Abbott

Abbott Nutrition's Quality and Adverse Event Reporting Requirements Policy

This Quality and Adverse Event Reporting Requirements Policy describes the overall quality and adverse event reporting requirements mandatory for all distributors who distribute products on behalf of Abbott Nutrition, a division of Abbott Laboratories Inc. ("Distributors"). Abbott may change the Quality and Adverse Event Reporting Requirements Policy at any time and shall maintain the current Quality and Adverse Event Reporting Requirements Policy on e-Abbott. In this policy, "Products" means all products of Abbott Nutrition, a division of Abbott Laboratories Inc. ("Abbott Nutrition") distributed by a Distributor.

Distributor Agreement

If the Distributor has executed an Institutional Distribution Agreement with Abbott ("Agreement"), to the extent the terms of this policy are not inconsistent with the applicable sections of the Agreement (including, without limitation, termination, governing law, and interpretation), the terms of this policy shall control.

1. General Requirements.
   a. Good Distribution Practices. Distributor must adhere to good distribution practices which must include written procedures describing the different operations that may affect the quality of Products and/or of distribution activity, including but not limited to the following as further defined herein:
      - Qualification and training of personnel
      - Approved Suppliers and Service Providers (e.g., providers of pallets) are used
      - Security
      - Premises and equipment: Cleaning and maintenance of the premises (including pest control)
      - Deliveries: Receipt and checking of deliveries
      - Handling
        - Rejected, expired and defective Product handling and destruction
        - Labeling/over labeling/stickering
        - Returned and restocking Products and
        - Handling of harmful and/or controlled Product
      - Storage including
        - Records of the storage conditions
        - Evaluation of temperature excursions
        - Inventory controls and Cycle Counts
        - Product status control
        - Stock rotation and control including performing first-in, first-out rotation and proper removal for expired product
        - Quarantine
      - Distribution including
        - Records of purchase orders from customers
        - Traceability at the item level
        - Picking and packing and
        - Mode(s) of transportation

   b. Premises and Equipment. Premises and equipment must be adequate to ensure proper management and distribution of Products. Distributor's warehouse facilities must:
      - Have controlled access
      - Have security features to protect against invasion, adulteration or theft
      - Have structural integrity, with hardened and sealed floors and no signs of leaks
      - Have sufficient lighting to allow accurate and safe operations
      - Separate washrooms and eating areas from operational areas
      - Be clean

- Be constructed to protect against floods
- Have surroundings that are free of agents that could cause infestation

c. Receiving. Receiving areas must:

- Protect deliveries from weather conditions or other elements that may have an adverse effect on materials/Products during loading and unloading;
- Be separate from storage areas;
- Deliveries must be examined at receipt in order to ensure;
- Materials/Products are not damaged; and
- The delivery consignment corresponds to the order.

d. Inventory. There must be a documented system for the recording of item numbers and expiration dates. Inventory must be periodically reviewed to assure the control of identity, quantity, location and status of each inventory item. Periodic Cycle Counts must be performed and documented in order to detect and investigate discrepancies and identify corrective actions and must be used as a tool for improvements of inventory management.

e. Product Status Control. There must be an adequate system to control and maintain product status (e.g., on test, approved, quarantined, restricted). The system must:

- Be under appropriate change control;
- Allow changes to product status to be made by appropriate quality personnel;
- Computerized systems must have appropriate validation.

f. Product Protection. Products must be stored so they are protected from deterioration by light, moisture or temperature in accordance with Abbott's label requirements. If temperature needs to be controlled, it must be monitored and recorded periodically. Temperature monitoring systems must be calibrated. Records of temperature must be reviewed regularly. The storage facilities must be clean and free from litter, dust and pests. Adequate precautions must be taken against spillage or breakage that attracts microorganisms or causes cross-contamination. Products with broken seals or damaged packaging or suspected of possible contamination must be withdrawn from saleable stock, and if not immediately destroyed, they must be kept separate so that they cannot be sold in error or contaminate other goods. Warehouse personnel must be trained in the procedures for the safe handling of Product spills.

g. Temperature-Sensitive Products. When specific temperature storage conditions are required, storage areas must be equipped to maintain the appropriate temperature and continuously monitored with calibrated temperature recorders or other devices that will indicate when the specific temperature range has not been maintained and for how long. Control must be adequate to maintain all Products of the relevant storage area within the specified temperature range. Product impact must be addressed directly to Abbott for any temperature excursions during storage and distribution. Unplanned temperature excursions and planned system deviations must be properly documented and approved by Abbott.

h. Distributor Delivery Packaging. Packaging must ensure protection against mechanical impact (damage) on Product during handling and transport. The transportation mode must be considered in determining the packaging material necessary.

i. Records. Records must be made at the time each operation is done and in such a way that all significant activities or events are traceable. Records must be clear and readily available. Records

retention schedules or equivalent documents must be established and maintained.

j. Traceability. Distributor shall maintain such traceability records with respect to the Product as shall be necessary to comply with Applicable Laws, including those applicable to "Good Distribution Practices". Upon Abbott's request, Distributor shall make all such foregoing records available for inspection by Abbott or its authorized representative.

k. Recall or Advisory Actions.

(i). In the event of the recall of one or more of the Products in the Territory and Field as the result of the action of a government agency, Distributor shall immediately notify Abbott in writing prior to making such recall. Each Party shall endeavor to reach an agreement with the other regarding the manner, text and timing of any publicity to be given such matters in time to comply with any applicable regulatory requirements.

(ii). In the event Abbott should request Distributor to recall a Product, Distributor shall cooperate fully with Abbott and take all appropriate actions to recall such Product including informing its customers and securing recovery from its customers of the recalled Product. All information regarding shipment of recalled Product, including the identity of customers, customer notification and Product reconciliation shall be promptly forwarded by Distributor to Abbott upon Abbott's request.

(iii). Abbott shall bear the expenses of any recall requested by it or resulting solely from defective manufacture or packaging by Abbott. Distributor shall bear the expenses of any other recall. In cases where the recall is unrelated to any fault of either Party, the expense of the recall shall be borne by the Parties equally. For the purposes of this Agreement, expenses of recall include, without limitation, the expense of notification and destruction or return of the recalled Product, but not the expense or service fees associated with salesmen's time which shall be borne by Distributor.

(iv). Distributor shall have and maintain at all times defined procedures to facilitate corrective action, including the actions described in this Section. Distributor shall make available to Abbott for inspection Distributor's process and records for adverse event and other regulatory reporting purposes at mutually agreed upon times. In all instances Distributor shall proceed with a recall only after having received written approval from Abbott.

(v). In the event Abbott releases a customer communication to the Distributor regarding recalls or corrective actions, the Distributor shall cooperate fully with Abbott and take all appropriate actions to the communication to Distributor's customers as outlined in the communication package provided.

Distributor shall maintain traceability records at the item level that will permit prompt identification of any product for recall that has been shipped. Distributor shall handle recalled materials according to the instructions provided by Abbott.

l. Adverse Event Reporting.

(i) Each Party shall immediately appoint a primary liaison ("**Liaison**") to communicate with the other Party regarding adverse events of a Product sold to applicable persons which directly or indirectly might lead to or might have led to the death of applicable persons or user or to a deterioration in their state of health ("**Incidents**").

(ii). During the Term of this Agreement, Distributor's Liaison shall notify Abbott's Liaison of any Incidents. Distributor shall report such Incidents to Abbott's Liaison by telephone or in writing within 1 business day of receipt of the information. Such reports to Abbott shall contain (i) the date the report was received by Distributor, (ii) the name of the reporter; (iii) the address and telephone number of the reporter; (iv) the applicable person's details; (v) a description of the Product malfunction or defect; and (vi) any additional relevant information.

(iii). Abbott shall evaluate and, as required, report such relevant Incidents to local authorities to the extent required by Applicable Law. If a reportable complaint occurs with respect to a Product and Distributor is required by Applicable Law to report the Incident, Distributor agrees to provide Abbott with a copy of the regulatory report prior to filing with the government authorities in the Territory and Field sufficiently in advance to allow Abbott time to comment on the proposed report. Distributor further agrees to make any revisions to such report reasonably requested by Abbott. Distributor shall promptly provide Abbott with a copy of the report as filed with the government authorities in the Territory and Field and with any additional documents passing between Distributor and such government authorities with respect to each reportable complaint.

2. Quality Audit. Distributor will permit Abbott Quality Assurance ("QA") personnel or designate to perform one (1) quality system audit per year. Additional audits may be performed by Abbott in case of non-conformance of the quality system or to ensure corrective actions from previous audits have been completed. Distributor will allow QA department representatives to have access to the Facilities for audit purposes. Such representatives will be escorted at all times by Distributor personnel while at the Facilities. Abbott will provide, at a minimum, 30 days notification to Distributor for all planned quality audits. However, the Parties agree that a shorter notice period may be warranted under exceptional circumstances. In either case, the Parties will act reasonably to agree on a date and scope for the audit. Distributor shall ensure that in the cases of non-conformances, investigations and actions are taken and documented to prevent re-occurrence Distributor will respond to all issues of non-conformance and other issue(s) identified in the audit of Abbott within 30 days or such other timeframe as may be specified in the audit report, which response will include details of any corrective actions taken or to be taken within the suggested timeframe indicated by Distributor.