GENERAL DYNAMICS
Ordnance and Tactical Systems

Corrective Action Response Guide

GUIDELINES FOR PERFORMING THE 8D PROCESS

1. Figure 1 illustrates the 8D process flow. The guidelines in this document may be scaled appropriately to the severity of the issue.

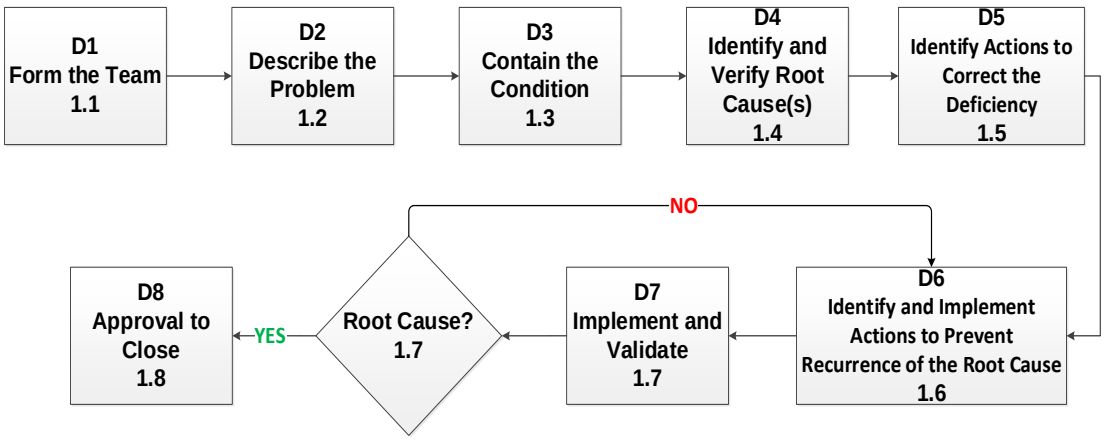

FIGURE 1

1.1 **Form the Team** – The Team Leader determines the personnel needed on the team including appropriate cross functional team members (e.g. Engineering, Manufacturing/Production, Program Management, etc.). Consider including a Quality Engineer on the team to help navigate through the root cause corrective action process. Consider including a Manufacturing Engineer on the team when the problem involves a manufacturing process, preferably the Subject Matter Expert (SME).

The Team Leader should use and update the 8D Report throughout the project to document the team's progress.

1.2 **Describe the Problem** – During this phase, if the deficiency has not already been defined in a corrective action request, the team describes the condition as briefly and completely as possible (for example, a 'Should Be - Is' approach is typically effective, along with when and where the deficiency occurred, its impact, etc). While defining the condition, fact-finding and data analysis activities should be applied to facilitate proper definition.

It is recommended that a process flow diagram or process flow map be included at this step of the process. This will help the team identify the what, where, when and impact.

1.3 **Contain the Condition** – During this phase, the team determines the scope of product affected by condition and institutes action to prevent the affected material from flowing "downstream." They define and implement those intermediate actions that will protect the customer (internal and/or external) from the condition. These actions are intended to be temporary until corrective and preventive action is implemented and verified.

Note: Containment actions may be required internally and/or at a supplier. Additionally, any previously delivered product that is determined to contain the deficiency must be disclosed in accordance with contract requirements.

Once containment actions are implemented, the team documents the actions taken on the 8D Report.

1.4 **Identify and Verify Root Cause(s)** – During this phase, the team identifies and verifies the root cause(s) of the condition. When identifying the root cause(s) the RCCA team should utilize the appropriate GD-OTS 5-Why worksheet while also considering other applicable problem-solving tools (e.g., fishbone diagram, fault tree, etc.) in order to determine the lowest level root cause(s). During this step, a subject matter expert (SME) may be added to the team if one is not already assigned. The SME will provide additional process knowledge. In the event human error was deemed to be a root cause, use the Human Factors Guide embedded here to more clearly identify the human factors root cause(s) and address preventive measures.

Human Factors Guide.docx

Once the root cause(s) is satisfactorily identified the team documents the results in step 4 of the 8D form.

1.5 **Identify Actions to Correct the Deficiency** – During this phase, the team determines corrective action for the root cause(s) and verifies that it eliminates the condition. Before implementing any corrective actions, the team should provide objective evidence that the selected corrective actions will resolve the condition and will not cause undesirable side effects. Additionally, the team should define other actions, if necessary, based on potential severity of the condition. Potential corrective actions include screening the suspect population and removing items that have the deficiency or returning the parts to a conforming condition using an approved rework process.

Caution: All rework process must have objective evidence that the process was approved during baseline qualification or a subsequent validation activity (e.g. FAT/TFAT, FPI, etc.)

1.6 **Identify and Implement Actions to Prevent Recurrence of the Root Cause** – During this phase, the team implements the preventive actions necessary to eliminate the root cause of the deficiency. Preventive actions may include actions such as error-proofing (i.e. poka-yoke), modifying work instruction, improving training programs, reviewing work flow, improving process monitoring, equipment upgrades, etc.

Caution: Ensure all preventive actions are properly validated and approved, as required per applicable contract 'no-change' requirements, prior to implementation.

1.7 **Validation**– During this phase, the team verifies that the preventive action does what it is suppose to do.
If the selected preventive action does not satisfactorily resolve the condition after implementation, the team must return to step "1.6 Identify and Implement Actions to Prevent Recurrence of the Root Cause" and perform additional analysis until a verified corrective action that generates sustained, measurable results is implemented.

During this step similar systems (other items provided to GD-OTS) with the potential for the same deficiency are identified and addressed.

1.8 **Approval to Close CA** – At this step, the completed 8D Report and associated documents should be sent to the issuer of the corrective action for final review and approval. When the issuer of the corrective action accepts the response, the corrective action response can be closed.

Note: Be sure to congratulate the 8D team once the corrective action response is successfully closed!

8D Sample

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Supplier 8D Corrective Action Report

To: Fred Smith		**Date: 03/05/2021**
Supplier: A1 Widgets		**Site Code: 8765**
Part/Product #: 123456789		**PO#: 654321**
GD-OTS SCAR #: SC00000999	**GD-OTS Quality Engineer (Originator):** John Doe	**Supplier CAR # (if applicable):N/A**
Encrypted Response Due Date: 03/05/2020	**Nonconformance (NC) #: N/A**	**Comments:** None

1. Form the Team - Establish a small group of people with the process/product knowledge, allocated time, authority and skill in the required technical disciplines to solve the problem and implement corrective actions.

Members (as applicable): Fred Smith, Brian Jones, Kelly Anderson, Jake Templeton

2. Problem Statement:

Shall Be (contractual requirement) : First Article Inspection equipment shall be calibrated prior to use.	**Is (deficiency):** First Article Inspection equipment (micrometer) calibration was past due at time of use.

3. Containment Action(s) – Action taken to identify, bound and segregate the population of parts, products, processes, or services potentially containing the identified defect. Advise how suspect product was contained upon identification of problem.	**Implementation Date:**
First Article Inspection was suspended until deficiency resolution. **It is mandatory to check one of the follow boxes:** ☐ This defect does not involve additional GD-OTS product ☐ This defect is present on additional GD-OTS product. All GD-OTS deliveries have been placed on hold pending disposition of affected product	03/05/2021

4. Root Cause(s) - Provide fundamental reason (s) for an event which, if corrected, would prevent recurrence. Attach "5 Why" analysis and other additional CAPA analysis documents as appropriate. If the cause is identified as operator error, human factors must be considered during the investigation. If the cause is identified as operator error, human factors must be considered during the investigation. See QS-GD-3.0.2.

The micrometer serial number did not appear on the monthly calibration report.
The micrometer due date was not entered into Gage-Master for it to appear on the monthly calibration report. Therefore it was not tracking.

Human factor contributor: At time of data entry, a fire alarm sounded. Clerk had to leave work area for one hour. Calibration clerk got distracted during data entry and failed to enter serial number into Gage-Master upon her return. Therefore software did not track due date.

5. Corrective Action(s) - Action(s) taken to correct the noted nonconformity or deficiency.	**Implementation Date:**
Micrometer taken out of service and calibrated.	3/9/2021

6. Preventive Action(s) - Action(s) taken to eliminate the cause of a potential nonconformity or deficiency in order to prevent occurrence or minimize the impact should it occur.	**Implementation Date:**
1. Update all equipment master records with calibration intervals.	03/10/2021
2. Verify all equipment on production floor is calibrated.	03/11/2021
3. Update Gage-Master software to require calibration interval entry when creating the Master Record	03/12/2021
4. Safety Bulletin to be published. Distraction Awareness.	04/01/2021

7. Validation – Implement and validate to ensure that preventive action does "what it is supposed to do". Detect any undesirable side effects. Address Similar Systems – List similar systems with the potential for the same defect. Provide objective evidence of validation.	**Implementation Date:**
1. Audit equipment master records to ensure all equipment is being tracked.	03/17/2021
2. Audit production floor equipment for calibration compliance	03/17/2021
3. Verify Gage-Master software requires the calibration interval entry at time of equipment master record creation.	03/18/2021
4. Verify Safety manager published a Human Factors article on how to avoid or deal with distractions at workplace.	04/02/2021

8. GD-OTS acceptance of Supplier response and approval to close SCAR. - Send encrypted response to GD-OTS Quality Engineer (Originator).	**Close Date:**
John Doe	04/19/2021

5-Why Sample

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5-WHY ANALYSIS WORK SHEET

CONTAINS GD-OTS PROPRIETARY INFORMATION

CAR / SCAR # SC00000999

Part # 123456789

Part Description: Widget

Description of Incident: First Article Inspection equipment (micrometer) calibration was past due at time of use.

Refer to QS-GD-3.0.2 Corrective Action Response Guide for additional instructions.

WHY 1:

Gage lab did not calibrate the micrometer prior to the due date.

WHY 2: ↓

Micrometer did not show up on the gage recall list.

WHY 3: ↓

Micrometer serial number was not being tracked by Gage-Master.

WHY 4: ↓

Technician did not enter serial number due date into Gage-Master for tracking.

WHY 5: ↓

Technician was distracted by fire alarm during data entry. Missed a data entry process step upon return.

Root Cause: The fundamental reason for an event, which if corrected, would prevent recurrence. Enter Root Cause in Section 4 on applicable 8D Corrective Action Report template (QS-TP-3.0.1 for suppliers, QS-TP-3.0.3 for GD-OTS internal). Review the Human Factors Analysis Worksheet on page 2. If a Human Factor was identified as part of the root cause that human factor shall be addressed on the applicable 8D Report.

Technician was distracted by fire alarm during data entry. Missed a data entry process step upon return. Calibration 'due date' was not entered into Gage-Master.

Note: Continue on separate page if 5-Whys are not enough to determine root cause.

Prepared By: Fred Smith **Date:** 03/09/2021

QS-TP-3.0.2 Date: 09/30/2021 Page: 2 of 2

5-WHY ANALYSIS WORK SHEET

CONTAINS GD-OTS PROPRIETARY INFORMATION

Human Factors Analysis Worksheet: Check the item number(s) below that was a contributing factor to the root cause. Refer to QS-GD-3.0.2 Corrective Action Response Guide for more information on the Human Factors noted below.

Item #	Dirty Dozen Human Factor
☐ 1	Lack of Communication
☐ 2	Complacency
☐ 3	Lack of Knowledge
☒ **4**	**Distraction**
☐ 5	Lack of Teamwork
☐ 6	Fatigue
☐ 7	Lack of Resources
☐ 8	Pressure
☐ 9	Lack of Assertiveness
☐ 10	Stress
☐ 11	Lack of Awareness
☐ 12	Norms

Details of Human Factor issue(s): The technician was entering new 'due dates' for recently calibrated equipment into Gage-Master when fire alarm went off. Technician was distracted by alarm. Upon return to workstation, Technician simply missed a step during data entry. Technician did not fully populate next due date in Gage-Master.

Refer to the Dirty Dozen preventive strategies outlined in QS-GD-3.0.2 Corrective Action Response Guide. **Be sure to address the human factors circled above when completing the root causes and preventive actions in the applicable 8D Report.**