

**RECOMMENDED GUIDELINES FOR COMPLETING
CORRECTIVE ACTION REPORTS WHEN USING QAMFORM 3 FROM ASA QAM TEMPLATE**

Revision: 01-18-2016

The following is a guideline on how to complete the Corrective Action Form that has been provided with the QAM Template. The Corrective Action Report is a template and the organization can decide to utilize its own existing form or create one that best fits the needs of its organization.

OVERVIEW OF THE CORRECTIVE ACTION FORM

The Corrective Action Report (CAR) has three sections. Section C has multiple person involvement. Each section is to be completed in sequential order, and at the various stages of the completion process. Once completed, don't forget to Close CAR in the organizations monitoring system.

Objective evidence is information that is verifiable and shows that the statement being asserted is true. This is usually a record but can be other items as long as it proves the statement being asserted is true. For example, if in order to show a fix to a finding, Company "A" trained their staff on Counterfeit parts, then objective evidence is the training record and remember the training record can be a company created training record.

SECTION	COMPLETED BY	WHEN	COMMENTS
A & B	Person in charge of the corrective action process, delegate or persons performing self-evaluations.	<p>Required by ASA-100</p> <ol style="list-style-type: none"> 1) Identification of a nonconformity during an internal audit 2) Identification of a nonconformity during a third party audit <p>Remember: QMS system may have additional requirements beyond the ASA-100 minimum.</p>	This is usually the DOQ or similar position as defined by the organization. This person completes this section and determines the responsible person to assign the corrective action report to who can best close the issue. (Complete Blocks 1 through 11)
Section C	Responsible Person that has been chosen to receive the CAR and close the discrepancy.	<p>Upon receipt of Section A & B in CAR.</p> <p>Timeframe is determined by company corrective action procedures typically no more than 30 days.</p> <p>If CAR is initiated due to 3rd party audit results make sure to monitor the timeline provided by 3rd party as this may be different from company timeframe.</p>	<p>Documented by the Responsible Person assigned the CAR. (Complete Blocks 12 through 19.)</p> <p>The Responsible Person MUST take action to:</p> <ul style="list-style-type: none"> o Block 12: Correct the finding. This is the immediate action taken to address the issue. o Block 13: Contain the finding. This is the action taken to make sure the finding does not spread. Note not all findings require containment. o Block 14: Check to see if there are other similar discrepancies in other areas of the QMS that need to be addressed. o Block 15: Discover the real root cause(s) through an analysis of the problem. There are many methods for conducting a root cause analysis, for example 5-why's or Causal Factor analysis,

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			<p>etc. There is ample guidance on Root Cause analysis provided at ASA annual conference, online at sites such as www.bluetunadocs.com, just to name a few suggestions.</p> <ul style="list-style-type: none"> o Block 16: Define what actions were taken for the corrective action, long term correction (fix) to implement.
Section C	Person in charge of the corrective action process, delegate or persons performing self-evaluations.	Support and/oversight during CAR Process	<p>When the situation finds itself appropriate, the Person in charge of the corrective action process, delegate or persons performing self-evaluations and the responsible person assigned the CAR may agree on multiple stages for status reporting of the CAR for Section C (e.g., after correction, after planning the corrective action, after completion of the corrective action).</p> <p>The Person in charge of the corrective action process, delegate or persons performing self-evaluations and the responsible person must agree with the corrective action(s) and corrective action plans (if applicable) within a maximum of “Enter the number of days”. (typically no more than 30 days is the norm) from the date of the finding being identified.</p>
Section C	Person in charge of the corrective action process, delegate or persons performing self-evaluations.	After verification of implementation & effectiveness	<p>This is to be completed in a timeframe that verifies the correction has been fully implemented and effective (Complete Blocks 20 through 22).</p>