Initiation and Management of the CAR process

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Comprehensive corrective action process to resolve CARs:

- Written by SAAS against the CB, and

- Written by the CB against their client
CARs and the Related Corrective Action Process

CARs
What are they?

Two types - Minor and Major:
Minor Cars

Minor Nonconformity – a nonconformity that judgment and experience indicates is not likely to:

- Result in the failure of the management system, or
- Reduce its ability to assure controlled processes

It is likely to be a failure or oversight in some part of the CB’s management system which is not systemic in nature, or a single observed lapse in one aspect of the management system.
Major Nonconformity – is either

- The absence or total breakdown of a system to meet the applicable standard requirement. A number of minor nonconformities against one requirement which, when combined, can represent a total breakdown of the system and thus be considered a major nonconformity.

- A nonconformity that judgment and experience indicate is likely either to result in the failure of the management system or to materially reduce its ability to assure controlled processes and products.
CARs and the Related Corrective Action Process

CARs
Do they both require corrective action?

YES!

What is the difference in correction actions, if any?

Timing of implementation - Urgency!
CAR Preparation

All CARs should be written in three parts as follows:

1. A statement of nonconformity
2. The requirement or specific reference to the requirement.
3. The objective evidence observed supporting the statement of nonconformity.
   - Sample size assessed,
   - number of persons interviewed,
   - procedure numbers, and
   - references to records reviewed should be included, if applicable.

* Note that the CAR cannot indicate any suggested methods to implement corrective action.
CAR Preparation

- Each CAR must be understandable by the client and CB/SAAS staff.
- Each CAR must use the words of the requirement in the normative document whenever possible.
- When the client’s (CB) procedural requirements are not met, their requirement shall also be identified or named.
- All nonconformities shall be recorded.
- Nonconformities may not be closed during the audit in which they were issued.
CARs and the Related Corrective Action Process

CAR Preparation

- When should CARs be written?
CARs and the Related Corrective Action Process

CAR Preparation: SAAS

- Document Review:

CARs are not raised at the document review stage.

Deficiencies in the submitted documentation to the appropriate accreditation requirements are documented by the SAAS auditor in a formal report.
CAR Preparation: SAAS

- Office audits:
  - CARs shall be explained to the auditee, when found, before proceeding to the next requirement or area.
  - The auditor shall inform the auditee of any potential nonconformity that has not yet been categorized as warranting a CAR.
CAR Preparation: SAAS

- **Witness audits:**
  - Any nonconformity to the planning process or related to audit procedures that are identified during the audit of the CB’s audit planning and preparation shall be reviewed with the CB auditor(s) at the time that they are found.
  
  - CARs may not be determined until well into the audit process, since the conduct of the CB’s auditor may require extended observation.
CAR Preparation: SAAS

- **Witness audits:**
  - A witness audit is an evaluation of the training and qualification processes of the CB.
  - CARs should be written against the lack of effective implementation of auditor training or assignment procedures of the CB and not against the individual auditor.
  - The audit should be value-added for the CB but should not be a training exercise for the particular CB auditor(s) participating in that audit.
CARs and the Related Corrective Action Process

CAR Preparation: SAAS

- Witness audits:

  When is a witness audit completed?

  - When all requirements of the audit plan have been completed,
  and
  - the audit report is completed and approved by the audit client (CB).
CAR Preparation: SAAS

- Witness audits:
  - CARs associated with the preparation and/or content of the CB’s audit report may be written after the on-site audit and after the SAAS lead auditor receives the audit report from the CB.
  - This must be covered in the closing meeting after the on-site audit.
CAR Preparation: SAAS

• Under no circumstance shall CARs be raised by a SAAS Auditor after the audit, if forgotten at the time of the audit.

• If a CAR was forgotten, it should be written and transmitted to SAAS in a separate note. SAAS shall, at its discretion, issue CARs directly to the CB under circumstances it deems necessary.
CARs: Issued by SAAS

- When the SAAS Lead Auditor prepares the final audit report, the CARs shall be attached to the audit report using CAR Form 415. This becomes a permanent record of the CAR, including the CB response to the CAR and the SAAS disposition of the CAR.

- Major CARs must be closed prior to recommendation of accreditation/reaccreditation.
CAR Preparation: SAAS

The SAAS Lead Auditor is responsible for all CARs written during an audit, including corrective action follow-up and CAR closure.
CAR Corrective action timing: SAAS and CB

The SAAS auditor and the CB representative shall agree on the timing for the CB’s response to SAAS for the CARs. In general, this will be as follows:

<table>
<thead>
<tr>
<th></th>
<th>Major CAR</th>
<th>Minor CAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define Plan</td>
<td>1 month</td>
<td>Define Plan</td>
</tr>
<tr>
<td>Close Out</td>
<td>3 months</td>
<td>Close Out</td>
</tr>
</tbody>
</table>
CARs: Issued by SAAS

Is the CB required to have a corrective action process?

Yes – 17021 section 10
Either: 10.2 – ISO 9001 8.5.2
Or
10.3.7
CARs: Issued by SAAS

• The CB shall enter the CAR into their corrective action process and resolve it within the time period determined when the CAR was written.

• Auditing the CAR closure also audits the CB’s corrective action process.
How can the CAR be closed?

By verifying the corrective action implemented by the client was effective in resolving the problem.
CAR Corrective Action Process

 Goals:

- Understand the four basic steps of effective corrective action
  - Containment action
  - Root cause determination
  - Determine and implement corrective action
  - Prove effectiveness of corrective action
Let’s look at each of the steps:

- Containment action
  - Where does the problem exist?
    - We know where the CB found it, can we assume that those are the only problem areas?
      - Of course not!
    - How do we find out where the problem exists?
      - Sample of sites
      - Internal audits
  - When in doubt, act on all sites
Root cause determination:

Root cause must be determined based on analysis and data, not opinions and beliefs.

- The symptoms must not be confused with the causes
- Analysis must be conducted using reliable techniques
- The full participation of the team is needed to get a wide variety of experience and points of view
Root cause determination:

- Goal is to work through the symptoms to get down to the root cause
- Generally, a root cause will involve a systemic problem
- Fixing the symptoms and ignoring the root causes will guarantee an increasing number of problems
- Root cause = when corrected problem will not recur
- **Left alone - problems will get worse**
CAR Corrective Action Process

- Determine the most effective corrective action
  - Must eliminate the root cause, not cover it up
  - Use appropriate techniques to select and develop corrective action proposals
  - Establish implementation plan with timing
  - Implement the action
Steps in the corrective action implementation process:

- Identify alternative solutions for the root cause elimination
- Select most appropriate solution based on meeting established criteria
  - Obtain management approval as required
- Establish implementation plan with timing and responsibilities defined
- Implement the corrective action
Corrective Action

- Develop and implement corrective action
- Corrective action team
- Operational constraints
- Resources
- Implemented corrective action
- Objectives
- Root cause
• Who should verify the effectiveness of corrective actions
  - Verification should be performed by an objective reviewer who has the necessary technical knowledge
    - Internal audit corrective action should be verified by the internal audit activity personnel
• Determine verification methods
  ▪ Evidence that the proposed action was actually implemented
  ▪ Evidence that the action eliminates and prevents recurrence of the nonconformance / noncompliance (eliminates the root cause)
  ▪ Understand what should be done to document corrective actions
CARs: Issued by SAAS

CAR Corrective action timing
Define Plan
From Form 415:
Action to be Taken By CB In Response to the CAR Raised
The following is to be completed by the CB and submitted to the SAAS Lead Auditor for evaluation

Root Cause:

Corrective Action Plan:
CARs and the Related Corrective Action Process

CARs: Issued by SAAS

CAR Corrective action
Close out
From Form 415:
Action Taken By CB In Response To CAR Raised
The following is to be completed by the CB and submitted to the SAAS Lead Auditor for evaluation

How corrective implemented:

Evidence of Effectiveness:
CARs and the Related Corrective Action Process

CARs: Issued by SAAS

CAR Corrective action
From Form 415:

SAAS Lead Auditor analysis and recommendation:

- Action plan acceptable, evidence received and verified, action deemed effective. No further follow-up required.
- Action plan acceptable, evidence of implementation received and not adequate to close CAR. Client requested to describe subsequent action taken and submit further evidence:
- Action plan acceptable, evidence of implementation needed, verify evidence at the following time:
- Action plan is unacceptable. Client is requested to propose additional action to address the nonconformity:

Signed by SAAS Lead Auditor: Date:
CARs: Issued by SAAS

The SAAS Director shall determine the action to be taken as a result of the CAR analysis. The status of all CARs shall be recorded on the SAAS Audit Tracking-Overview (310) and Audit Tracking-Details (310A).
CARs and the Related Corrective Action Process

CARs: Issued by SAAS

Who is responsible for the corrective action?

The CB
CARs and the Related Corrective Action Process

CARs: Issued by SAAS

Who is responsible for closing the CAR?

SAAS
CARs and the Related Corrective Action Process

CARs: Issued by SAAS

CARs

How can SAAS close the CAR?

By verifying the corrective action implemented by the CB was effective in resolving the problem