



Modern Industries Inc.

How to Complete a STAR (Action Request)

1. Definitions

1.1. Action Plan, Action Taken or Correction:

1.1.1. Actions taken to correct the non-conformance. Including but not limited to: Returned item(s), WIP, Inventory and other product that may contain the same non-conformance

1.2. Root Cause Analysis, Cause or Root Cause:

1.2.1. A root cause is an initiating cause of a chain of events which leads to a non-conformance. Root cause is used to describe the depth in the chain where an intervention will change the performance and prevent the non-conformance. Note: There can be more than one cause for a non-conformance.

1.3. Mistake proofing or Corrective Actions:

1.3.1. Corrective Action taken to eliminate the cause of a detected nonconformity and prevent a reoccurrence.

1.4. MP Level

1.4.1. Self-evaluation of the Mistake-Proof or Corrective Action. Select a mistake-proof level from the following choices:

1.4.2. Levels

1.4.2.1. I (Best) Action taken eliminates the opportunity for error. The root cause is totally eliminated.

1.4.2.2. II (Better) Action taken does not eliminate opportunity for error, but detects the problem as it begins to happen.

1.4.2.3. III (Good) Action taken does not eliminate opportunity for error, but will detect the problem after it happens again.

1.4.2.4. NA (None) Explain rationale as to why mistake-proofing is not applicable in this case.

1.5. Objective Evidence

1.5.1. Items, documents, pictures, record etc. that proves the corrective actions are in place. Proof of corrective action implementation.

2. Instructions

2.1. Containment Form.



2.1.1. Complete and return the provided Word document form within 24hrs.

2.1.2. Complete all of the following sections:

- Answer questions 1 through 6.
- Enter a name, email address, phone number, fax number and date.
- Enter a comment addressing any “Yes” answers provided in questions 1 through 6.

2.2. STAR

2.2.1. Review the definition listed in paragraph 1 to determine the type of statement required prior to filling in each section.

2.2.2. Complete all of the following sections:

- Action Plan (Reference paragraph 1.1)
- Root Cause Analysis (Reference paragraph 1.2)
- Mistake Proofing (Reference paragraph 1.3)
- MP Score (Contains a list of levels that can be viewed by double clicking the gray box. Reference paragraph 1.4)
- Effectivity date for implementation of the plan
- Serial number Effectivity (As applicable)
- Plan Submitted by (Name and Title)
- Phone
- Date

2.2.3. Complete and return the provided Word document form.

2.2.4. Provide Objective Evidence supporting each of the corrective actions. Corrective actions without objective evidence will not be accepted.

2.2.5. Return the completed corrective action form (Word Document) and the objective evidence by the due date.

3. GUIDANCE FOR REVIEW OF CORRECTIVE ACTION RESPONSE

3.1. Prior to submitting a corrective action response, use this guide to test the completeness of a proposed response.

3.1.1. Root Cause Analysis

- a. Does the root cause address all of the specific non-conformances identified in the finding(s)?
- b. Ask “Why” five times.



- c. Does it make sense?

3.1.2. Root Causes generally fall into one of the following areas:

- Design
- Planning
- Procedures/Work Instructions
- Training System
- Tools/Equipment
- Work Environment
- Supervision

3.1.3. Unacceptable root cause includes:

- An excuse for the condition
- Blaming others (customer, auditor, operator error, etc...)
- Unaware of requirements
- A repeat statement of the condition found

3.1.4. Mistake Proofing /Corrective Actions Taken

- a. Does it match the root cause? Does it include a fix to the specific problem identified?
- b. Does it provide for control of the problem?
- c. Were all related areas addressed?
- d. Were personnel re-trained?
- e. Were procedures revised when appropriate?
- f. Has a verification plan been established to follow-up for implementation of corrective action?
- g. Has a completion date been established?
- h. Has responsibility been assigned?

3.1.5. Unacceptable Mistake Proofing /Corrective Actions includes:

- Corrective Actions to be implemented in the future.
- Corrective Actions not fully implemented.

3.1.6. Objective evidence must be submitted with the corrective action response!



REVISION LIST:

DATE	CHANGE DESCRIPTION
04/28/2007	Initial Release
05/05/2010	Revised paragraphs 1.1, 2.1.1, 2.3.1 and 2.4.1 to add clarity. Corrected numbering
6/17/2010	Added 1.4 and revised 1.5.; 11/23/2010 added section 2.5.
01/18/2011	Added Section "3. GUIDANCE FOR REVIEW OF CORRECTIVE ACTION RESPONSE" and reformatted.
06/01/2011	Added section 2.1, revision list and reformatted.