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LOCKHEED MARTIN

Corrective Action Webinar

Lesson 9 – Follow-up for Effectiveness

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Agenda

- **Overview of Previous Webinars**
- **Command Media**
- **Follow-up**
  - Verification vs. Validation
  - Obtaining Objective Evidence
  - Additional Considerations
- **Closing the Corrective Actions**
  - Document Results
  - Monitor and Measure
  - CAP Failures & Recurrences
- **Case Studies**
- **Summary**

Overview of Previous Webinars:

SQE CA Initiation:

- **Webinar 1: Command Media Expectations**
- **Webinar 2: Procedures & Expectations**
- **Webinar 3: CAR Levels & Criteria**
- **Webinar 4: CAR Writing**

Supplier CA Engagement:

- **Webinar 5: Containment**
- **Webinar 6: DCMA CARs**
- **Webinar 7: Root Cause Analysis**
- **Webinar 8: CAP Development**
- **Webinar 9: CAR Acceptance Criteria**

Webinar 10 → Corrective Action Follow-up

What is CA Follow-up??

- **Definition:**
  - A review conducted with sufficient detail to assess whether the corrective actions have been implemented, are effective, and will prevent recurrence of the original event.

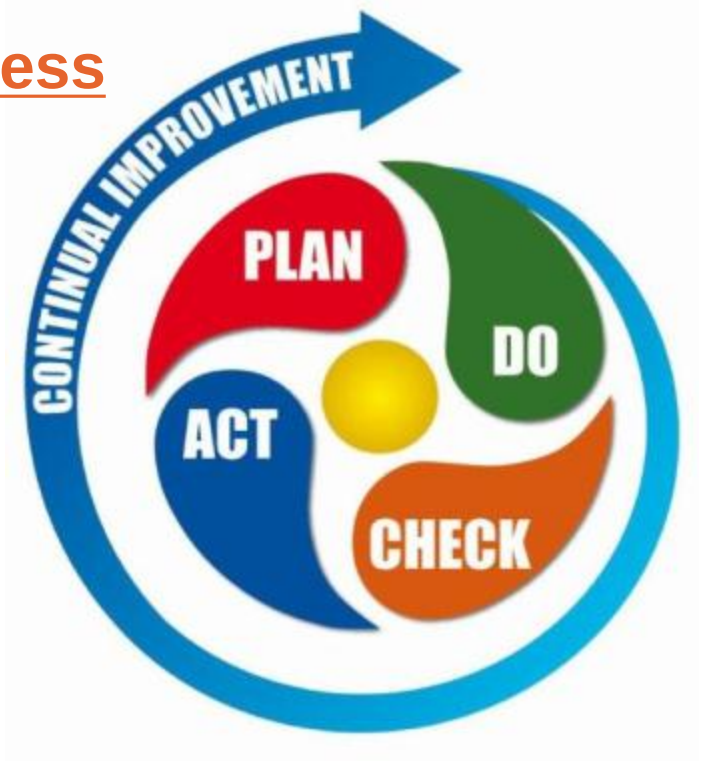
- **Key Word: EFFECTIVE**
  - Corrective action(s) achieve the desired outcome of eliminating the issue/finding and preventing recurrence.
  - Extent to which planned activities are realized and planned results achieved.

Focus = Gauging CA Effectiveness

COMMAND MEDIA

Plan-Do-Check-Act Cycle

- **AS9100 and ISO 9001 present a structured process**
  - Define the problem
  - Determine action to take
  - **Review actions for effectiveness**
  - **Make changes as needed**



Corrective Action is a continuous cycle

AS9100 Industry Requirements

8.5.2 Corrective Action

The organization shall **take action to eliminate the causes of nonconformities**…A documented procedure shall be established to define requirements for…

e) records of the results of action taken (see 4.2.4),

f) reviewing the effectiveness of the corrective action taken,

h) specific actions where timely and/or effective corrective actions are not achieved

AC-2018 & QX

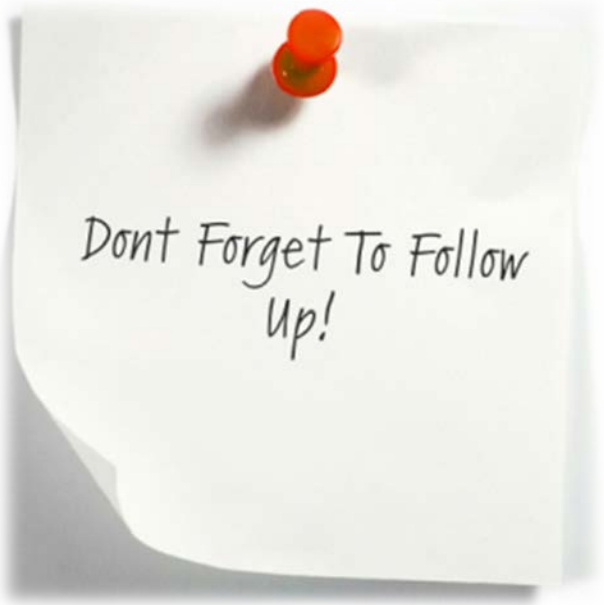
- **AC-2018 – Supplier Approval and Control**
  - Para 3.B.1.C. **CAR Responses** - SQM will:
    - ***Establish validation follow-up date within 30 days of C/A effectivity*** *(effectivity being the point that all corrective actions have been taken, validated and incorporated into the product)*
    - *Perform validation of C/A - if follow-up validation is successful/accepted update SQMS with validation, CAR results and other entries to close the CAR*
- **QX**
  - 1.5 *Records:* Seller shall:
    - *a. maintain complete* ***records of*** *the following: … corrective and preventive actions, and* ***effectiveness of corrective actions****…*
  - 2.2 *Corrective Action:* Seller shall:
    - *d. provide effective corrective and preventive action upon request*

Document CA Effectiveness

FOLLOW-UP

Steps for Follow-up

1. **Verification**
2. **Validation**
3. **Closure**
4. **Monitor & Measure**



Test the CA against the initial plan – adjust as required

Supplier CAPs

- **Suppliers:**
  - Implement corrective actions per the CAP schedule
  - Verify process reflects corrective actions in place
  - Notify SQE when CAP is complete
  - Validate effectiveness and maintain records

- **SQEs:**
  - Establish separate LM validation follow-up date within 30 days of C/A implementation
  - Perform verification and validation of Corrective Actions
  - Update LM Records of results (CAR / ICA / etc)

Suppliers should conduct follow-up prior to the SQE

Verification vs. Validation

- **Verification** – Corrective Action ***Implementation***
  - Confirmation with objective evidence:
    - *corrective action plan was implemented as planned*
    - *specified requirements have been fulfilled*
  - Step 1 of Follow-up

- **Validation** – Corrective Action ***Effectiveness***
  - Confirmation with objective evidence:
    - *Corrective action plan effectively eliminated the nonconformity and prevents it from recurring*
    - *Particular requirements for a specific intended use are fulfilled*
  - Step 2 of Follow-up

Objective Evidence of Implementation & Effectiveness

Poor Assumptions

- If a supplier says they did something, then they must have.
- All actions are effective unless stated otherwise.
- All CA is directly related to the problem causes, or they wouldn't have done it.
- A verbal statement is sufficient for objective evidence.
- Once CA is implemented, the issue can be closed.
- There is no reason to check other parts or similar processes.

Don't Assume!

Objective Evidence (OE)

- **Definition:** any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements or tests which can be verified.

- **Hard evidence / proof / factual**
  - Records, data, observation, measurement, test

- **Scale evidence to the problem severity**
  - No defined quantity – SQM recommends 3+
  - Random sampling vs. 100% inspection

Objective Evidence is vital to Follow-up

Objective Evidence (OE) *(continued)*

- **Communicate your needs**
  - Work with the supplier to set the ECD for follow-up
  - Tell the supplier what you want to see, when, and why

- **Follow-up delivery method matters!**
  - Inspect, witness, interview, physical record, electronic record, email attachment, etc.

Objective Evidence is best witnessed in person

Objective Evidence (OE) *(continued)*

- **Examples**
  - Physical Inspection
  - Records / Documents
  - Procedures / Policies
  - Planning / Routers
  - Test log / report
  - Non-conformance report
  - Witness statement
  - Observation / Photos
  - Quality metric / measurement
  - ETC….

Select OE appropriate to the CAP

Objective Evidence (OE) *(continued)*

- **Examples**
  - Late orders
    - *Review updated procedures, interview 3 employees, review training records and ensure they received the revised training, review 10 recent service records, …*
  - Overdue calibrations
    - *Review updated process, interview personnel, check calibration logs, randomly check 5 calibrated tools on the production floor,…*
  - Dimension oversized
    - *Review process/design changes, review training/certification log, interview production, inspect next 3-6 processed parts,…*

Trust but Verify

Additional Considerations

- **Do implemented corrective actions differ from the original plan?**
  - Find out why… the changes may be valid, but need to be documented appropriately.
  - Ensure CA eliminates the cause(s) & prevents recurrence
  - Look at the potential impact and consider the outcome.

- **Have ALL corrective actions had enough time to take effect?**
  - Additional follow-up may be necessary
  - Periodic checks will also help ensure CA continues to be effective. (PVR, Sampling, Process Walk, etc.)

CA Effectiveness requires diligence

Additional Considerations

- **Does the problem exist on other parts / assemblies / processes / areas?**
  - This should be included in the investigation and/or corrective action implementation.
  - This important question is frequently overlooked.

- **Is the fix a Band-aid?**
  - Need to ensure corrective actions will last long term.
  - Be wary of one-time discipline or training.
  - Challenge procedural changes – will they be followed?
  - Suggest use of mistake-proofing or process improvements

Effective CA is all-inclusive and long-term

Additional Considerations

- **Are employees aware of the changes?**
  - Procedural / Process changes
  - Updated / new required training
  - All-hands meetings, employee communications

- **Have the appropriate parties been notified?**
  - Partner/sister companies, other divisions / business units
  - SQM, SCM, TSM, Quality, Engineering, etc.
  - DCMA, FAA, NADCAP, GIDEP, etc.

- **Any other considerations??**

Communicate!

CA Closure

- **Document the follow-up actions**
  - Date conducted
  - Verification + Validation results
  - Objective Evidence witnessed

- **If Validation is Successful:**
  - Close CAR / ICA issue

- **If Validation is Unsuccessful:**
  - Reject / Revise corrective actions
    - **Perform further root cause analysis
  - Schedule new follow-up date

Monitor & Measure

- **Going forward, what will show sustainment??**
  - Trend Analysis
  - Sampling Plans
  - Acceptance Inspections
  - Spot Checks
  - Re-test the process

  - Internal Audits
  - Variation Management, CPK, SPC, PCD, PFMEA

**Routinely review closed CAPs

Measure → Analyze → Improve

Recurrences

- **AC-3031 definition:**
  - Repeat of an issue within 12 months after the date, item, unit, lot number or other commitment for which CA was validated and attributed to the same cause.

- **Required Actions:**
  - Reopen Corrective Action or Create new Corrective Action and note that the issue is a recurrence
    - *If LM CAR created for original issue, then open a new CAR and select Yes under "Is this a re-occurrence?"*
    - *Reference the previous CA identification number or CAR*
    - *Consider elevating as necessary*

CASE STUDIES

Squawk: *"Whining sound heard on engine shutdown."*
Corrective Action: *"Pilot removed from aircraft."*

Squawk: *"Aircraft handles funny."*
Corrective Action: ***"****Aircraft told to straighten up, 'fly right,' and be serious."*

Squawk: *"Evidence of hydraulic leak on right main landing gear."*
Corrective Action: *"Evidence removed."*

Squawk: *"Something loose in the cockpit."*
Corrective Action: *"Something tightened in the cockpit."*

Case Study #1 – Oversized Hole

- **Problem Description**
  - 0.380 max hole diameter checks 0.393.
- **Containment**
  - Check parts in WIP
- **Root Cause Analysis**
  - Operator error
- **Corrective Action**
  - Re-train operator
  - Add additional inspection step

Case Study #1 – Oversized Hole *(cont.)*

- **Problem Description**
  - 0.380 max hole diameter checks 0.393.
- **Containment (REVISED)**
  - Check parts in WIP, stores, previously delivered, and all similar processes.
- **Root Cause Analysis (REVISED)**
  - Direct Cause – manual lathe not capable due to poor maintenance
  - Root Cause – Process engineering selected manual machine to process job
  - Contributing Causes – Operator training, lack of planning, machine capability, lack of preventive maintenance
- **Corrective Action (REVISED)**
  - Train operator in use of chamfer gauge and preventive maintenance
  - Move process to NC machine capable of meeting tolerance requirements
  - Revise/improve preventive maintenance plan for all machines
  - Complete capability analysis for process requirements and machine capability.

Review the CAP prior to follow-up

Case Study #1 – Oversized Hole *(cont.)*

- **Corrective Action (REVISED)**
  - Train operator in use of chamfer gauge and preventive maintenance
  - Move process to NC machine capable of meeting tolerance requirements
  - Revise/improve preventive maintenance plan for all machines
  - Complete capability analysis for process requirements and machine capability.

- **Follow-up??**
  - How should the LM SQE conduct follow-up?
  - What evidence should be presented?
  - When should the SQE check for effectiveness?

Case Study #1 – Oversized Hole *(cont.)*

- **Corrective Action (REVISED)**
  - Train operator in use of chamfer gauge and preventive maintenance
  - Move process to NC machine capable of meeting tolerance requirements
  - Revise/improve preventive maintenance plan for all machines
  - Complete capability analysis for process requirements and machine capability.

- **Suggested Follow-up Actions**
  - Review training records and any relevant certs
  - Review NC machine capability analysis
    - *Review engineering changes / approvals*
    - *Review planning changes / approvals*
  - Review maintenance plans to requirements and check expiration on machines
  - Check next 5 parts to ensure hole size tolerance

Objective Evidence of CAP Implementation & Effectiveness

Case Study #2 – Pump Tube

- **Problem Description**
  - Found that pump assembly p/n 12345 cannot function properly during acceptance testing. Upon investigation, we found rubber flashing within the pump tubes prohibiting air flow. Tubes p/n 2320 thru 2339 are all affected.

- **Containment**
  - Developed repair method to eliminate defect in received parts.
  - Stop shipment put out for affected pump tubes
  - Inspected WIP & finished product for the defect and repaired.
  - Investigation revealed no delivered goods are affected.

- **Root Cause Analysis**
  - Cause Map revealed the following root causes:
    - *Sub-tier supplied part was incorrect due to a process change*
    - *Incoming inspection did not reveal the issue with the tubes*
    - *Operator failed to identify the part was not as designed during install*
    - *Tubes are removed during supplier testing*

Case Study #2 – Pump Tube *(cont.)*

- **Corrective Action**
  - Issued Corrective Action to sub-tier for Flashing left in the unit.
  - Verified process in place to check tubes during receiving. Added verbiage to specifically check for flashing.
  - Added planning for assembler to visual check tubes prior to install.
  - Added requirement for QA Inspector to check for Flashing in the material and record results on Roving Inspection Sheet.
  - Trained all affected employees for awareness and understanding of changes
  - Modified test process to include all tubes during final testing
  - Implemented for similar assemblies: p/n 23456, 54321, & 34567.

- **Follow-up??**
  - How should the LM SQE conduct follow-up?
  - What evidence should be presented?
  - When should the SQE check for effectiveness?

Case Study #2 – Pump Tube *(cont.)*

- **Suggested Follow-up Actions**
  - Verification
    - *Review sub-tier CAR response*
    - *Review planning changes*
      - receiving, assembly, inspection, test
    - *Review training records*
  - Validation
    - *Check next receiving lot of tubes from sub-tier*
    - *Witness new process to ensure changes are in place*
    - *Initiate a PVR to check next 5 pumps prior to delivery*

Case Study #3 – Ineffective CA

- **Follow-up Results**
  - Your follow-up confirms that all corrective actions have been implemented within a heat treat process that previously failed, which was identified due to a cracked parts.
  - The next 3 heat treat batches that you witness all follow the improved process as planned, but nondestructive testing on the 3rd batch identifies the hardness is not within the required tolerance.
  - The 3rd batch is rejected and the process is stopped.

- **Next Step**
  - What actions should you take, if any?

Case Study #3 *(continued)*

- **Required Actions**
  - Reject the follow-up in SQM Web Aps
    - *Notify the Supplier*
  - Conduct further root cause analysis with supplier
    - *Suggest use of more in-depth tool or new approach*
  - Create new corrective action plan
    - *Reject or Validate previous actions*
    - *Additional containment may be necessary in the interim*
  - Schedule new follow-up date
    - *Wait until revised corrective actions have taken effect*
    - *More in-depth follow-up may be necessary*

Rejecting Follow-up requires additional RCCA

Summary

- **Verification**
  - Objective Evidence of CAP implementation
- **Validation**
  - Objective Evidence of CAP effectiveness
- **Closure**
  - Records of the results
- **Monitor & Measure**
  - Gauge effectiveness results and prevent recurrence

Follow-up for Corrective Action Effectiveness