Hazard Analysis Critical **Control Point Process**









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HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

HACCP is an effective and rational means of assuring food safety from harvest to consumption. Preventing problems from occurring is the paramount goal underlying any HACCP system.

For a successful HACCP program to be properly implemented, management must be committed to a HACCP approach. A commitment by management will indicate an awareness of the benefits and costs of HACCP and include education and training of employees. Benefits, in addition to enhanced assurance of food safety, are better use of resources and timely response to problems.

7 Principles of HACCP for the Food Industry

HACCP is a seven-step process, which must be continuously updated to ensure a company has a preventative system of hazrd control in place to maintain food safety. The seven steps of the HACCP system address the analysis and control of biological, chemical and physical hazards.

1	Conduct Hazard Analysis - Prepare a list of steps in the process where significant hazards could occur.
2	Establish Critical Control Points - A critical control point is a point, step or procedure at which control can be applied and a food-safety hazard can be prevented, eliminated or reduced to an acceptable level
3	Establish Critical Limits - These are the scientific limits that establish whether or not a process is in control.
4	Establish Monitoring Procedures - These are necessary to eliminate or reduce hazards that have been established. These procedures monitor the process within the critical limits for food safety.
5	Establish Corrective Action - Predetermined corrective action should take place if a process goes out of control, as indicated.
6	Verification - This is the principle within HACCP that makes the system self-correcting and double-checked. A third party must be the verifier.
7	Record-keeping - This is an HACCP requirement that must be kept to support most of the prerequisite programs. HACCP programs take into consideration CCPs that could severly compromise food safety.

Source: "A Uniform approach to HACCP," by Dr. Al Baroudi, President, Food Safety Institute International

HACCP Program Definitions

- AAMI Association for the Advancement of Medical Instrumentation
- ANSI American National Standards Institute
- **ATP -** Adenosine Triphosphate
- BRC British Retail Consortium
- **CCP -** Critical Control Point
- Chemical Hazard Laundry chemicals used while washing garments
- **EPA -** Environmental Protection Agency
- FSMA Food Safety Modernization Act
- **GFSI -** Global Food Safety Initiative
- **GMP** Food Manufacturing Practices
- HACCP Hazard Analysis Critical Control Point
- HARPC Hazard Analusis and Risk-Based Preventative Controls

Hygienically Clean Garments - Free of pathogens in sufficient numbers to cause human illness (ANSI/AAMI ST 65:2008)

Microbial Hazard - Pathogen that survives the laundering process

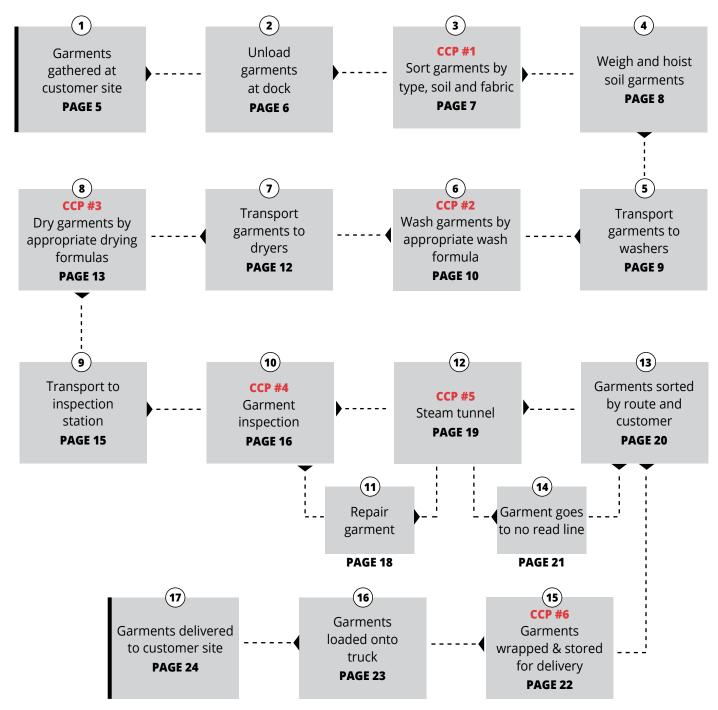
Physical Hazard - Any loose item that should not be on the garments or that can contaminate food

PPE - Personal Protective Equipment

SQF - Safe Quality Food

AUT







Soiled garments gathered at customer and segregated by type of garment in plastic bags. Soiled garments are transported to production facility in plastic bags or garment cages to avoid cross contamination with other microbial soiled garments.

CONTROLS

- Garment rental customer Phase 2 Installation
- AbsorbU GSE Training
- Proper Personal Protective Equipment (PPE)
- Designated carts and tubs for soil pick-ups

VALIDATION

- Auditing of routes (dock auditor)
- Scheduled internal HACCP audit
- Customer onsite audits

POTENTIAL HAZARDS



Physical Hazards

Soiled garments



Microbial Hazards

- Soiled garments
- Cross contamination from other soiled products



Chemical Hazards

None





Garments are removed from route trucks or relays and moved to garment soil sorting area.

CONTROLS

- Cart repair identification
- Relay truck unloading
- Route truck unloading
- Auditing of routes
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

Monthly Sonic Aire delinting

VALIDATION

- Auditing of Routes (dock auditor)
- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB

POTENTIAL HAZARDS

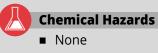


- **Physical Hazards**
- Soiled garments
- Vehicle properly aligned with dock



Microbial Hazards

Soiled garments







Garments are soil sorted by type of garment (i.e. shirts vs. pants) and by color of garment (i.e. color shirt vs. white shirt) and loaded into segregated garment only slings.

CONTROLS

- Soil Garment Sorting
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

Monthly Sonic Aire delinting

VALIDATION

- Scheduled internal HACCP audit
- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits







Slings of soiled garments sorted by soil and type are weighed to ensure proper washer load size. Prior to hoisting up soil garments operator selects monorail storage line for garments.

CONTROLS

- CEPr 5.1.1 attachment 2b- Equipment and gauges calibration list (New Berlin)
- New Berlin soil garment sorting
- NBWI4.6.86 Hoist Inspection
- NBWI 4.6.89 Safe Sling Practices and Methods
- NBWI4.6.90 Trolley and Sling Inspection
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

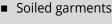
- Monthly hoist inspections
- Annual OSHA required hoist inspections
- Monthly Sonic Aire delinting

VALIDATION

- Scheduled internal HACCP audit
- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits

POTENTIAL HAZARDS

Physical Hazards





Microbial Hazards

- Soiled garments
- Inaccurate weighing of soiled garments



Chemical Hazards

None





GARM13 (11-16)

Transport garments to washer

DESCRIPTION

Garments are released from hoist onto the monorail system to await washing.

CONTROLS

- NBWI 4.6.86 Hoist Inspections
- NBWI 4.6.89 Safe Sling Practices and Methods
- NBWI 4.6.90 Trolley and Sling Inspection
- Cart repair identification

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Quarterly monorail inspections
- Monthly Sonic Aire delinting

- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits







Operator brings soil garment slings to washer and loads into washer. Empty soiled garment slings are then transported on the monorail back to soiled hoist sling staging line. Operator enters proper wash formula into the washer key pad and into washer that matches garment type and color being washed. Operator starts the wash cycle. Optimal food soil specific wash formulas:

- Fresh water only for washing food processing garments
- Proper chemistry is utilized to provide optimal food soil removal and suspension
- Wash formula structure with good mechanical action aids in physical soil & microbial removal for optimal cleanliness & quality
- Dilution effect from multiple rinses suspends soil/microorganisms and rinses them down the drain
- pH swings (alkaline & acids) provides ranges of soil removal opportunities, microbial pH intervention and proper final pH for skin control of garments (acidic)
- Wash formulas are monitored for temperature greater than 160 degrees F for at least 25 minutes, chemistry delivery and proper final pH of garment
- Utilization of EPA registered laundry disinfectant (Advacare) rather than chlorine bleach

CONTROLS

All hard surfaces of washer where garments contact are regularly disinfected to minimize cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- Air Operating Permit
- Wastewater Discharge Permit

POTENTIAL HAZARDS Physical Hazards None Microbial Hazards Incorrect wash formula selected



Chemical Hazards

 Laundry chemicals used in wash process

Forduction 14 years at ITU AbsorbTech

- Washer program list
- 75LBS wascomat log
- Machine 1-9 (80lb, 135lb, 450lb, 900lb) washer log
- Chemical tank inspection- bulk tanks
- Chemical tank inspection- day tanks
- NBWI4.6.00 Washroom & dryer room operation overview
- NBWI4.6.22 Washer start up and shutdown
- NBWI4.6.24 Washer (w7) 135lb operation
- NBWI4.6.28 Ellis 900lb washer 1 operation
- NBWI4.6.34 Small washer 75lb wascomat operation
- NBWI4.6.57 Change chemical drums
- NBWI4.6.92 Ellis VOC 900lb washer 2 operation
- NBWI4.6.93 Washer 4 ellis 450lb operation
- NB4.6.97 Ellis 900lb washer 3 operation
- NBWI4.6.102 washer (8&9) 80lb unimac operation
- NBWI4.6.103 open pocket washer extractor operation

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly washer inspections
- Monthly washer inspections
- Monthly Sonic Aire delinting
- Yearly washer inspections

- Monitored monthly by a trained ECOLAB specialist
 - Calibration of dispensing system for proof of chemical delivery
 - Titration of wash formulas for proof of chemical delivery & optimal pH, detergency, oxidation parameters
 - Written service report proving titration results, other findings and recommendations
- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled Internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits



Operator unloads washer into slings or carts. Operator then hoists the slings and sends to dryer area or rolls the cart to dryer area. Braun washer unloads directly onto shuttle and takes directly to Braun dryer.

CONTROLS

All hard surfaces of carts where garments contact are regularly disinfected to minimize cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- NBWI 4.6.89 Safe Sling Practices and Methods
- NBWI 4.6.90 Trolley and Sling Inspection
- NBWI 4.6.00 Washroom and Dryer Room Operation Overview
- NBWI 4.6.103 Open-Pocket Washer Extractor Operation
- NBWI 4.6.104 Washer 6 200 lb. Braun Operation
- NBWI 4.6.93 Washer 4 Ellis 450lb Operation
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

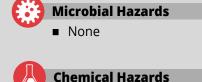
- Monthly hoist inspections
- Monthly lift inspections
- Monthly Sonic Aire delinting
- Quarterly monorail inspections

VALIDATION

- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits



POTENTIAL HAZARDS



None



Operator unloads slings or carts into dryer. Operator enters proper dry formula/time into dryer controls for garment type being dried. Operator starts the dry cycle. Washer unloads onto shuttle and directly into dryers. Dryers start per formula used for washing.

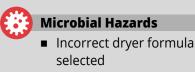
Dryers Formula Temperatures are greater than 160 degrees F

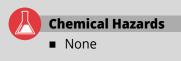
CONTROLS

All hard surfaces of dryers and carts where garments contact are regularly disinfected to minimize crosscontamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- NBWI 4.6.00 Washroom and Dryer Room Operation Overview
- NBWI 4.6.25 Dryer 5 Operation
- NBWI 4.6.27 Ellis Whisper 450lb Dryer 1&2 Operation
- NBWI 4.6.37 Small Dryer 13 Operation
- NBWI 4.6.39 Cleanout Dryer Basket Holes
- NBWI 4.6.49 Lint Collector
- NBWI 4.6.81 Small Dryer 11 & 12 Operation
- NBWI 4.6.85 Small Dryer 11 & 12 Temp Controls Setting
- NBWI 4.6.89 Safe Sling Practices and Methods
- NBWI 4.6.90 Trolley and Sling Inspection

POTENTIAL HAZARDS Physical Hazards None







GARM13 (11-16)

- NBWI 4.6. 103 Open-Pocket Washer Extractor Operation
- CEPR 5.1.1 Attachment 2b Equipment and Gauges Calibration List (New Berlin)
- Environmental Management System Reference CHALLENGE Dryer 5 Settings
- Environmental Management System Reference WHISPER Dryer 1 Settings
- Environmental Management System Reference WHISPER Dryer 2 Settings
- Dryer 1-13 load log
- Dryer Daily Visual Lint Trap Check
- Air Operating Permit
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Daily dryer inspections
- Weekly dryer inspections
- Monthly dryer inspections
- Monthly Sonic Aire delinting

- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits



Operator moves clean dry garments from dryer area to steam tunnel staging area.

CONTROLS

All hard surfaces of carts where garments contact are regularly disinfected to minimize cross-contamination of clean garments on surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- Cart Identification
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

Monthly Sonic Aire delinting

VALIDATION

- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor -ECOLAB
- Customer onsite audits



POTENTIAL HAZARDS





Critical Control Process #4

DESCRIPTION

Clean garments are removed from the garment cart and placed on a hanger. During this process the operator visually inspects the clean garment per the Corporate-Garment Quality Specifications. If the clean garment does not meet the Corporate- Garment Quality Specifications the garment's RFID chip is scanned into the mending RFID antenna, placed on the steam tunnel conveyor, travels through the steam tunnel and drops off the conveyor to the garment mending area.

CONTROLS

All hard surfaces of carts where garments contact are regularly disinfected to minimize cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- NBWI 4.6.02 Tunnel start-up and shutdown
- NBWI 4.6.08 Steam tunnel operators
- Corporate- Garment Quality Specifications
- Inspect, fold, and sort aprons and coveralls
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

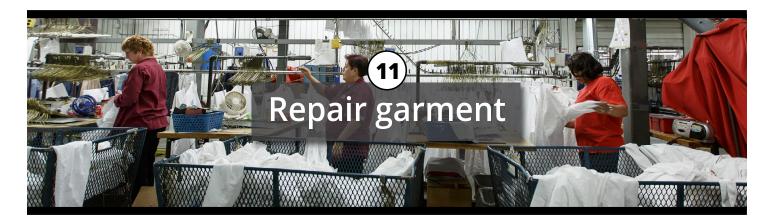
- Weekly steam tunnel inspection
- Monthly steam tunnel inspection
- Monthly Sonic Aire delinting

POTENTIAL HAZARDS



- Quarterly steam tunnel inspection
- Yearly steam tunnel inspections

- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits



All garments are visually inspected for necessary repairs and the repair is performed. After garment is repaired the garment is placed on the steam tunnel conveyor sent through the steam tunnel for proper microbial intervention.

CONTROLS

All hard surfaces where garments contact are regularly disinfected to minimize cross-contamination of clean garments on surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- Corporate- Garment Quality Specifications
- Button Installation
- Garment Mending
- Snap Installation
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Monthly Sewing Machine Inspection
- Monthly Button Machine Inspection
- Monthly Sonic Aire delinting

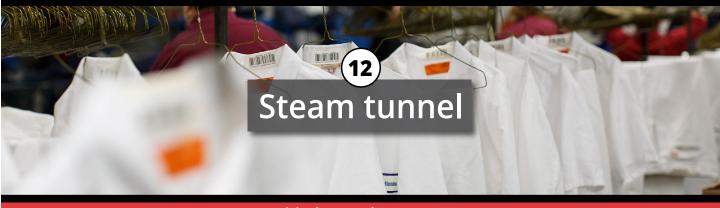
VALIDATION

- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor -**ECOLAB**
- Customer onsite audits

POTENTIAL HAZARDS







Critical Control Process #5

DESCRIPTION

Garments travel through a steam tunnel set at 300 degrees Fahrenheit allowing the actual garment temperature to reach 285 degrees Fahrenheit. The garment travels through the steam tunnel for approximately 4 ½ minutes to ensure proper microbial intervention and to ensure proper garment finishing (i.e. removal of wrinkles).

CONTROLS

- NBWI 4.6.02 Tunnel start-up and shutdown
- NBWI 4.6.08 Steam tunnel operators
- Spindle Monitoring Program

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly Steam Tunnel Inspection
- Monthly Steam Tunnel Inspection
- Monthly Sonic Aire delinting
- Quarterly Steam Tunnel Inspection
- Yearly Steam Tunnel Inspection

- Monitored monthly by a trained ECOLAB Specialist who provides a written service report regarding the steam tunnel performance
- 14001 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits





Garments travels through a designate sort room via the RFID chip where the operator visually inspects the clean garment per the Corporate- Garment Quality Specifications. As the garment travels through the sort room the clean garments are sorted and prepared by customer for each route.

CONTROLS

- Corporate- Garment Quality Specifications
- Garment Sort Room Operation
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly Sort Room Inspections
- Monthly Sort Room Inspections

- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor -ECOLAB
- Customer onsite audits







Garments travels through a designate sort room via the RFID chip where the operator visually inspects the clean garment per the Corporate- Garment Quality Specifications. As the clean garment travels through the sort room the clean garments will go to a no read line if the RFID antenna is unable to read the RFID chip. Once a new RFID is assigned to the garment it is sent back to Steam Tunnel: CCP#5.

CONTROLS

All hard surfaces of carts where garments contact are regularly disinfected to minimize cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- Corporate- Garment Quality Specifications
- Garment Sort Room Operation
- Bag and Tag Garment Processing

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly Sort Room Inspections
- Monthly Sort Room Inspections

VALIDATION

- ATP testing of table top
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits







Final inspection on the clean garments is performed by the operator per the Corporate- Garment Quality Specifications. The clean garments are wrapped appropriately to minimize cross-contamination and are now ready for delivery back to the customer site.

CONTROLS

- Designated lined clean only garment carts or tubes for transportation
- Final Loading Check
- Garment Sort Room Large Side Loading
- Garment Sort Room Operation
- Garment Sort Room Small Side Loading
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly Sort Room Inspections
- Monthly Sort Room Inspections

VALIDATION

- Monitored monthly by a trained ECOLAB specialist
 - Monthly hygienically clean testing for textiles is performed by chemists at ECOLAB
 - Routine ATP Testing on customer specific garments worn in food services and operations
- ATP testing of garment cages/tubs
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor ECOLAB
- Customer onsite audits



POTENTIAL HAZARDS



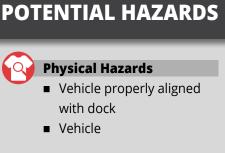


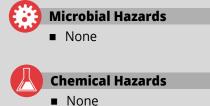
Load clean wrapped garments from rail, cart, or cage onto route truck.

Controls

- Route Truck Loading
- Load Garments
- Set Up for Route Truck Loading
- Final Loading Check
- AbsorbU Genuine Service Excellence training
- Proper Personal Protective Equipment (PPE)
- Designated lined clean only garment carts or tubs for transportation

- Auditing of Routes (dock auditor)
- 14001 employee training matrix
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor -ECOLAB
- Customer onsite audits









Clean wrapped garments are driven to customer site. Garments are stored in designated location at the customer site as directed by the customer.

CONTROLS

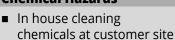
- Garment rental customer phase 3 How to service (RSSR's)
- AbsorbU Genuine Service Excellence training
- Proper Personal Protective Equipment (PPE)

VALIDATION

- Auditing of Routes (dock auditor)
- Scheduled internal HACCP audit
- Customer onsite audits

POTENTIAL HAZARDS







All employees receive documented training in personal hygiene, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

CONTROLS

- AbsorbU Genuine Service Excellence and Certified Production Excellence training
- Master sanitation schedule

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

 Updates to the training material are made when changes are made to the Safe Quality Foods (SQF) certification program which is recognized by the Global Food Safety Initiative (GFSI), recommended improvements by our customers, or internal changes are identified

Validation

- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor -ECOLAB
- Customer onsite audits





Our pest control vendor performs monthly inspections for any type of pest activity. Changes to the inspection may result from the findings or from customer audits.

CONTROLS

- 14001-2004 contractor vendor/visitor log
- 14001-2004 contractor/vendor/visitor personal hygiene training as part of orientation package
- Pest control managed program

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

Corrections made based on monthly vendor recommendations

- Scheduled internal HACCP audit
- Customer onsite audits
- Scheduled external HACCP audit with chemical vendor ECOLAB



Description

Describe the process used for acting on actual and potential non-conformances identified in the HACCP system including corrective action with intent to correct system flaws by addressing root causes rather than just fixing the immediate incident only

Controls

- HACCP corrective action procedure
- HACCP corrective action tracking form

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

 Updates to the corrective action procedure or forms are made when changes are made to the Safe Quality Foods (SQF) certification program which is recognized by the Global Food Safety Initiative (GFSI), recommended improvements by our customers, or internal changes are identified

Validation

- Scheduled internal HACCP audit
- Customer onsite audits
- Scheduled external HACCP audit with chemical vendor ECOLAB

ITU AbsorbTech HACCP System Procedure Nonconformity, Corrective & Preventive Action

1.0 Purpose

To describe the process used for acting on actual and potential non-conformances identified in our HACCP process including corrective and preventive action with the intent to correct system flaws by addressing root causes, rather than just fixing the immediate incident only.

2.0 Scope

All covered portions of the ITU AbsorbTech management systems

3.0 Definitions

AoC = Area of Concern (system weaknesses or not following the management system in place)

Corrective action = action to eliminate the cause of a detected nonconformity or other undesirable situation

CRM = an electronic system used to track customer activity and requests

Incident = an event that may result in a crisis or nonconformity.

Non-conformance = a situation where the actual condition is not in accordance with planned conditions.

OFI = Opportunities for Improvement (recommendations to the management system) Preventive action = action initiated to prevent breakdown, crisis or potential nonconformity Requirement – need or expectation that is stated, generally implied or obligatory

4.0 Statement of Work - Responsibility / Action

This procedure also requires that trends in corrective actions be evaluated to see if deeper-rooted preventive actions can also be implemented. Inputs that are evaluated for potential corrective or preventive actions include, but are not limited to OFIs, audit findings, score cards, safety audits, process audits, incident evaluations, customer communications, and inspection reports. Results of corrective actions taken must be recorded and retained; as well as reviews performed on the effectiveness of actions taken.

4.1 All Employees

Identify nonconformity or potential nonconformity and if possible, its source. Nonconformities and potential nonconformities are identified in real time and through reviews.

- 4.2 When competent to do so, take steps to bring process, equipment or procedure back into conformity. Steps taken to bring equipment or process back to conformity can include, but are not limited to:
 - a. Turn off equipment
 - b. Adjust gauges
 - c. Get help
 - d. Alert appropriate manager/ lead person / operator
 - e. Complete paperwork and forward as appropriate

4.3 Appropriate Manager / Maintenance

Contact the HACCP Team and provide a copy of all applicable information

ISSUED	REV-DATE	PAGE	APPROVAL	FOLDER	FILE NAME
11/05/12	10/09/15	1 of 4	ON FILE	Procedures	C EPr 5.3.1 Nonconformity, Corrective
					And Preventive Action
Review Date:	10/09/15				
Printed 11/29	/16				

ITU AbsorbTech HACCP System Procedure Nonconformity, Corrective & Preventive Action

whenever an incident relates to the HACCP system. If unsure about applicability, a copy of the form or report or other communication should be forwarded to the team for review.

If customer related, forward information to both the appropriate Service & Sales manager and to the HACCP Team as appropriate.

4.4 HACCP Team / Responsible Group or Individual(s)

Review incident evaluations, documents, issue or other communication methods with responsible group or individual(s) as needed. Assign tasks to resolve. If not an HACCP related issue, follow normal practices. Proceed to step 4.5 if related to MS.

Actions on unrelated items will be handled per the originating document process. If review warrants, initiate a Form 1 – Corrective Preventive Action.

4.5 HACCP Team, Responsible Group or Individual(s)

Record actions taken to repair or correct smaller incidents and related decisions in the meeting minutes.

- a. Actions could be changing PM frequency or writing an OFI.
- b. Decisions could be: Do nothing, forward to appropriate department, correct the situation, investigate further, initiate corrective / preventive action form, and perform a RCA.
- c. Decisions and actions should be initiated in a timely manner.

Initiate a corrective / preventive action form when an incident warrants an MS action.

- a. Investigate: gather any reports or forms that were completed, interviews (re-interview if needed.) with persons involved, photographs, other externally supplied documents, HACCP records, and other as appropriate to the incident.
- b. Initiate a root cause analysis when appropriate.
 - i. <u>Form 2 Multiple Whys</u> or <u>Corporate Root Cause Analysis</u> or other may be used_to determine true cause(s).
 - ii. If a root cause cannot be determined, develop preventive action measures to ensure future occurrences have minimal impacts.
- c. Determine action.
 - i. Assign tasks
 - ii. Include responsible group or individual(s)
 - iii. Include immediate and long term actions to correct and prevent incident from occurring.
 - iv. Include anticipated implementation.
- d. Determine effectiveness measures. Include measures of evaluating actions taken relative to the desired result.

Maintain the HACCP Corrective / Preventive Action Log.

ISSUED 11/05/12	REV-DATE 10/09/15	PAGE 2 of 4	APPROVAL ON FILE	FOLDER Procedures	FILE NAME C EPr 5.3.1 Nonconformity, Corrective And Preventive Action
Review Date: Printed 11/28/*					

ITU AbsorbTech HACCP System Procedure Nonconformity, Corrective & Preventive Action

4.6 Responsible Group or Individual(s)

Complete assigned tasks and report back to HACCP Team.

4.7 HACCP Team

Review Corrective / Preventive Action Log or the System Improvement Log per the facility HACCP Team Task Guides.

4.8 HACCP Team / Responsible Group or Individual(s)

Monitor effectiveness of actions on appropriate time schedule (typically done in the quarter following completion unless otherwise noted.) Follow up reviews on action effectiveness may include, but are not limited to:

- a. Process or task compliance
- b. PM's completed
- c. Proper form(s) have been completed
- d. Proper records being kept and up to date
- e. Likelihood of recurrence reduced
- f. Impact of recurrence reduced
- g. Material use reduced
- h. Revisions made to existing documents; or created where none exist
- i. Work instructions being followed
- j. New equipment purchases
- k. Personnel informed and trained on changes
- I. Aspect review

If results were ineffective, return to step 4.5.

Once the effectiveness review has been conducted, a satisfactory resolution has been adopted and action taken deemed effective, it is considered complete. Record results and retain for 3 years. If concern directly affected or was initiated by a customer the resolution is recorded in the CRM data base.

4.9 Appropriate Manager

Communicate actions/solutions as appropriate.

5.0 Special Circumstances

All nonconformance and areas of concern findings found during internal audits will be followed up by initiating a corrective action and by performing a root cause analysis.

6.0 Records

Form 1 – Corrective Preventive Forms Form 2 - Multiple Whys or Corporate Root Cause Analysis Facility Corrective / Preventive Action Logs

7.0 Reference Documents

ISSUED	REV-DATE	PAGE	APPROVAL	FOLDER	FILE NAME
11/05/12	10/09/15	3 of 4	ON FILE	Procedures	C EPr 5.3.1 Nonconformity, Corrective And Preventive Action

Printed 11/28/16

ITU AbsorbTech HACCP System Record Form 1 - Corrective / Preventive Action Form

Corrective / Preventive Action Subject					Fa	acility		
Choose Action type:	Corrective	Preventive	CA or PA Form#		Date			
1. Result of audit finding?	Yes	No	2. Attachments? If yes, list or indicate None					
	. Describe the incident or concern. Clearly describe what happened to ensure all matters of concern are adequately addressed. Use additional space if eeded. Attach additional documentation when available.							
 Related Aspect? If yes, list b 	Related Aspect? If yes, list below or indicate None S. Related Regulation? If yes, list below or indicate None							
6. MS Team Review Date:		7. Investigation: Inf	erviewees, reports received	l, photographs, oth	er - attach available e	documents		
8. RCA completed? Yes. List	RCA method used.			No RCA - why not?				
9. Identified Root Cause(s) fro	om Multiple Whys or	other RCA:						
10. Corrective or Preventive Action(s) Steps - as a part of corrective / prevention action steps, change all associated procedures, work instructions, etc. or if applicable, create work instructions and logs, records, checklists or PMs where none exist; reference specific work instruction / procedure tilles in detail as applicable; list attachments and save in corresponding Attachment folder.		Responsibility	Notes		Target Date	Completion Date		
11. What is the expected resu	llt?							
12. Post Corrective / Preventi	ve Action Measurem	ent Effectiveness Re	eview Date:					
13. Did actions taken address identified root cause(s)?			Yes		No**			
14. Were action(s) taken effec	tive?		Yes			No**		
15. Actions/solutions commu	nicated?		Yes No		No**			
If No**, describe what additional actions are needed with responsibilities / dates, or state reason that the action must be delayed or cannot be completed.								

ITU AbsorbTech HACCP System Record Form 2 - RCA Multiple Whys

RCA#		
Statement of	Nonconformity	/ / Requirement Reference
	WHY?	
I	WHY?	
r!		
	W(1)/2	
	WHY?	
	WHY?	
L	ROOT CAUSE	
!		<u> </u>]

Revision Date: 11/13/13

1.0 QUALITY SYSTEMS/HACCP				
Description	Audit Findings	Score		
1.1 Suitability of Specifications				
1.2 Quality Manual/System Implemented				
1.3 Product Traceability Exercise				
1.4 Documented Work Instruction and Procedures				
1.5 Personnel Training and Records				
1.6 Complaint Handling				
1.7 Non Conforming Product - Segregation and Disposal				
1.8 Corrective Action Procedures				
1.9 Use of Sub Contractors (production/storage)				
1.10 Flow Diagram				
2.0 FACTORY	PREMISES AND LOCATION			
Description	Audit Findings	Score		
2.1 Condition of Perimeter/Yard				
2.2 General Condition of Buildings				
2.2 General Condition of Buildings				
2.2 General Condition of Buildings2.3 Condition of Floors				
2.2 General Condition of Buildings2.3 Condition of Floors2.4 Condition of Walls				
 2.2 General Condition of Buildings 2.3 Condition of Floors 2.4 Condition of Walls 2.5 Condition of Ceilings 				
 2.2 General Condition of Buildings 2.3 Condition of Floors 2.4 Condition of Walls 2.5 Condition of Ceilings 2.6 Condition of Doors 				
 2.2 General Condition of Buildings 2.3 Condition of Floors 2.4 Condition of Walls 2.5 Condition of Ceilings 2.6 Condition of Doors 2.7 Condition of Windows 				

2.11 Cleaning Records		
2.12 Condition and Cleanliness of Overheads		
2.13 Atmosphere/Air Conditions		
2.14 Air Filtration		
2.17 Flow of Drains		
3.0 P	ERSONAL HYGIENE	
Description	Audit Findings	Score
3.1 Changing Areas		
3.2 Conditions of Cloakrooms/Toilets		
3.3 Wearing of Protective Clothing Hats, Hairnets, Snoods		
3.4 Cleaning and Control of Protective Clothing		
3.5 Control of Jewellery, Watches, Nail Varnish, Body Piercing		
3.6 Type of Plasters		
3.7 Handwashing Facilities		
3.8 Use of Handwashing Facilities		
3.9 Restrictions on Smoking		
3.10 Is workwear worn in smoking room and toilets?		
3.11 Control of Food/Drink in Process Area		
3.12 Medical Screening		
3.13 Hygiene Training		
3.14 Control and Condition of Canteen		

4.0 INFESTATI	ON/ FOREIGN BODY CONTROL	
Description	Audit Findings	Score
4.1 Pest Control Contractor		
4.2 Pest Control Documentation/ Records		
4.3 Proofing of Doors		
4.4 Proofing of Windows		
4.5 Insectocutors		
4.6 Insect Control/Evidence		
4.7 Rodent Control/Evidence		
4.8 Bird Control/Evidence		
4.9 Waste Disposal		
4.10 Glass Risk/Control		
4.11 Foreign Body Risks and Elimination		
4.12 Machine Grease/Oil Risks		
5.0 RAW	MATERIALS CONTROL	
Description	Audit Findings	Score
5.1 Chemical/packaging specifications and records		
5.2 Audit of Raw Material Suppliers		
5.3 Approved Suppliers List		
5.4 Storage of Chemicals		
5.5 Segregation of Chemicals		
5.6 Stock Rotation and Records		
5.7 Control of Chemical Usage/traceability		
5.8 Storage/Inspection of Packaging		

	6.0 PROCESSING	
Description	Audit Findings	Score
6.1 Condition/cleanliness and Maintenance of		
Processing/Finishing and Storage Equipment		
6.2 Cleanliness of Processing and Storage		
Equipment		
6.3 Batch Control		
6.4 On line Inspection/ Quality Control Schedule		
and Records		
6.5 Process Control Charts/Records		
6.6 Calibration of Instruments		
6.7 Contamination Risk During Processing and		
Packing		
6.8 Operator Hygiene Practices During		
Processing and Packing		
6.9 Finishing/Packaging		
6.10 Coding		
7.0 1	PRODUCT QUALITY	
Description	Audit Findings	Score
7.1 Laboratory Facilities		
7.2 Audit of External Laboratory		
7.3 Laboratory Methods -Microbiological Analytical		
7.4 Chemical Analysis Schedule/Records		
7.5 Microbiological Analysis Schedule/Records		

8.0 PACKED PRODUCT STORAGE AND DISTRIBUTION				
Description	Audit Findings	Score		
8.1 Location of storage on or off site.				
8.1 Hygiene/Housekeeping of Stores				
8.2 Vehicle Hygiene Control				
8.3 Stacking of Cleaned Product				
8.4 Condition/Control of transport system. New or reused.				
8.5 Cleanliness of vehicles, schedule and records.				