
3. Repair (*1)

Note:
(*1) All Use As Is, Repair or Standard Repair dispositions that violate Customer order requirements shall be submitted for Customer approval.

4.2.7 Process Controls
a. Special process controls are addressed by process procedures generated by Manufacturing Engineering and approved by Quality Assurance. The requirements
for monitoring the process and the criteria for determining nonconformance are clearly described.

b. The business processes are continually monitored by Quality Assurance and CA is initiated based on adverse trends or individual causes of NC(s) per ATS-QAP-1006, Corrective Action(s) System.

4.2.8 **Quality Council**

Establishment - The Quality Council is established and performs the duties as defined in ATS-QAP-1009, Management Review.

5.0 **NOTES, DEFINITIONS, ACRONYMS**

5.1 Notes

5.1.1 Dispositions which are beyond the scope of our Company Material Review Authority (MRA) shall be handled in accordance with customer requirements. During Quality Planning, Quality Assurance is responsible for identifying the MRA restrictions for programs under their cognizance.

5.2 Acronyms

CA(s) - Corrective Action(s)
DR - Defect Report
MRA - Material Review Authority
MRB - Material Review Board
PR - Preliminary Review
NC(s) - Nonconformance(s)
NCM - Nonconforming Material
PR - Preliminary Review
QA - Quality Assurance

6.0 **CUSTOMER/GOVERNMENT RIGHTS**

6.1 General

6.1.1 As required by contract, the Customer Representative(s) will have the right to:

a. Review and approve this procedure and any other procedure developed to implement this procedure prior to use.

b. Concur with selection of MRB members and personnel appointed PR authority at time of selection or any time thereafter.

c. Observe all MRB and PR activities and associated records and data.
Appendix A.1 – DR - Documentation Form Completion Instructions

When a separate Defect Report – Documentation form (FORM 1071) is used, the following instructions shall be used to complete the form:

1) **Check Inspection Type** - Check one of the pre-defined Inspection Types (i.e. Final Inspection, etc.) for the work activity this being performed.

2) **DR No.** – An assigned number assigned by the Inspector. See the top of the form for instructions. Example: DRC-10-01-03-01 or DC-10-01-03-01

   Inspector’s initials – Month – Day – Year – Sequential number

   The last two digits represent a sequential number starting at 01 representing the number of Defect Reports written by the same inspector on the same day.

3) **Contract Worker File Name** – This is the name assigned to the record being reviewed.

4) **Prepared By** - Record Inspection Operator’s Name (First and Last Names) or Stamp Number in this block.

5) **Date** - Record the date when the Item was inspected in this block.

6) **Item No.** - Record an Item Number for each non-conformance recorded in the Non-conformance Description section starting with 1 (i.e. 1, 2, 3, 4, 5, etc.).

7) **Qty Defects** - Record the Quantity of rejects for the defect code in block 15 below. There maybe more than one defect per rejected item.

8) **Defect Code** - Record a Defect Code that matches as close as possible to the Non-conformance Description.

   1 – Missing the Required Document
   2 – Document Information is incomplete
   3 – Information is not Legible/Clear
   4 – Required Signature/Date information is missing
   5 – Candidate Failed Required Drug or Background Check
   6 - Other

9) **Non-conformance Description** - Record the nature of the non-conformance.
Appendix A.1 – DR - Documentation Form Completion Instructions

(continued)

10) **Dispos. Code** (**): Using the MRB Disposition Codes at the bottom of the DR form, select and record the appropriate MRB Disposition Code in this block.

MRB Disposition Codes (**):

1 – Rework
2 – Use As Is
3 – No Defect

11) **Fixed By/Date** - When a Production Operations person performs a Rework activity, the Production Operations person shall initial/stamp and date this block. No Operator entry is required in this block for the following MRB Dispositions: Scrap, Use As Is or No Defect

12) **Inspected By/Date** - When an Inspector performs re-inspection as necessary to confirm that the non-conformance has been corrected or dispositioned properly for closure, the Inspector shall initial/stamp and date this block.

13) **PR/MRB Approvals** - See Appendix B - MRB Approval Signatures in this document for proper signatures.

14) **DR Close Out** - When each individual nonconformance line item on the Defect Report are closed, the Inspection person shall initial/stamp and date this block to indicate closure of the non-conformance’s.
Appendix A.2 – DR; Material Form Completion Instructions

When a separate Defect Report form (FORM 1069) is used, the following instructions shall be used to complete the form:

15) **Defect Report Type** - Check one of the pre-defined Defect Report Types for the work activity this being performed.

16) **DR No.** – An assigned number using the date (100900) followed by a dash sequential number (-01), or stamped with a pre-assigned sequential number to prevent duplicate numbers.

17) **Drawing Part No.** - Record the Part Number for the Item that is being worked on in this block. If no part number, leave blank.

18) **Drawing Revision** - When a part number is assigned, record the drawing part number revision. If no part number or revision, leave blank.

19) **Prepared By** - Record Inspection or Test Operator’s Name or Stamp Number in this block.

20) **Item Description** - Record the Part Description of the Item being worked on in this block (see the Items drawing for the proper name as required).

21) **Date** - Record the date when the Item was inspected or tested in this block.

22) **Process Code No.** - Record the Process Code for the Item being worked on in this block.

23) **Supplier PO No.** – Record internal Purchase Order number in this block. If not applicable, leave the block empty.

24) **Supplier Packing Slip No.** – Record the Supplier Packing Slip No. in this block. If not applicable, leave the block empty.

25) **Supplier RMA No.** – Record the Supplier RMA Number in this block. If not applicable, leave the block empty.

26) **Supplier Name** – Record the Supplier Name in this block. If not applicable, leave the block empty.
Appendix A - DR Form Completion Instructions
(continued)

27) **W/O No.** - Record the Work Order number in this block. If not applicable, leave the block empty.

28) **Lot No.** - Record the Lot number in this block. If not applicable, leave the block empty.

29) **Customer RMA No.** – Record the Customer RMA number in this block. If not applicable, leave the block empty.

30) **Customer Name** – Record the Customer name in this block. If not applicable, leave the block empty.

31) **Traceability Date Code/Serial No.** - When the item received has Date Code(s), Serial Number(s), or special Lot Identification number(s), record this information in this block for traceability purposes. When not provided, leave this block blank.

32) **Qty Rec’d** – Record the quantity received in this block.

33) **Qty Accepted** – Record the quantity accepted in this block. Example: If you inspected 7 items, and only 2 were accepted, then record 2 in this block.

34) **Qty Rej’d** - Record the quantity rejected in this block. Example: If you inspected 10 Items, and 3 were rejected, then record 3 in this block.

35) **Item No.** - Record an Item Number for each non-conformance recorded in the Non-conformance Description section starting with 1 (i.e. 1, 2, 3, 4, 5, etc.).

36) **Qty Defects** - Record the Quantity of rejects for the defect code in block 15 below. There maybe more than one defect per rejected item. **Do not record S/N in this block.**

37) **Defect Code** - Record a Defect Code that matches as close as possible to the Non-conformance Description.

38) **Non-conformance Description** - Record defect location (Top-front side has scratch near hole A1) description, item serial number or other information as necessary that will further define the nature of the non-conformance.
Appendix A - DR Form Completion Instructions  
(continued)

39) **Dispos. Code (*)** - Using the MRB Disposition Codes at the bottom of the DR form, select and record the appropriate MRB Disposition Code in this block.

40) **Fixed By/Date** - When an Operator (Assembly, Test or Inspector) performs a Rework or Repair activity, the Operator shall initial/stamp and date this block. No Operator entry is required in this block for the following MRB Dispositions: Scrap, Use As Is, No Defect or Return to Vendor.

41) **Inspected By/Date** - When an Inspector performs re-inspection as necessary to confirm that the non-conformance has been corrected or dispositioned properly for closure, the Inspector shall initial/stamp and date this block.

42) **Is Re-Testing required? No Yes** - When a non-conformance is detected after successfully passing earlier test operations and a rework/repair must be performed (i.e. welding, rolling, heat treatment, placing new chemicals in lot, etc.), it may be necessary to re-perform some portions of or all the test activities accomplished earlier. Test and/or Inspection are responsible for determining if retest is or is not required, and defining the type of retest required when necessary.

43) **PR/MRB Approvals** - See Appendix B - MRB Approval Signatures in this document for proper signatures.

44) **DR Close Out** - When the DR from blocks are properly completed, the Test/Inspector/QA person shall initial/stamp and date this block to indicate closure of the non-conformance’s.
Appendix B - PR/MRB Member Approvals

The role of Preliminary Review and Material Review Board members is a very critical function at our Company. Therefore membership and participation is through approval only. The following functions/personnel are granted PR/MRB approval:

**Defect Report - Documentation**

1 - Preliminary Review (PR) - Material

- a) Quality Assurance or Inspector (block) Final Inspector or Quality Assurance

2 - Material Review Board (MRB) - Material

- a) Production Operations Management (block) Production Operations Mgmt. or President
- b) Quality Assurance or Inspector (block) Final Inspector or Quality Assurance
- c) Customer As Specified by the Customer

**Defect Report - Material**

1 - Preliminary Review (PR) - Material

- a) Quality Assurance or Inspector (Block) Receiving or Final Inspector, or Quality Assurance

2 - Material Review Board (MRB) - Material

- a) Engineer (Block) Production Operations Mgmt. or President
- b) Quality Assurance or Inspector (Block) Receiving or Final Inspector, or Quality Assurance
- c) Customer (Block) As Specified by the Customer