



**NewYork-Presbyterian Hospital
NewYork Weill Cornell Medical Center
Department of Food & Nutrition**

**HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) PLAN
FOR ENTERAL FEEDING PREPARATION AND ADMINISTRATION**

FLOW PROCESS	HAZARD	CONCERN: CCP or CP	CONTROL CRITERIA	MONITOR METHOD: Procedure	ACTION PLAN: Criteria Failure
Purchase ↓	Contamination of enteral feeding products by chemical, microbiological or particulate matter; breakdown in quality control at point of production.	CP (CONTROL POINT)	<ul style="list-style-type: none"> Purchase from approved, inspected and certified vendors. 	<ul style="list-style-type: none"> Monitor vendors for adherence to purchasing specifications. Inspect delivery upon receipt. Receive notification from vendors/FDA regarding quality control issues. 	<ul style="list-style-type: none"> Reject delivery not adhering to specifications without exception. Follow food recall procedures to address quality control issues.
Receiving ↓	Contamination of enteral feeding products by chemical, microbiological or particulate matter through improper receiving methods.	CP	<ul style="list-style-type: none"> Verify delivery based upon receiving criteria. Immediately remove received enteral feeding products for appropriate storage. 	<ul style="list-style-type: none"> Monitor receiving process and vendor adherence to specifications for delivery. Document vendor problems on Vendor Receiving Report. 	<ul style="list-style-type: none"> Coach/counsel employees in proper receiving techniques. If necessary, revise receiving procedures according to HACCP guidelines.
Storage ↓	Contamination of enteral feeding products by chemical, microbiological or particulate matter due to improper storage and handling procedures.	CP	<ul style="list-style-type: none"> Liquid protein module: verify adherence to temperature standards for freezer units prior to thawing and for refrigeration units during/after thawing. MCT module and all other products: prevent from freezing and store at < 86° F. Verify the correct temperature for dry storage areas. Verify adherence to “first in first out” (FIFO), safety and sanitation standards in all storage areas. Remove dented cans from circulation. 	<ul style="list-style-type: none"> Monitor temperatures in refrigeration/freezer units and dry storage areas. Monitor product expiration dates. Verify safety and sanitation process by conducting monthly Safety and Sanitation Inspections. 	<ul style="list-style-type: none"> Immediately remove enteral feeding products in affected refrigerator/freezer to a unit that is operating within standards; discard mixed or portioned product that has exceeded 2 hour limit of storage without temperature regulation. Shut down and repair refrigerators/freezers unable to maintain temperature standards. Remove products in affected dry storage areas to an area that meets temperature standard. Return to vendor/discard products that have exceeded

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<p style="text-align: center;">↓</p> <p style="text-align: center;">Thaw</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Preparation</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Cold Holding</p> <p style="text-align: center;">↓</p>					<p>expiration date as noted by the manufacturer.</p> <ul style="list-style-type: none"> Return dented cans to vendor. Coach/counsel employees in monitoring and action procedures.
	Contamination of enteral feeding products due to inappropriate thawing and/or utilization of thawed item beyond specified time frame.	CCP (CRITICAL CONTROL POINT)	<ul style="list-style-type: none"> Thaw liquid protein module and Unsweetened Health Shakes completely using approved method of thawing under refrigeration only. Do not thaw at room temperature. Label each unopened carton of liquid protein module with the date placed in the refrigerator for thawing. If unopened and unused after 5 days, the product is to be discarded. Unsweetened Health Shakes are labeled with an expiration date 12 days from transfer from freezer to thaw under refrigeration. 	<ul style="list-style-type: none"> Monitor thawing temperature. <i>Do not use until completely thawed.</i> Verify thawing schedule to enteral formula production schedule. 	<ul style="list-style-type: none"> Thaw fully if frozen and reject items of questionable quality. Discard thawed items that have exceeded expiration date. Coach/counsel employees in proper thawing methods. If necessary, revise thawing procedures according to HACCP guidelines.
	Introduction of microbes, chemicals or particulates by process and/or equipment cross contamination and/or employees.	CP	<ul style="list-style-type: none"> Train employees in proper enteral feeding product handling techniques and sanitation. Wash hands prior to preparing feedings or modular components. Prepare according to enteral formula recipe. Use tap water for reconstituting Pediatric Vivonex and Ceralyte. See Departmental HACCP Plan Section 4. <i>Note: Sterile water is used for the preparation and dilution of enteral feedings for neonates, For adult and pediatric feedings, distilled or sterile water is used upon specific order only.</i> Clean and sanitize equipment and utensils prior to use. Protect enteral feeding products from cross contamination. 	<ul style="list-style-type: none"> Verify cleaning and sanitizing process. Observe that separation of enteral feeding products and raw or processed food items and cleaning compounds is maintained. Verify adherence to enteral formula orders and recipes. 	<ul style="list-style-type: none"> Discard questionable enteral for-mula ingredients. Reject ingredients not meeting acceptance criteria. Coach/counsel employees in proper enteral formula preparation methods. If necessary, revise enteral formula preparation procedures according to HACCP guidelines.
	Spores germinate and microorganisms multiply at	CCP	<ul style="list-style-type: none"> Seal, label and date (date opened) opened cartons of liquid protein module used in EFPL. Store and hold under refrigeration at $\leq 40^{\circ}$ F. 	<ul style="list-style-type: none"> Monitor refrigeration temperature and verify accuracy of temperature monitoring device. 	<ul style="list-style-type: none"> Monitor refrigeration temperature for $\leq 40^{\circ}$ F. If temperature standards are not being met, immediately

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 Delivery to Nursing Unit 	temperatures above 40° F.		Discard any open carton that has been unused after 48 hours of opening. <ul style="list-style-type: none"> • Seal, label and date (date opened) opened bottles of MCT oil used in EFPL. Store and hold in dry storage (do not refrigerate). Discard any open bottle that has been unused after 3 months of opening. • Seal, label and date (date opened) opened cans of Polycose and Promod. Discard any opened can that has been unused after 1 month of opening. • Seal, label: formula, rate of administration, patient name, room # and date (date prepared) all reconstituted mixed enteral formula and portioned protein, fat or carbohydrate modules. • With the exception of unopened cans of enteral formula, MCT oil and powdered CHO module (which are stored at room temperature), store any mixed, reconstituted or portioned modules under refrigeration at ≤ 40° F until delivered to patient care units for administration. • Verify temperature accuracy of refrigeration monitor. • Inventory product to detect items at or near expiration. 	<ul style="list-style-type: none"> • Conduct daily inventory of prepared or open enteral feeding products to verify expiration and discard procedures. 	not being met, immediately remove prepared or open enteral feeding products to refrigerator that maintains the required temperature. <ul style="list-style-type: none"> • Coach/counsel employees in enteral feeding product monitoring methods. • Discard formulas that have exceeded shelf life criteria.
	Surviving microorganisms can grow in inadequately maintained mixed enteral feeding products. Spores that survived can begin to grow during the inadequate temperature delivery process.	CP	<ul style="list-style-type: none"> • After preparation, enteral feeding products will be stored on dinner meal service carts under refrigeration until delivered to nursing units according to delivery schedule. 	<ul style="list-style-type: none"> • Monitor timeliness of delivery of enteral feeding products to nursing units. 	<ul style="list-style-type: none"> • Discard mixed or portioned product that has exceeded 2 hour limit of storage without temperature regulation. • Coach/counsel employees in enteral feeding product delivery procedures. • If necessary, revise delivery procedures according to HACCP guidelines.

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<p style="text-align: center;">↓</p> <p>Cold Holding On Nursing Units</p> <p style="text-align: center;">↓</p>	Chemical and particulates cannot be destroyed.				
	Surviving microorganism can grow in inadequately maintained mixed or open enteral feeding products. Spores can survive and begin to grow during the inadequate refrigeration holding process. Chemical and particulates cannot be destroyed.	CCP	<ul style="list-style-type: none"> • Verify that all mixed enteral formulas, modular components and open containers of enteral feeding products are sealed, labeled as to contents, patient name, room # and dated. • Store and hold mixed enteral feeding formulas and liquid protein module under refrigeration at ≤ 40° F in nourishment station refrigerators. • Verify temperature accuracy of refrigeration monitor. Inventory product to detect items at or near expiration. All mixed enteral formulas, opened containers of formula or containers of liquid protein module, MCT oil, CHO powder or protein powder are discarded 24 hours after the production date by Food & Nutrition staff. Opened cans of enteral formula are to be discarded by Nursing staff and are not to be stored in the refrigerator. 	<ul style="list-style-type: none"> • Monitor refrigeration temperature and verify accuracy of temperature monitoring device. • Conduct daily inventory of prepared or open enteral feeding products to verify expiration and discard procedures. 	<ul style="list-style-type: none"> • Monitor refrigeration temperature for ≤ 40° F. If temperature standards are not being met, immediately remove prepared or modular components to a refrigerator that maintains the required temperature. • Coach/counsel employees in enteral feeding product monitoring methods. • Discard formulas that have exceeded shelf life criteria.
<p>Enteral Feeding Administration</p> <p style="text-align: center;">↓</p>	All enteral feeding products, at room temperature, can support microbial growth. Formula manipulation or using procedures that increase handling of formulas or administration systems increases the potential for contamination.	CCP	<ul style="list-style-type: none"> • Wash hands prior to handling feedings and administration systems. • Avoid touching any part of the container or administration system that will come in contact with the feeding. • Inspect seals and reservoirs for damage prior to utilization. • Assemble feeding systems on a clean, dry, disinfected surface. • Avoid adding medications directly to the feeding. If necessary, flush tube after administration with tap water. • Date/time each component of the system also indicating patient name and formula (on feeding bag). <i>Limit hang time of feeding to 4 hours.</i> • Empty feeding bags of product completely prior to pouring newly 	<ul style="list-style-type: none"> • Monitor staff for adherence to proper enteral feeding administration techniques. 	<ul style="list-style-type: none"> • Discard product that has exceeded limit for hang time. • Coach/counsel staff on proper enteral formula administration procedures. • If necessary, revise enteral formula administration procedures according to HACCP guidelines.

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<p style="text-align: center;">↓</p> <p>Sanitize (On-going process through various stages of the system)</p>			<p>opened product into the bag.</p> <ul style="list-style-type: none"> • Use administration sets with Y-ports and drip chambers and cap disconnected sets. • Position container to prevent reflux of feeding up the feeding set. • Irrigate feeding tube with tap water (or as specified). • Change administration sets every 24 hours. 		
	<p>Destruction of microbes during the cleaning and sanitizing process. Introduction of microbes, chemicals or particulates by cross contamination and/or employees.</p>	<p>CP</p>	<ul style="list-style-type: none"> • Train employees in proper enteral feeding product handling techniques and sanitation. • Clean and sanitize surfaces, equipment and utensils prior to use. • Protect products from contamination. 	<ul style="list-style-type: none"> • Verify cleaning and sanitizing process. • Observe that separation of enteral feeding preparation and storage and sanitation processes is maintained. 	<ul style="list-style-type: none"> • Re-clean and re-sanitize all preparation equipment. • Coach/counsel employees in proper sanitation procedures. • Discard enteral feeding products contaminated during sanitation process. • If necessary, revise sanitation procedures according to HACCP guidelines.