1.0 Purpose of Procedure

This document describes Product Resources' corrective action process. It decribes the process of and provides instructions for initiating, assigning, acting on, approving, and verifying corrective action. It assigns responsibility and authority related to corrective action, and it sets expectations for the completion of corrective actions.

2.0 Scope of Process

The scope of this process is the corrective action process.

3.0 Process Owner(s)

3.1 Quality Manager

3.2 QA

4.0 Procedure

4.1 Initiating and Corrective Action Types

Requests for corrective action are created in the QMS system by employees. The same form is used for all types of requests but categorized as to type. In the QMS system, select ISO Functions, Corrective Actions, New Corrective Action to initiate.

The Corrective Action Types are listed below along with their descriptions:

- Audit Issue: This corrective action type is used for all audit nonconformances where the audit type is not an internal audit nor a registrar audit. This is used for a customer performing a supplier audit of Product Resources. This is also to be used when an audit noncompliance is generated by an external auditor from regulatory bodies such as NRTLs, notified bodies, or governmental agencies. Quality should be selected as the initial responsible party.

- Customer Complaint: This corrective action type may be used by any employee who receives a complaint from a customer.

- Inspection Issue: This corrective action type may be used by any employee who discovers a product/item issue at any incoming, in-process, or outgoing inspection.

- Internal Audit (major or minor): This corrective action type may be used by the internal audit committee to record a nonconformance found during an internal audit. The committee shall discuss the type, minor or major and the responsible party. These CAR types can be generated by the audit module of the QMS system.

- Management Review: This corrective action type is used as part of the Management Review process, specifically for the recording of Management Review action items. Note that frequently root cause analysis may not apply to the corrective action usage.

- Nonconforming Product: This corrective action type may be used by any employee who discovers a product/item issue at any time in the production process.

- Process Issue: This corrective action type is used by any employee who detects or suspects a problem relared to our usage of company procedures or processes.

- Supplier Issue: This is initiated by QA to request action/analysis for a nonconforming condition that originates external to Product Resources at the supplier level. Returned product may or may not accompany this type of corrective action. A copy will automatically be emailed to the supplier via the the QMS system. Purchasing shall be listed as the initial responsible party. It is the joint responsibility of QA and Purchasing to follow this corrective action type through to completion.

- Surveillance Audit (major or minor): This is to be entered when the audit noncompliance is generated by an external auditor from Product Resources' QMS registrar(s). Quality should be selected as the initial responsible party.

The person initiating the corrective action request must determine, based on the information known up front, the corrective action type. The person initiating the corrective action, after determining the type, describes the situation that has lead to the request for corrective action (Description). There is other information to complete: An initial responsible party must be selected. For certain corrective action types, see above, Quality or Purchasing is to be selected as the initial responsible party; otherwise select someone with the best knowledge to analyze the given situation. (A summary table including initial responsible parties can be found below.) A priority level must be chosen. There is the opportunity to associate the corrective action with a customer or supplier or both, and there are other fields available to assist in describing and managing the corrective action. One can also attach related files as example and evidence.

Submitting one of the above requests via the QMS system causes the QMS system to notify the initial responsible party. The corrective action is serialized by the QMS system and the corrective action may be referenced by number.

The QA Manager has the authority to initiate corrective actions based on the form described above, based on the analysis of data, or based on the output of Management Review (see also 91-9004 and 91-9005).

See also 91-5001 (Service and Returns) and note that an RMA may also create a Corrective Action. When it is apparent that failure to take the additional actions of root cause determination and containment and/or permanent actions that the Corrective Action process yields will result in further nonconforming or failed product, the Service Manager is tasked with flagging the RMA for Corrective Action, and the closure of the RMA will open a related Corrective Action.

Similarly internal audits in the QMS system may generate CARs as results upon their closure; see also 91-7001 (Internal Audit).

The QA Manager has the authority to assign responsible parties to corrective actions. Responsible parties have the responsibility for root cause analysis and/or action determination, and as appropriate the responsible party may change as the corrective action progresses from initiation to investigation to root cause to action determination and action completion.

CAR Type	**Initial Responsible Party** **(see Initiating)**	**Required Approver(s)** **(see Approval, min of 2)**
Audit Issue	Quality	Quality
Customer Complaint	Best knowledgeable party	Quality
Inspection Issue	Best knowledgeable party	Best knowledgeable party / party responsible for process
Internal Audit	Best knowledgeable party	Best knowledgeable party / party responsible for process
Management Review	Best knowledgeable party	Best knowledgeable party / party responsible for process
Nonconforming Product	Best knowledgeable party	Best knowledgeable party / party responsible for process
Process Issue	Best knowledgeable party	Best knowledgeable party / party responsible for process
Supplier Issue	Purchasing	Best knowledgeable party / party responsible for process
Surveillance Audit	Quality	Quality
Any CAR in which a safety issue is revealed (see 4.9)	As above	Quality

4.2 Investigation and Root Cause

The responsible party investigates the problem description, working towards a root cause. Depending on type of CAR, this can take the form of reviewing QMS procedures and work instructions, reviewing production and test records (DHR), reviewing manufacturing documentation (DMR), asking questions of others including external parties such as suppliers and customers, running an experiment, and so on. This activity is to lead to understanding the root cause or causes. A field called Investigation is available to capture things learned in the investigation stage. (Note that prior to this field's availability, investigation was being written into the root cause.) CARs that have been initiated via an RMA or resulting from an internal audit will already investigation information, and the extent to which additional investigation is needed will vary from CAR to CAR.

Based on investigation, the responsible party then completes root cause. Root cause is to answer why did the problem occur and why it was not detected. "Five Whys" are available both to consider multiple root causes and to drill down on a given root cause until the responsible party feels that the real root cause has been reached, forming the basis for the next step, taking action.

Note that for corrective actions of type Management Review, the process normally begins at the action stage, as management has already considered (see Management Review minutes) cause and has requested that one or more particular actions be taken.

4.3 Analysis – Bounding and Containment, Corrective, and Prentive Actions

With the investigation complete and one or more root causes available, the responsible party considers, documents, and begins to execute actions. They fall into three categories, where any one or more of these may be applicable for the given situation and determined cause(s):

- Bounding and Immediate/Containment Action: What, if applicable, will be done to correct or contain the negative outcome/output that has already occurred? When the CAR is product-related, bounding is to be addressed, and a Bounding field is available to document bounding. Bounding is, what is the scope of affected product or material? Is/are there impacted raw material, WIP, or finished goods? Is there impacted product that has shipped to this customer? These are to be identified, and then the immediate/containment action is to consider how to contain the problem in each of the categories identified in bounding.

- Permanent/Corrective Action: What, if applicable, will be done to cause the system to not produce the negative outcome/output going forward and/or to be able to detect it? Corrective action should be related to the root cause.

- Preventive Action: If investigation and analysis have revealed secondary actions that will be taken to prevent a similar occurrence in the same product or process or the same occurrence in a different product or process, these actions are documented as associated preventive action. Note that actions taken against problems that have already occurred in a given product or process are always corrective or containment and never preventive. Prenventive actions expand beyond the immediate problem.

Note that these actions are collected under “Analysis” in the QMS system.

When action is determined, the action is to be completed before submitting the CAR for approval. The exception is when another part of our QMS will cause the action to be completed. For example, if a document/procedure change is called for, a document revision request will keep track of its completion, and the CAR can move forward for approval once the document revision request has been identified. Otherwise the completion of action is documented along with the action.

4.4 Approval

The responsible party selects two (or more) parties that will be approvers of the corrective action. Selection of approvers is based on a combination of knowledge in the subject area of the given corrective action and responsibility and authority in the company for the process at hand. Note that the approvers may include the responsible party for the CAR if the criteria for approvers have otherwise been met. Quality is a required

approver for certain CAR types, namely Audit Issue, Customer Complaint, and Surveillance Audit. (A summary table including required approvers can be found above.)

Once the approvers have been chosen, the responsible party submits the corrective action for approval, and the QMS system informs the approvers that review for approval is requested.

It is the job of approvers to read the corrective action description and then the determined root cause(s) and action(s).

An approver should ask: Has a meaningful root cause been reached (as opposed to the re-statement of the problem)? Have corrective actions taken addressed the root cause? Have containment actions taken contained the problem, and if a product matter has bounding been addressed? If the answers to these are yes, an approver should approve of the corrective action.

A corrective action is approved when all selected approvers have approved. The QA Manager is notified by the system for all approved CARs. A corrective action is not closed at this point; rather it proceeds to Verification.

4.5 Verification and Closure

Verification is an assessment that the corrective action has been effective. The verifier and verification date can be chosen prior to approval and is confirmed by the final approval. The chosen verifier is to be a party that can judge effectiveness of the corrective action. The verification date is to permit enough time to elapse so that the system can work and yield new outputs/outcomes, if that is needed to judge effectiveness. Some corrective actions can be verified immediately and some will require that multiple months elapse.

The CAR's responsible party can note verification requirements. Verification can take the form of a review of recent history, an extra internal audit, an inquiry, comparing new measurements to old, or any other appropriate method to assess effectiveness of the corrective action.

The assignment of the verifier is communicated by the QMS system.

The verifier should ask: Has the corrective action been effective? Do we now have conforming outputs or outcomes, or a trend of improvement? If yes, the verifier should complete verification. The verifier should also note and address any verification requests that have been made and left in the verification area by the CAR's responsible party.

Once verified, the corrective action is closed. If the verifier judges the corrective action to have been ineffective, the corrective action can be returned to an open state to have the root causes and actions reconsidered.

4.6 Risk

Responsible parties are to apply risk based thinking in the action, approval, and verification stages. No formal risk exercise is required.

4.7 Expectations on CAR Completion and Due Dates

Timely CAR completion is important to risk management and customer satisfaction. CARs are initiated with priorities of either Normal, Hot, or Cold, and for each of these the QMS system assigns default, company-selected due dates: Normal is 21 days, Hot is 14 days, and Cold is 35 days.

These due dates refer to the time to bring a CAR from initiation to submitting for approval, encompassing investigation and root cause to determining and completing actions that will be completed inline with the CAR.

Note that there is no default due date concept for the verification step, as when a CAR can be verified for effectiveness is quite varied depending on the business cycle of what is being verified. For verifications, an approver will set the due date in accordance with when it is believed the given subject matter can be verified for effectiveness based on what the business cycle permits.

Once a due date is established, it is the expectation that the responsible party for CAR completion or verification will complete it by that due date.

To facilitate awareness of due dates, the QMS system has been set up to begin notifying responsible parties (by email) of approaching due dates. For CAR completion, this takes place when approximately a third of the time to the due date remains; this number of days carries forward if a due date is rescheduled. For verification, notification comes 10 days before the due date.

Due dates can be changed with justification. QA can set a new due date as can other appointed QMS system administrators. In setting a new due date, the complexity of investigation and root cause determination and/or the time required to carry out determined actions is considered or having the means to assess effectiveness for a verification is considered.

4.8 Corrective Action and Preventive Action (CAPA) Systems Monitoring

QA holds periodic meetings for corrective action for the purposes of working together to drive corrective and preventive actions to completion and to keep corrective and preventive actions current. Others are invited as needed to review the content of and get input on particular corrective and preventive actions.

4.9 Safety Issues

At any point in the CAR process when it becomes known, the initiator or responsible party shall select Death, Injury, or Safety Hazard when a safety issue is revealed and MDR Reportable when a reportable issue is found with a medical device.

When a safety issue has been determined, Quality shall be one of the approvers to facilitate customer and other notification. (A summary table including required approvers can be found above.)

5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.