10.1. General

BAI shall continually improve the suitability, adequacy and effectiveness of the QMS through the use of the analysis and evaluation, outputs from management review, correction and corrective action reports, breakthrough change, innovation and re-organization.

Related policy and procedures shall ensure that nonconforming product, work, or problems that do not conform to requirements are identified and managed, to prevent unintended use or delivery of services. This procedure ensures that non-conforming product, work, or problems are corrected, where applicable, and subject to verification after correction to demonstrate conformity. Where required by the agreement, the proposed rectification of non-conforming product, work, or problems is reported for concession to the customer, the end user, regulatory body, or other applicable authority.

Identification of nonconforming product, work, or problems with the quality system or with inspection activities can occur at various points within the quality system, and technical operations such as customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, inspection report checking, management reviews, and internal or external audits.

Where the evaluation indicates that the nonconforming product or work could recur, or that there is doubt about the compliance of BAI operations with its own policies and procedures, the corrective actions procedure shall be followed to identify the root cause/s of the problem and to eliminate cause/s.

10.2. Nonconformity and Corrective Action

The process for nonconforming work is further defined in the GP BAI-09 Control of Nonconforming Product and Services and GF BAI-19 Corrective Action.

When a nonconformity occurs, including any arising from complaints, BAI:

a. Reacts to the nonconformity and, as applicable:
    1. Takes action to control and correct it;
    2. Deals with the consequences;
b. Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    1. Reviewing and analyzing the nonconformity;
    2. Determining the causes of the nonconformity;
    3. Determining if similar nonconformities exist, or could potentially occur;
c. Implements any action needed;
d. Reviews the effectiveness of any corrective action taken;
e. Updates risks and opportunities determined during planning, if necessary; and
f. Makes changes to the quality management system, if necessary.

The Deputy QMR has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product. Personnel responsible for product quality have the authority to stop production to correct quality problems in accordance with GP BAI-20 Control of Nonconforming Products and Services; related procedures are summarized below:

Identification. Identification of nonconforming product originates from inspection, internal testing, product audits or customer complaints. Employees clearly mark or otherwise identify nonconforming product or suspect material. Product with unidentified or suspect status is classified and processed as nonconforming.

Documentation. The Section Head enter the nonconformance into the corrective action system identifying the nonconforming product and job order number if applicable, description of nonconformance, and location where the nonconforming product is being held pending further review or disposition.

Segregation. Nonconforming product is segregated pending evaluation and disposition.

Evaluation. The Section Head performs the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. Where needed, Specialist and other technical personnel may become involved in the evaluation and recommendation for disposition.

Disposition. The results of the evaluation and resultant disposition determinations are documented. Dispositions resulting from the evaluation of nonconforming product may include: reconstitute to meet specified requirements; obtain (from relevant authority) a waiver of or deviation from requirements; scrap or other disposal methods. Reconstituted nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

Responsible personnel notify the customer immediately upon discovering that nonconforming product has been shipped. In the event, nonconforming product is detected after delivery or use has started, the Section Head notifies concerned personnel and initiates action appropriate to the effects, or potential effects, of the nonconformity. Where appropriate, product recall is initiated based on trace and recall data and records.

BAI takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

BAI retains documented information as evidence of:

a. The nature of the nonconformities and any subsequent actions taken; and

b. The results of any corrective action.

The QMR has overall responsibility for managing the corrective action process defined in GP BAI-19 Corrective Action and summarized below:

Evidence of nonconforming product, customer dissatisfaction, or ineffective processes is used to drive our corrective action system because a problem exists requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence. Management with responsibility and authority for corrective action are notified promptly of product or process non-conformities. Investigating and eliminating the root cause of these failures is a critical part of our continual improvement process.

Follow-ups are conducted (through the internal audit process) to ensure that effective corrective action is taken appropriate to the impact of the problem encountered. In addition, the QMR summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are corrected and data indicates that the same or similar problems have not recurred. Results of these analyses and related recommendations are presented to Top Management for review and action during management reviews.

The QMR has overall responsibility for managing our preventive action process defined in PL BAI-08 and 09 Risks Registers and summarized below:

Data from internal audits, customer feedback, employee suggestions, and other appropriate data is collected and analyzed to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We review and initiate preventive actions through our preventive action process.

We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses. In addition, the QMR summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. The preventive action system is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to Top Management for review and action during management reviews.

10.3. Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, BAI works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

At BAI, the continual improvement process begins with the establishment of our quality policy and objectives for improvement, based on objectives contained in our Work Plan and Strategic Performance Management System (SPMS) targets/goals. Customer satisfaction, internal audit, process and product performance data, and the cost of poor quality are then compared to progress against objectives to identify additional opportunities for improvement. Appropriate improvement initiatives are established, supported and monitored for achievement through the use of our management review process. We also consider corrective and preventive actions a vital part of our continual improvement program.

Corrective actions according to GP BAI-19 Corrective Action are initiated when desired results are not achieved in order to prevent recurrence and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. All management actions are prioritized and implemented on the basis of data analysis: the impact of failures/problems is used to prioritize needed corrective actions and risks are evaluated to identify and prioritize needed preventive actions.

The overall effectiveness of continual improvement program (including corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives) is assessed through our management review process (GP BAI-23 Management Review).

Essentially, such actions are effective if the problems corrected do not re-occur, potential problems identified do not occur, and other improvement actions accomplish the desired results or objectives. Inputs to the management review process are used to establish new/change improvement objectives and to initiate/prioritize additional improvement actions.

The QMR and DQMR have the overall responsibility for establishing and implementing an effective continual improvement system which includes improvement actions, as outlined above, and corrective and preventive actions.

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