1.0 PURPOSE

To describe the site requirements for:

1.1 Conducting an investigation, and identifying and implementing corrections and corrective actions for CAPAs (i.e., High impact or elevated nonconformances or potential nonconformances).

1.2 Identifying the requirements for managing Global CAPAs Events.

2.0 SCOPE

This procedure applies to nonconforming and potentially nonconforming materials/products, processes, and quality system elements that have been escalated to CAPA Events.

Regulatory requirements of specific markets that are more stringent than this procedure will apply to AMO operations serving those markets.

3.0 RESPONSIBILITY

Specific titles for responsible parties are addressed in ANA-03-F002, AMO Añasco Process Owner Matrix

4.0 TERMINOLOGY

To achieve consistency in Divisional documents, terms contained in this document convey the same meaning as described in the Abbott System Glossary. Exceptions or unique terms within this document are included in this section.

Click on the link below to access the Abbott Quality System Glossary.

Abbott Quality System Glossary
### 5.0 REFERENCES

<table>
<thead>
<tr>
<th>Term or Acronym/Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAPA Event</strong></td>
<td>Product, process, or quality system non-conformances that are systemic in nature or whose Impact Assessment is High (or as escalated by Management or CRB), requiring an investigation and may require a correction, corrective or preventive action.</td>
</tr>
<tr>
<td>CA/PA</td>
<td>Corrective Action and Preventive Action</td>
</tr>
<tr>
<td>CRB</td>
<td>CAPA Review Board</td>
</tr>
<tr>
<td><strong>GQMS</strong></td>
<td>Global Quality Management System. GQMS is an Information Technology (IT) system that supports the Abbott Corporate policies for CAPA.</td>
</tr>
<tr>
<td>Global CAPA Event</td>
<td>A CAPA Event that has impact or potential impact to more than one AMO site not under the same site quality system.</td>
</tr>
<tr>
<td>Nonconformance (NC)</td>
<td>A nonfulfillment of a specified requirement related to product, process or the Quality System.</td>
</tr>
</tbody>
</table>

ANA-03-S002 | AMO Añasco CAPA Review Board Procedure  
ANA-03-S003 | AMO Añasco Nonconformance and Potential Nonconformance Procedure  
ANA-03-S004 | AMO Añasco Impact Assessment Procedure  
ANA-03-F001 | Risk Impact Assessment Form – Añasco  
ANA-03-F002 | AMO Añasco Process Owner Matrix  
ANA-03-F003 | Notification of Event (NOE)  
FQA01087 | CAPA Extension Form  
FQA01447 | Certificate of Inventory Destruction Form  
AQ03-01-01-UG | Global Quality Management System (GQMS) Training User Guide  
AMO-03-F004 | Global Assessment Form  
AMO-04-S001 | AMO Product Escalations to Regulatory Action Committee (RAC) Procedure  
SOP303056 | Quality Data and Trending Procedure  
AMO-03-G001 | Business Codes Guidelines  
AMO-03-D001 | GQMS Business Codes List  
AMO-03-D003 | Global CRB Member Listing  
AMO-18-S001 | AMO Division Risk Management Procedure  
AMO-03-S005 | GQMS Trending Procedure  
AMO-19-S001 | Global QA Shipment Hold Process  

AMO-05-T001 REV. 04
6.0 REQUIREMENTS

6.1 General

6.1.1 A CAPA system addresses existing and/or potential quality issues or events identified with materials/products, processes, equipment, and/or quality systems and assess the global (within division/business) impact of the cause.

6.1.2 All identified non-conformances are evaluated to determine if a CAPA Event has occurred. See Diagram 1 and Diagram 2 for a list of inputs and a high-level process flow.

Note: Alternate investigation path or type might be pursued based Management and/or CRB discretion as described in the Investigation Decision section for details.

6.1.3 CAPA Events will be assessed to determine the need for a Global CAPA investigation as described in the Global CAPA section of this procedure.

6.1.4 GQMS or alternative systems may be used to manage event records. For GQMS use AQ03-01-01-UG, Global Quality Management System (GQMS) Training User Guide.

6.1.5 When using the GQMS system all CAPA events will be entered as a nonconformance as described in ANA-03-S003, AMO Añasco Nonconformance and Potential Nonconformance Procedure and evaluated as described in ANA-03-S004, Impact Assessment Procedure and ANA-03-F001 Risk Impact Assessment Form – Añasco, to determine if a CAPA Event has occurred.

6.1.6 When using the GQMS system, if a CAPA event has occurred the investigation will be conducted using the Post Investigation functionality.
6.2 Process Flow Diagrams

Diagram 1: CAPA Entry Process Flow

Nonconformance/Potential NC
- Internal Audit Observations
- External Audit Observations
- Supplier Audits
- Supplier Performance Metrics
- Service Records
- Customer Complaints
- Post Market Surveillance
- Process Deviations
- Non-Conforming Materials
- Supplier Non-Conformance
- TPM Non-Conformance
- Out of Calibration
- Environmental Monitoring excursions
- Management Review Elevation
- Other feeder systems as determined by QA.

Impact
- High or Elevated Nonconformance/Potential Nonconformance (ANA-03-S003)

Add Global CAPA Process Requirements

Global CAPA?

Follow Nonconformance Process (ANA-03-S003)
Diagram 2: CAPA Event Process Flow

Inputs
- Nonconformances that have triggered a CAPA Event
  Includes Identification and Evaluation elements from ANA-03-S004

Process
- Global Impact Assessment
- Investigation
- Resolution Plans
- Effectiveness

Outputs
- Completed Assessment checklist
- Identify Global CRB members (as necessary)
- Data Analysis
- Probable or Root Cause
- Resolution Decision
- Correction
- Corrective Action
- Preventive Action
- Effectiveness Decision(s)

Tracking and Trending

Effectiveness Check Verification
### 6.3 Roles

Table 1: Roles and Responsibilities

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities / Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiator</td>
<td>• Initiates an exception report (ER).</td>
</tr>
<tr>
<td></td>
<td>• Records the required information to describe the nonconformity or potential nonconformity.</td>
</tr>
<tr>
<td>Owner</td>
<td>• Ensures completion of impact assessment.</td>
</tr>
<tr>
<td></td>
<td>• Manages the issue through completion including investigation planning.</td>
</tr>
<tr>
<td></td>
<td>• Ensures appropriate approvers are assigned.</td>
</tr>
<tr>
<td></td>
<td>• Ensures that ER is approved minimally by one CAPA Certified Approver.</td>
</tr>
<tr>
<td>Investigator</td>
<td>• Conducts the investigation.</td>
</tr>
<tr>
<td></td>
<td>• Identifies the cause(s).</td>
</tr>
<tr>
<td></td>
<td>• Evaluates where else the quality issue may occur.</td>
</tr>
<tr>
<td></td>
<td>• Determines the need for Action Plans</td>
</tr>
<tr>
<td></td>
<td>• Documents the findings.</td>
</tr>
<tr>
<td>Resolution Planner</td>
<td>• Develops corrections, corrective actions and/or preventive actions.</td>
</tr>
<tr>
<td></td>
<td>• Develops effectiveness plan(s).</td>
</tr>
<tr>
<td>Implementer</td>
<td>• Executes according to action plan and effectiveness plans.</td>
</tr>
<tr>
<td>Approver</td>
<td>• Ensures that all information is accurate and complete, including</td>
</tr>
<tr>
<td></td>
<td>✓ content and technical integrity</td>
</tr>
<tr>
<td></td>
<td>✓ Investigation is thorough and supports identified cause(s)</td>
</tr>
<tr>
<td></td>
<td>✓ The need for an appropriate action plan has been addressed</td>
</tr>
<tr>
<td>Confirmer</td>
<td>• Confirms that the</td>
</tr>
<tr>
<td></td>
<td>✓ Nonconformity was remediated</td>
</tr>
<tr>
<td></td>
<td>✓ Planned activities were completed</td>
</tr>
<tr>
<td></td>
<td>✓ Remediation activities did not adversely affect the material/product process and/or quality systems</td>
</tr>
<tr>
<td>Verifier</td>
<td>• Verifies that the</td>
</tr>
<tr>
<td></td>
<td>✓ Actions taken have reduced or eliminated recurrence/occurrence of the quality issue (i.e., nonconformance)</td>
</tr>
<tr>
<td></td>
<td>✓ Implementation of the actions has not created adverse consequences to material product, process and/or quality system (i.e., a new problem)</td>
</tr>
</tbody>
</table>
6.4 Identification and Evaluation

6.4.1 Refer to ANA-03-S003, AMO Añasco Nonconformance and Potential Nonconformance Procedure, for details of the initiation and evaluation process.

6.4.2 The criteria for elevating non-conformances to CAPA Events are included in:

6.4.2.1 ANA-03-S003, AMO Añasco Nonconformance and Potential Nonconformance Procedure

6.4.2.2 SOP303056, Quality Data and Trending Procedure.

6.4.3 Quality issues are identified through detection, review, and/or analysis of relevant quality system data using appropriate statistical methodology. Quality data sources may include but are not limited to:

6.4.3.1 Manufacturing operations (e.g., product rejections and production process control records)

6.4.3.2 Processes

6.4.3.3 Audit Observations

6.4.3.4 Quality records

6.4.3.5 Customer complaints

6.4.3.6 Adverse Event and Medical Device Reporting (MDR)

6.4.3.7 Product Actions (e.g., recalls)

6.4.3.8 Returned product and/or

6.4.3.9 Supplier performance

6.4.4 Inputs into the CAPA system for material/product, process and/or quality system issues include but are not limited to:

6.4.4.1 Nonconformities

6.4.4.2 Failed CAPA effectiveness checks

6.4.4.3 Issues identified by Management Review and based upon Management evaluation

6.4.4.4 Trends from process performance and product quality monitoring

6.5 Investigation Decision

6.5.1 The impact assessment and assigned impact level determine the need for an investigation. If an investigation is not required a justification shall be provided.

6.5.2 Events will be managed as follows in GQMS based on the outcome of the impact assessment (or alternate system may be used):
### Investigation Elements

<table>
<thead>
<tr>
<th></th>
<th>Low Impact</th>
<th>Medium Impact</th>
<th>High Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process</strong></td>
<td>Nonconformance (ANA-03-S003)</td>
<td>Nonconformance (ANA-03-S003)</td>
<td>CAPA (ANA-03-S001)</td>
</tr>
<tr>
<td><strong>Investigation Type</strong></td>
<td>None</td>
<td>Track &amp; Trend</td>
<td>CAPA Investigation – use GQMS Post investigation form</td>
</tr>
<tr>
<td><strong>Global Assessment</strong></td>
<td>None</td>
<td>None</td>
<td>Required</td>
</tr>
<tr>
<td><strong>Resolution Actions</strong></td>
<td>Correction</td>
<td>Correction CA/PA considered based on issue</td>
<td>Correction CA/PA expected</td>
</tr>
<tr>
<td><strong>Effectiveness Check</strong></td>
<td>None</td>
<td>Consider based on CA/PA</td>
<td>Expected</td>
</tr>
</tbody>
</table>

#### 6.5.3 Alternate Investigation Path

**Alternate Investigation Path:** Management and/or CRB may modify the investigation approach summarized in table above at their discretion. The decision is to be documented with a justification as part of the Impact Assessment process in the section “Alternate Investigation Path Justification” of form ANA-03-F001.

**6.5.3.1** If a Track & Trend or Base Investigation is selected as an alternate investigation path or type, then the process defined in ANA-03-S003 must be followed.

**6.5.3.2** If a Post Investigation is selected as an alternate investigation path or type, then the process defined in ANA-03-S001 must be followed. Global Assessments are required for Post Investigations as established in this procedure (ANA-03-S001).

**6.5.4** In cases where the cause is known, an assessment is conducted within the context of the evaluation process to determine if an investigation is necessary. The justification should include the investigation steps performed during this assessment that support the cause is known decision. The steps are documented and

**6.5.4.1** are supported by objective evidence that is clear and concise.

**6.5.4.2** are written so the reader can understand the issue, circumstances and actions taken.

**6.5.4.3** ensure other associated causes are not overlooked.

**6.5.5** If an investigation is already in process, this investigation will be reviewed to determine whether the investigation is related and the proposed resolution plan will address the nonconformities. The link to the process investigation shall be clearly documented.
6.6 Investigation

6.6.1 A documented investigation shall be performed to determine:

6.6.1.1 Cause
6.6.1.2 Resolution plans (corrections, corrective actions, preventive actions, effectiveness checks)

6.6.2 Investigation Details

6.6.2.1 Investigations are performed:

6.6.2.1.1 Based on an approved investigation plan
6.6.2.1.2 Commensurate with high impact risk
6.6.2.1.3 That include the use of problem solving tools and techniques that integrate a root cause analysis approach

6.6.2.1.3.1 Examples of Quality Tools are 6Ms, Fishbone, 5 Whys, Contradiction Matrix, Is-Is not, Design of Experiments (DOE), Process Maps

6.6.2.1.4 To identify cause of the issue (e.g., root, probable, or inconclusive); root cause is the preferred outcome

6.6.2.1.5 To determine resolution plans

6.6.2.2 The following information is included or referenced to document the investigation:

6.6.2.2.1 Background information
6.6.2.2.2 Identification of root or probable cause

The completed investigation shall be consistent with the investigation plan. Provide a justification for an evaluation or activity cited in the investigation plan that will not be executed.

The man, machine, material, method, measurement and Mother Nature (6Ms) categories can be evaluated. For each category document a listing of the possible causes evaluated. Refer to Appendix 2 for examples for the categories that could be considered during the root cause analysis. This table is an example only and not meant to be an exhaustive list.

6.6.2.2.2.1 For any category not evaluated, document a rationale.

6.6.2.2.2 There needs to be a clear relationship between the possible cause and the quality issue.

6.6.2.2.3 Collect the data necessary and/or objective evidence to support the decision of retaining or eliminating any possible causes, if applicable.

6.6.2.2.3 Investigation shall be performed using a root cause thought process. Include the objective evidence to support the investigation details, if applicable.
6.6.2.4 Investigation details, include objective evidence for conclusions

6.6.2.3 Executive Summary to include:

6.6.2.3.1 Description of the issue (e.g., problem statement)

6.6.2.3.2 Description of impact

6.6.2.3.3 Identified cause(s) (if determined)

6.6.2.3.4 Summary of actions planned (Correction, Corrective and/or Preventive Actions)

6.6.2.3.5 Interim actions taken (if applicable)

6.6.2.4 References/attachments are identified within the ER and labeled as necessary.

6.6.2.5 Effectiveness check (commensurate with risk and when Corrective Actions are taken)

6.6.2.6 Corrections, corrective actions and/or preventive actions commensurate to the cause(s) identified during the investigation process need to be adequate with timing commensurate to the action.

6.6.2.7 The results of the Global CAPA assessment (AMO-03-F004).

6.6.2.8 Risk management file review summary and a copy of the completed Impact Assessment Form.

6.6.2.9 Escalated complaint and confirmed product malfunction investigations that were escalated to CAPA will be reported to Product Safety upon the conclusion of the investigation. Target to notify Medical Events Group contact is within five (5) business days.

6.6.2.10 Upon completion, the following information is consolidated (or referenced) for approval to complete the investigation:

6.6.2.10.1 Description of the issue (e.g., problem statement)

6.6.2.10.2 Investigation details; background information

6.6.2.10.3 Executive Summary of results and conclusion(s)

6.6.2.10.4 Identified cause(s) (if determined) and

6.6.2.10.5 Data supporting the identified cause(s)

6.6.3 Global CAPA Process

6.6.3.1 Triggers into the Global CAPA process

A Global Pre-assessment of CAPA Event is to be initiated by the event owner and reviewed by the site CRB (ANA-03-S002, CAPA Review Board Procedure) to determine if the event may impact other sites and documented using (AMO-03-F004, Global CAPA Assessment Form). Sites under the same site quality system are treated as a single site for the purposes of this assessment. The items to consider are:

6.6.3.1.1 Product manufactured or developed at multiple sites

6.6.3.1.2 Quality System shared by multiple sites
6.6.3.1.3 Transfer of information/ product between sites

6.6.3.1.4 Potential impact to other Abbott Divisions: (Consider only for critical or catastrophic risk as defined in AMO-18-S001, AMO Division Risk Management Procedure)

6.6.3.1.5 If the pre-assessment identifies the CAPA Event as a possible Global Event, then notify Division Global CRB Representative to determine if it is to be handled as a Global CAPA Event. If during the course of the investigation new information is identified that has the potential to impact other sites or businesses an updated Global CAPA Assessment Form must be completed. The Division Global CRB Representative may also determine whether an event should be elevated to Abbott Quality and Regulatory for further global evaluation.

6.6.3.2 Global CAPA Assessment

The Division Global CRB Representative will contact the affected site’s CRB Primary Contact to provide details of the CAPA event to conduct the Global CAPA assessment. The results of the Global CAPA Assessment may be:

6.6.3.2.1 The Event is not considered a Global Event (rationale is to be provided).

6.6.3.2.2 The Event is Global and will be approved using a Global CRB (GCRB).

The assessment, Event Owner, and GCRB members are documented on form (AMO-03-F004, Global CAPA Assessment Form) and attached to the ER.

6.6.3.3 Global CRB (GCRB)

Each Global CAPA Record will have a GCRB that is defined in the Global CAPA Assessment Form (AMO-03-F004). The GCRB will meet as needed. GCRB members will vary depending on the scope of the CAPA Event. Multiple GCRBs may exist at any point in time.

In order to convene the GCRB meeting, the Site GCRB Chair or designee, all GCRB members as defined in the Global Assessment Form, and at least one functional area representative must be present to form a quorum. GCRB meeting attendance in person is preferred, but virtual attendance is acceptable.
Designated Global CRB representative from each site must be available at the GCRB.

- Refer to AMO-03-D003, Global CRB Member Listing, for a listing of the GCRB primary contact per site.

The GCRB has the same responsibilities as a site CRB described in ANA-03-S002, CAPA Review Board Procedure. GCRB meeting minutes are to be stored at the responsible site per the requirements of the local quality management system.

6.6.3.4 Global CAPA Processing

All CAPA process elements must be addressed as described in this procedure with the GCRB functioning as the review and approval authority of the record.

Global ERs with investigations or corrective actions that are past due, request multiple extensions, fail effectiveness verification, or meet a higher risk threshold such as for CAPA events associated with Product Recalls, shall follow the escalation approval criteria defined in AMO-03-S004, CAPA Review Board Procedure.

6.6.3.5 Global CAPA Tracking and Trending

Global CAPA events will be reflected in each affected site metrics. The Division QA Manager is responsible for presenting Global CAPA metrics at Division Management review meetings.

6.6.3.6 Global CAPA Event Approvals

GCRB approves all elements of the Global CAPA

6.6.3.7 Global CAPA Business Codes

Global ERs are to be identified with global business codes associated with product, process or quality system (AMO-03-D001, GQMS Business Codes Listing). Refer to AMO-03-G001, GQMS Business Code Guidelines, for guidance on how to determine the business codes.

6.6.4 Resolution Plans

6.6.4.1 Evaluate the need for a correction, corrective and/or preventive action based upon the impact of the quality issue. The resolution action shall effectively reduce or eliminate recurrence/occurrence of the quality issue. When it is determined that a resolution plan is not necessary in response to a quality issue, appropriate justification shall be documented and approved.

Resolution plans may include:

6.6.4.1.1 Corrections (immediate or planned)

Planned corrections are approved prior to implementation. Corrections may be implemented using approved, pre-established plans (e.g., procedures). Documentation includes:

6.6.4.1.1.1 the material/product, process or quality issue
6.6.4.1.2 the action to be taken
6.6.4.1.3 a method to determine whether the issue has been corrected
6.6.4.1.4 justification why the correction will have no adverse consequence to the material/product/process and/or quality system.
6.6.4.1.5 an implementer (action owner) and
6.6.4.1.6 a due date (or completion date for immediate corrections) with justification for timeframe selected
6.6.4.1.7 If no correction is required, a justification shall be provided.
6.6.4.1.8 The action plans require a detailed justification to support the due dates for implementation.

6.6.4.2 Corrective and/or Preventive Actions

During resolution planning, for each cause, determine if a corrective action/preventive action is necessary. A justification/rationale is documented when it is determined that a corrective action is not necessary. If there is a possibility that the issue could occur elsewhere then any corrective/preventive action(s) extends (or will extend) to the additional areas.

The Corrective and Preventive Action plans defined under the Resolution Plan must include clear details of actions including planning, and execution steps with predefined dates, resources and identified implementers.

Justification for due date justification is required.

Review and approval of Resolution Plans including due dates shall be completed within fourteen (14) calendar days from date of investigation approval. Resolution plans must be submitted for CRB review and approval.

6.6.4.1.3 If applicable, establish an interim mode of control and provide the rationale on how this interim action will be executed. The interim mode of control will be applied until the implementation of the corrective / preventive action.

6.6.4.2 Identify if similar actions have been previously assigned and are not completed. If the similar action is open reference this action and the ER number in the resolution plan.

6.6.4.3 The amount of time allowed for corrective and preventive actions will depend on the complexity of the actions. This will require a reasonable estimate of the time needed to complete the actions. Estimate of the time
required to complete the deliverables needed for an action shall be established to justify the adequacy of the timeframe for its completeness.

6.6.4.3.1 If during the execution of the corrective/preventive action it is determined that the action is too complex to manage under the CAPA System it can be closed referencing a major project. The closure of this action will require a Project Description and a reference number of one of the following:

- 6.6.4.3.1.1 Project
- 6.6.4.3.1.2 Validation Plan
- 6.6.4.3.1.3 Quality Plan

6.6.4.4 If during the completion of an action and/or evaluation of the effectiveness check, a new action is identified that will require additional time to document and execute new action(s), issue an additional corrective or preventive action, if applicable. Revise the ER resolution plan to include this new corrective or preventive action. The new action item identified as a result of this evaluation requires QA approval.

6.6.4.5 Resolution Plan Details

6.6.4.5.1 Rationale for chosen actions and date when actions will be completed.

6.6.4.5.2 Actions taken to address quality issues are shown to be effective and not adversely affect material/product and/or processes through:

- Verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (e.g., assessing impact via change control).
- Or
- Validation - documented objective evidence that provides a high degree of assurance that a specific process shall consistently produce a product meeting its predetermined specifications and quality attributes (e.g., qualifying a new piece of equipment).

6.6.4.5.3 Corrections, Corrective and/or Preventive Actions shall be implemented using approved plans or procedures.

6.6.4.5.4 Person responsible for action completion.

6.6.4.5.5 Corrective Actions shall include communication of information related to the issue to the personnel directly responsible for assuring the quality of the product or prevention of the issue.

6.6.4.5.6 Quality System changes may include a pilot prior to full implementation to ensure the change is effective and does not adversely affect quality system processes.
6.6.5 Implementation

6.6.5.1 All resolution plans shall be documented with objective evidence confirming that all plan elements are fulfilled.

6.6.6 Effectiveness Check

6.6.6.1 The Effectiveness Plan will document the required effectiveness checks to demonstrate the actions taken have effectively reduced or eliminated recurrence/occurrence of the quality issue.

6.6.6.2 When an Effectiveness Check is not necessary in response to a quality issue, appropriate justification shall be documented and approved.

6.6.6.3 Effectiveness checks are performed after implementation of the action, when required, by collecting and analyzing data over an established time frame.

6.6.6.3.1 Effectiveness Check Plan must be:
   6.6.6.3.1.1 Capable of detecting the recurrence of the quality issue
   6.6.6.3.1.2 Measurable using pre-defined methods of data collection and analysis techniques
   6.6.6.3.1.3 Attainable with defined acceptance criteria (within process capability, proportionate to the impact/risk of the quality issue)
   6.6.6.3.1.4 Developed to address the entire scope of the ER
   6.6.6.3.1.5 Based on a defined timeframe and include statistical rationale where possible
   6.6.6.3.1.6 Based on documented rationale for the chosen approach
   6.6.6.3.1.7 Reviewed periodically against the expected results (if duration is greater than 3 months)
   6.6.6.3.1.8 Based on monitoring data but cannot be solely based on monitoring customer complaints

6.6.6.4 Effectiveness verifies if the:
   6.6.6.4.1 Corrective/Preventive action eliminated or reduced the cause of problem or recurrence/occurrence of the quality issue
   6.6.6.4.2 Corrective action or preventive action had no adverse consequences on materials/ products/ processes/ quality systems
   6.6.6.4.3 Planned results were achieved

6.6.6.5 Issue an additional corrective or preventive action, if during the completion of an action and/or evaluation of the effectiveness check, a new action is identified that will require additional time to investigate and/or to execute actions. Revise the Exception Report resolution plan to include this new
corrective or preventive action. The action items identified as a result of this evaluation / investigation requires QA approval.

6.7 Tracking and Trending
CAPA system data shall be evaluated to identify trends, which may indicate the need for investigation, and/or resolution plans.

Tracking and Trending processes must include the following:
6.7.1 Documented process to execute and review output
6.7.2 Defined review intervals with documented results
6.7.3 Statistically based evaluation criteria
6.7.4 GQMS data shall be evaluated as described in AMO-03-S005, GQMS Trending Procedure.

6.8 Metrics and Reports
6.8.1 The status of actions and due dates will be provided to action implementers, implementer area managers and site management for review on a weekly basis.

6.8.1.1 Action reports for:
6.8.1.1.1 Open Investigation Due Date
6.8.1.1.2 Open Correction / Corrective Action / Preventive Action Confirmation Date
6.8.1.1.3 Open Effectiveness Verification Date
6.8.1.2 These reports will contain the following information:
6.8.1.2.1 ER Number
6.8.1.2.2 ER Initiation Date
6.8.1.2.3 Event Description
6.8.1.2.4 Impact Level
6.8.1.2.5 Action Type / ID (e.g. CA - 1)
6.8.1.2.6 Action Implementer
6.8.1.2.7 Event Owner
6.8.1.3 Due Date Extension Report
6.8.1.3.1 Report will contain the same field as Section 9.1.2
6.8.1.3.2 Add the Status Report Field to determine the quantity of extensions for the following:
6.8.1.3.2.1 Investigation
6.8.1.3.2.2 Correction / Corrective Action / Preventive Action
6.8.1.3.2.3 Effectiveness Verification

6.8.2 An aging report will be provided to site management on a monthly basis and to division management for quarterly review to assure timely implementation of actions.
6.8.2.1 Investigation Phase aging report to include:

6.8.2.1.1 Event Owner
6.8.2.1.2 Impact Level
6.8.2.1.3 Base Investigation days open since the ER initiation date (target ≤ 30 days)
6.8.2.1.4 Post Investigation days open since the ER initiation date (target ≤ 60 days)

6.8.2.2 Resolution Plans not approved after Investigation completion

6.8.2.2.1 Days open since initiation date of ER

6.8.2.3 Corrective and/or Preventive Actions (CA/PA)

6.8.2.3.1 Days open since initiation date of ER
6.8.2.3.2 Days open since investigation approval
6.8.2.3.3 Days remaining until confirmation due date

6.9 New Information

As new information is learned throughout the CAPA process, consider whether an update to bracketing, containment, Impact Assessment and/or the Global CAPA determination is necessary.

6.10 Documentation

6.10.1 The CAPA Event documentation shall:

6.10.1.1 Be accurate and appropriate (e.g., technically sound)
6.10.1.2 Include relevant data/information generated during the investigation process
6.10.1.3 Be complete, for example: all objective evidence is included, attached or referenced. All attachments must be easily identifiable and clearly labeled.
6.10.1.4 Be written in sufficient detail so that a person unfamiliar with the event can understand the event, conclusions and required actions
6.10.1.5 Be clear, concise, and well organized
6.10.1.6 Be documented in English for all High and Medium impact level events within the text fields in GQMS. Use of a local language is acceptable as long as it is accompanied by a translation in English. Attachments may be in the local language as long as a summary of the contents is provided in English.
6.10.1.7 When data searches are performed the following are required:

6.10.1.7.1 Source of data
6.10.1.7.2 Search criteria
6.10.1.8 When a status report is needed to update the ER, the following would be included:

6.10.1.8.1 Details of completed actions
6.10.1.8.2 Details of open actions including planned completion dates.
6.10.1.8.3 Justification for any delay and resulting impact to product or process

6.10.1.9 Attachment(s) Identification:

6.10.1.9.1 Attachment Number (e.g. Attachment 1, Attachment A)
6.10.1.9.2 ER number
6.10.1.9.3 Page Number
6.10.1.9.4 Total Document Pages
6.10.1.9.5 Print Name / Signature / Date (Only on the first page of each attachment).

6.11 Approvals

6.11.1 Two approvers; at least one of the approvers must be QA and a CAPA Certified Approver GQMS confirmers and verifiers shall be QA CAPA Certified.
6.11.2 Refer to approval matrix in ANA-03-S002, AMO Añasco CAPA Review Board Procedure.

7.0 Notification of Product Disposition

7.1 Investigation approval

7.1.1 Product Disposition as “Accept”:

7.1.1.1 The investigator is responsible to initiate the “Shipment Hold Release” form following SOP303069, Quarantine and/or Hold Procedure. The form and a copy of the approved ER report will be submitted to Product Release Exempt Personnel.

7.1.1.2 Product Release Exempt Personnel is responsible to close SAP/NC following SOP303069, Quarantine and/or Hold Procedure.

7.1.2 Product Disposition as “Scrap” and completed as Immediate Correction:

7.1.2.1 The investigator is responsible send a copy of the approved ER report will be submitted to Product Release Exempt Personnel.

7.1.2.2 Product Release Exempt Personnel is responsible to close SAP/NC following SOP303069, Quarantine and/or Hold Procedure.

Note: Use form FQA01447 Certificate of Inventory Destruction Form, to document/certify inventory or material destruction as required.
7.2 Planned Corrections:

7.2.1 Product Disposition as “Rework - Accept”:
7.2.1.1 The Planned Correction Implementer is responsible to initiate the “Shipment Hold Release” form following SOP303069, Quarantine and/or Hold Procedure. The form and a copy of the approved ER report will be submitted to Product Release Exempt Personnel.

7.2.1.2 Product Release Exempt Personnel is responsible to close SAP/NC following SOP303069, Quarantine and/or Hold Procedure.

7.2.2 Product Disposition as “Scrap”:
7.2.2.1 The Quality Approver is responsible to submit a copy of the approved planned correction to Product Release Exempt Personnel.

7.2.2.2 Product Release Exempt Personnel is responsible to close SAP/NC following SOP303069, Quarantine and/or Hold Procedure.

7.3 Timing Requirements

The minimum timing requirements for key process stages are established below:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td>• Document quality issue within 7 calendar days of the identification date.</td>
</tr>
<tr>
<td>Base ER</td>
<td>• Target to approve Base investigations within 30 days calendar of the initiation date.</td>
</tr>
<tr>
<td>Investigation</td>
<td>• Target to approve Post investigations within 60 calendar days of initiation date.</td>
</tr>
<tr>
<td></td>
<td>• Investigation must be reviewed monthly, if investigation is open &gt;90 calendar days, an elevated and documented review and acceptance is required by the CRB.</td>
</tr>
<tr>
<td>Resolution Plans</td>
<td>• Approve the Resolution Plans within 14 calendar days of investigation approval.</td>
</tr>
<tr>
<td></td>
<td>• Weekly reports shall be distributed to track progress of the resolution plans (establishment of plans, corrections and CAs/PAs closure).</td>
</tr>
<tr>
<td></td>
<td>• Status of implementations and effectiveness checks shall be reviewed weekly. Past due implementations, and effectiveness checks shall be escalated to the site QA head.</td>
</tr>
</tbody>
</table>
### Extension Requests

- Request must be submitted for approval within a target of at least 14 days prior to the previously established due date. Extension applies to:
  - Investigation
  - Correction
  - Corrective/Preventive
  - Effectiveness Verification

If the request is submitted under the 14 days target, include justification (e.g., unforeseen manufacturing, validation and/or change control situations, etc.) within the CAPA Extension Form, FQA10187, or attachments, that is submitted for approval.

### Escalation Criteria

#### Record Type

<table>
<thead>
<tr>
<th>Events with Impact Assessment of medium or high are reviewed by CRB to determine if escalation is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late Investigations</td>
</tr>
<tr>
<td>Past Due Resolutions Plans</td>
</tr>
<tr>
<td>Late Corrective/Preventive Actions</td>
</tr>
<tr>
<td>Late or Failed Effectiveness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Escalation Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRB will notify Site QA Director to evaluate if escalation to RAC is required as defined in procedure AMO-04-S001.</td>
</tr>
<tr>
<td>Notification to QA Director following section 6.8 Metrics and Reports.</td>
</tr>
<tr>
<td>Failed Effectiveness reports will be submitted to Site QA Director on a weekly basis.</td>
</tr>
<tr>
<td>Approval by Functional Area Manager of the event owner, CAPA System Manager and Director (QA or site).</td>
</tr>
<tr>
<td>Approval by QA VP (3rd extension)</td>
</tr>
<tr>
<td>For Finished Product – Approval by Division Head of Quality</td>
</tr>
<tr>
<td>For Material – Approval by Quality Director</td>
</tr>
</tbody>
</table>

### CAPA Record Management

#### 7.5.1 Discontinued, Cancelled or Voided

- If at any time it is determined that a CAPA, correction, corrective action or preventive action is a duplicate or is no longer necessary, they may be discontinued, cancelled or voided by documenting the justification and obtaining QA Approval.

#### 7.5.2 ER Version

- If versioning impacts the original action implementation dates add the chronology of approval/implementation dates
7.5.2.1 Investigation versioning

7.5.2.1.1 If an investigation is versioned, add the chronology of the investigation approval date(s).

7.5.2.2 Correction/Corrective/Preventive Action

7.5.2.2.1 If a versioning impacts the original action approval/implementation dates for:

7.5.2.2.1.1 resolution plan, add the chronology with the approval dates

7.5.2.2.1.2 actions implementation, add the chronology with the implementation dates

7.5.3 Linking CAPA

7.5.3.1 If an investigation already exists for the same quality issue, the CAPA for the new quality issue may refer to the existing CAPA with the following conditions:

7.5.3.1.1 Investigation is related

7.5.3.1.2 Proposed resolution plans will address all nonconformities

7.5.3.1.3 A reference to the existing investigation is clearly documented

7.5.3.1.4 Documented agreement from the owner of the existing record.

7.5.4 CAPA Extensions

7.5.4.1 When a CAPA requires timeliness updates, they should contain the following elements

7.5.4.1.1 Bracketing of the event should be documented.

7.5.4.1.2 Containment should be documented. If no containment is required, a justification needs to be documented.

7.5.4.1.3 Description/details of completed activities

7.5.4.1.4 Description/details of open actions including planned completion dates

7.5.4.1.5 Justification / rationale for why the issue has not been completed

7.5.4.1.6 Impact to product or process

7.5.4.1.7 Identification of individual(s) responsible for completing the remaining activities and update,

7.5.4.1.8 An interim mode of control will be established until the implementation of the corrective / preventive action.

7.5.4.2 The CAPA extension shall be documented in the GQMS System

7.5.4.3 Complete Form FQA01087, CAPA Extension Form.

Refer to Step 6.13, Escalation Criteria for the approval requirement.
<table>
<thead>
<tr>
<th>Revision</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Clarify roles and responsibilities for Product Disposition.</td>
</tr>
<tr>
<td>12</td>
<td>To include the following instructions: Include requirement of documenting the Project Number, Validation Plan or Quality Plan if a corrective action will be closed making reference to a major project. Include Bracketing and Containment information in Status Report Requirements.</td>
</tr>
<tr>
<td>13</td>
<td>Add note in section 7.1.2.2, including instructions as required, to document/certify inventory or material destruction. FQA01447 added in reference section.</td>
</tr>
</tbody>
</table>
## Appendix 1 – 6Ms Quality Tool

The following table lists examples under each category that may be considered and documented when performing root cause analysis. The list of examples is not all inclusive.

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Man                       | • Conduct interviews with representative personnel and document the details of the interview including  
- Name of the person interviewed  
- Date and times of the interview  
- All relevant dates and times  
- Statements about equipment condition before and after the incident  
- The procedures used and/or  
- Any observations.  
• Review personnel training records for those involved in the event including effectiveness of the training. |
| Machine                   | • Verify that correct equipment was used.  
• Evaluate the equipment condition and determine if the equipment will be repaired or replaced, if applicable.  
• Review equipment documentation, e.g., maintenance, preventive maintenance, set-up, use, cleaning, calibration, standardization.  
• Review recent changes to the equipment.  
• Check computer printouts/charts for error messages.  
• Check utility support systems, e.g., heating/cooling control. |
| Material                  | • Review  
- Materials/products usage and relevant change history  
- Relevant history for additional materials/products used in the process, e.g., vendor change for raw material, filters, components, etc.  
- Material/product test data  
- Material/product handling and storage  
- Restrictions or substitutions.  
• Check material/product retest and expiration dating. |
| Method                    | • Review  
- Applicable process and operating procedures (are they clear and understandable?)  
- Change history  
- Cleaning documentation  
- Process and test specifications  
- Design specifications  
- Laboratory and in process assay results and trends  
- Batch records  
- Original or source data for accuracy and information pertaining to the event  
- Yield accountability.  
- Verify issue and effective date of master documents in use at time of event. |
| Measurement               | Review  
• Measuring instrument calibration history.  
• Capability of the measuring instrument or manual method. |
| Mother Nature / Environment | Review  
• Environmental conditions (e.g., temperature, humidity, environmental monitoring).  
• Weather conditions (e.g., storms). |