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	QUALITY MANUAL	
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8.5.1. Control of Production and Service Provision

BAI implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a. The availability of documented information that defines:
 1. Handling service provision and samples;
 2. Sampling (only as applicable to the laboratory units)
 3. Service Records (e.g. laboratory, inspection records). The results of each service provided (e.g. laboratory and or inspection) carried out by the BAI are reported accurately, clearly, unambiguously, objectively, and in accordance with the applicable documented method. The results are normally reported in a form of report or certificate that include all the relevant information agreed and requested by the customer and necessary for the interpretation of the said service results, and all information required by the method used.
 4. Reports/Certificates (e.g. laboratory, inspection reports/certificates)
 5. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 6. The results to be achieved;
- b. The availability and use of suitable monitoring and measuring resources;
- c. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
- d. The use of suitable infrastructure and environment for the operation of processes;
- e. The appointment of competent persons, including any required qualification;
- f. The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g. The implementation of actions to prevent human error; and
- h. The implementation of release, delivery and post-delivery activities.
- i. Identification and traceability of projects by having a unique numbering system
- j. Work instructions and other important data must be current and correct.
- k. Any changes are managed following the Control of Changes Matrix
- l. Release of services are controlled following the Approval Matrix

8.5.2. Identification and Traceability

Where appropriate, BAI identifies its Products and Services or other critical process outputs by suitable means. Such identification includes the status of the Product or Service with respect to monitoring and measurement requirements. Unless otherwise indicated as

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nonconforming, pending inspection or disposition, or red tagged, all Products or Services shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, BAI controls and records the unique identification of the Product or Service.

The divisions control the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

The documented procedure GP BAI-11 Identification & Traceability Procedure defines these methods in detail.

8.5.3. Property Belonging to Customers or External Providers

BAI exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and/or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.


8.5.4. Preservation

BAI preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure GP BAI-22 Packaging and Storage of Finished Products includes defines the methods for preservation of product.

The SH/UH/Analyst/Specialist/Equipment Custodian has overall responsibility for establishing and implementing a system to ensure product conformity to requirements is preserved during internal processing and delivery to the intended destination. This system, defined in GP BAI-22 Packaging and Storage of Finished Products includes the handling, storage, packaging, delivery, and protection of final product and in-process constituents of the final product, to ensure:

- Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery;
- Each department ensures controls are implemented to prevent mixing conforming and Non-conforming materials;
- Packing ensures specified packaging is utilized.
- All components and products are suitably packed to prevent deterioration or damage during storage and delivery.

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BAI utilizes stock rooms, storage areas, shelving, and other means to segregate and store materials. Access to stockrooms is limited to authorized personnel, with this authorization recorded in the employee's 201 file.

Any material handling equipment utilized in BAI operations is used in accordance with the manufacturer's operating instructions. A copy of those instructions is maintained by the section heads and made available to required personnel. Any person using material handling equipment for the first time is given training on the use of the equipment by a qualified person/analyst/specialist.

8.5.5. Post-Delivery Activities

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, BAI considers:

- a. statutory and regulatory requirements;
- b. the potential undesired consequences associated with its of Products and Services;
- c. the nature, use and intended lifetime of its of Products or Services;
- d. customer requirements;
- e. customer feedback.

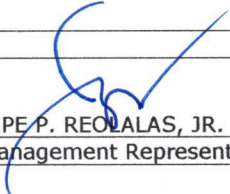

8.5.6. Control of Changes

BAI reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document GP BAI-02 Change Management Procedure.

Documents are changed in accordance with procedure GP BAI-01 Control of Documents.

BAI retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Prepared by:	Reviewed/Approved by:
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