1.0 Applicable Standards

ISO 17021

2.0 Purpose

This procedure describes how customer complaints/complaints from interested parties/improvements to the quality system and products are made. The intent of this procedure is to provide a formal mechanism to support the implementation of corrective and preventive actions and to ensure that needed actions are effectively implemented.

3.0 Scope

This procedure applies to all products and all parts of the quality system.

4.0 Authority and Responsibility

The President is responsible for the operation of the Corrective and Preventive Action System. All employees who receive CPAR's are responsible for responding to them in a timely and effective manner.

5.0 Quality Activity

1. Anyone working for the company may generate a corrective/preventive action request. Valid requests may be created under the following conditions:

- A customer complaint regarding a product or service;
- Real or potential product nonconformities

- Significant real or potential failure of part of the quality system:
- Vendor nonperformance;
- Recognition of an opportunity for improvement.
- Data collected during monitoring of the Quality system and processes.

The initiator should obtain a Corrective/Preventive Action Request Form (10.2.F1) from his/her supervisor and complete the sections necessary to describe the problem. He/she should then route the sheet to the President.

2. The President reviews the Corrective/Preventive Action request and decides if the request has merit. (This review is necessary to prevent frivolous requests from encumbering the system). If the request is deemed to be valid, the President also assigns a response due date according to the criteria defined on the form and logs the corrective action or preventative action in the corresponding log. The President endorses valid requests and routes the form to the person who is responsible for investigating and addressing the request. In general, this will be the manager or supervisor of the area in which the problem was noted. The President also files a copy of the request form in the CPAR "Routed for Action" file until the request is returned after having been acted upon (see section 5.4)

3. The person who is responsible for addressing the request should keep in mind that he/she should focus on correcting the root cause(s) of the deficiency or potential deficiency The recipient should respond to CPAR within the timeframe specified on the form.
In the case of complex issues, the preliminary response may consist of a plan for addressing the problem including cross-functional team members from other appropriate departments and a tentative schedule for implementation.

The recipient completes the "response" portion of the corrective/preventive action request form and routes the form to the President. If the corrective/preventive action requires a change to a procedure, the recipient records information about the change on the corrective/preventive action form, and ensures that the change is implemented.

4. The President is responsible for reviewing the response and assessing its adequacy. If the response is inadequate, the form is returned to the recipient with a request to improve upon the action taken. If the response is satisfactory, the President signs the corrective / preventive action request and files the form in the "To be verified" file.

5. The implementation and effectiveness of actions is verified by the President (or a designee) verifying that the action has been implemented (must provide reasonable time to assess effectiveness) and appears to be working. The person who performs the verification completes the "Verification" portion of the form and routes it to the President. The President reviews the results & closes out the form.
If the implementation of the action appears to have lapsed or become ineffective, the verification portion of the form is completed as "unsatisfactory implementation and/or effectiveness". A new CPAR (with a new tracking number) is issued. The new CPAR number is noted on the original CPAR.

6. Corrective/Preventive action requests are filed by tracking number in the "Closed" file in the Quality Department for at least one year after the date of closure, after which time they may be disposed of at the discretion of the President.

6.0 Applicable Documents / References

Form – CPAR form