

Hazard Analysis Critical Control Point Process



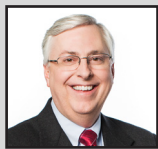
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Third Generation Owners

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HACCP Program Overview

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 hazard 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 severely 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 Analysis 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

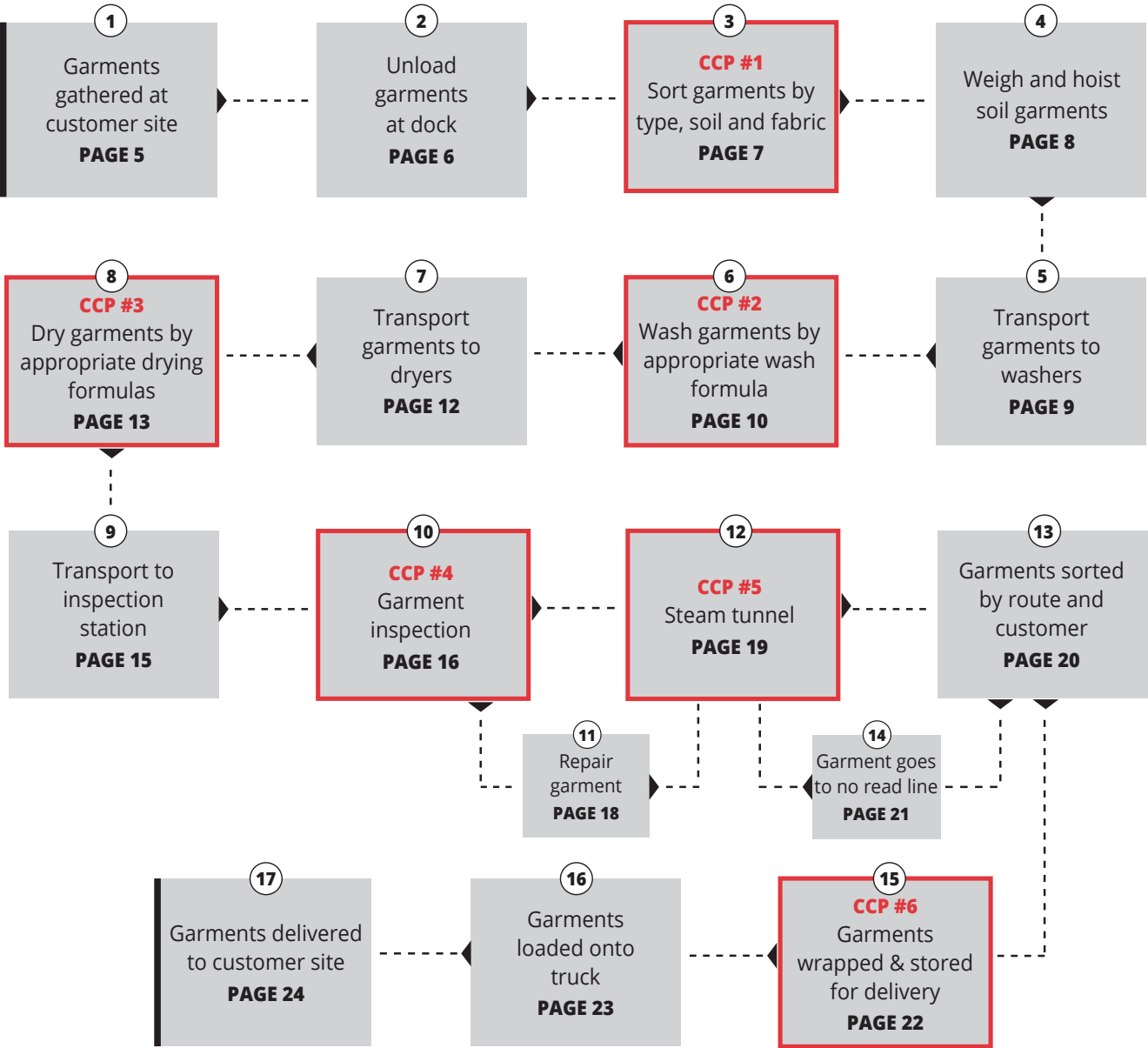
Physical Hazard - Any loose item that should not be on the garments or that can contaminate food

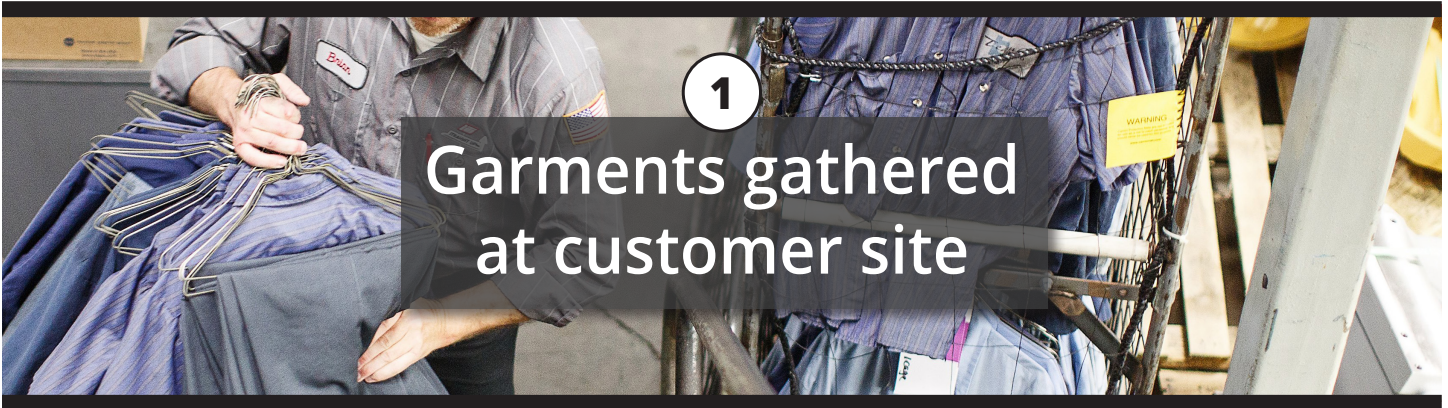
PPE - Personal Protective Equipment

SQF - Safe Quality Food



The following diagram depicts the flow of garments through the ITU AbsorbTech laundering process. It includes both process Control Points and Critical Control Points at each laundering stage. Each stage details Control and Preventative aspects which are covered under applicable ISO 14001 work instructions. All work instructions, and additional documentation referenced in this booklet, are included in the ITU AbsorbTech HACCP manual which is available for review during a site audit of our processing facilities.





DESCRIPTION

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 (Route Manager and 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



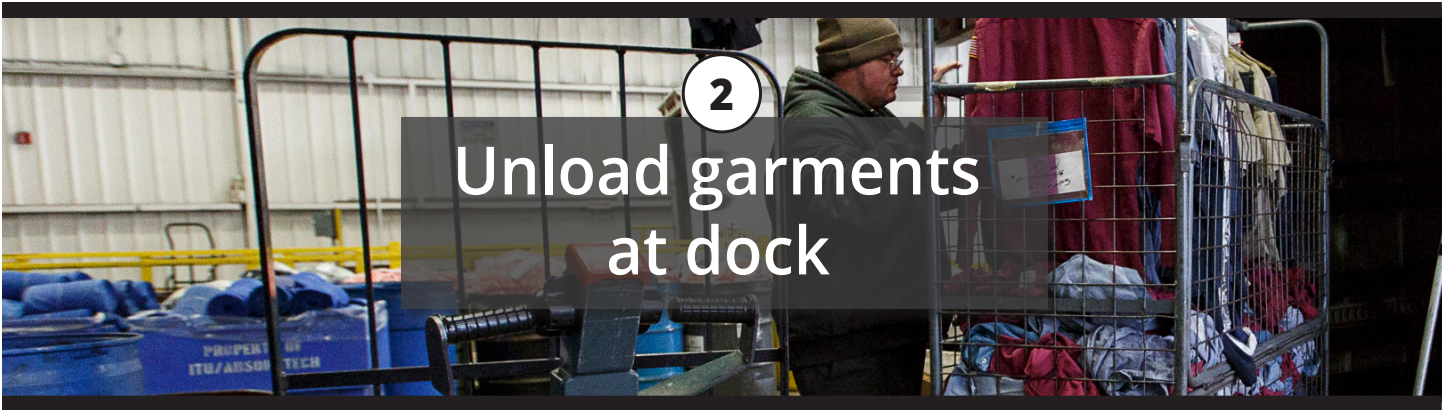
Chemical Hazards

- None



Kurt

Route Service & Sales
24 years at ITU AbsorbTech



2 Unload garments at dock

DESCRIPTION

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)
- ISO 14001-2004 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



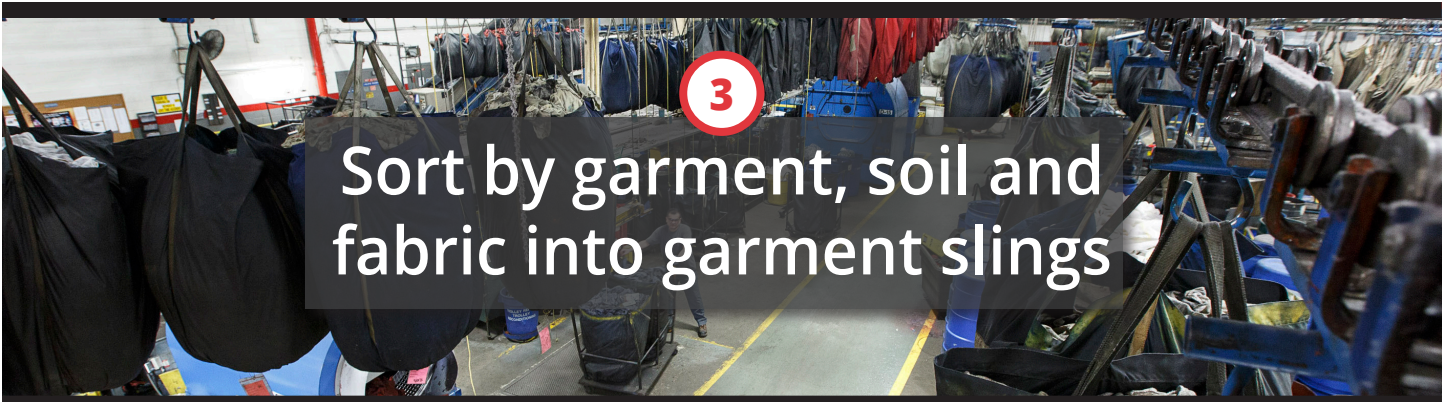
Chemical Hazards

- None



Jeff

Dock Auditor
2 years at ITU AbsorbTech



Sort by garment, soil and fabric into garment slings

3

CRITICAL CONTROL POINT #1

DESCRIPTION

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

POTENTIAL HAZARDS

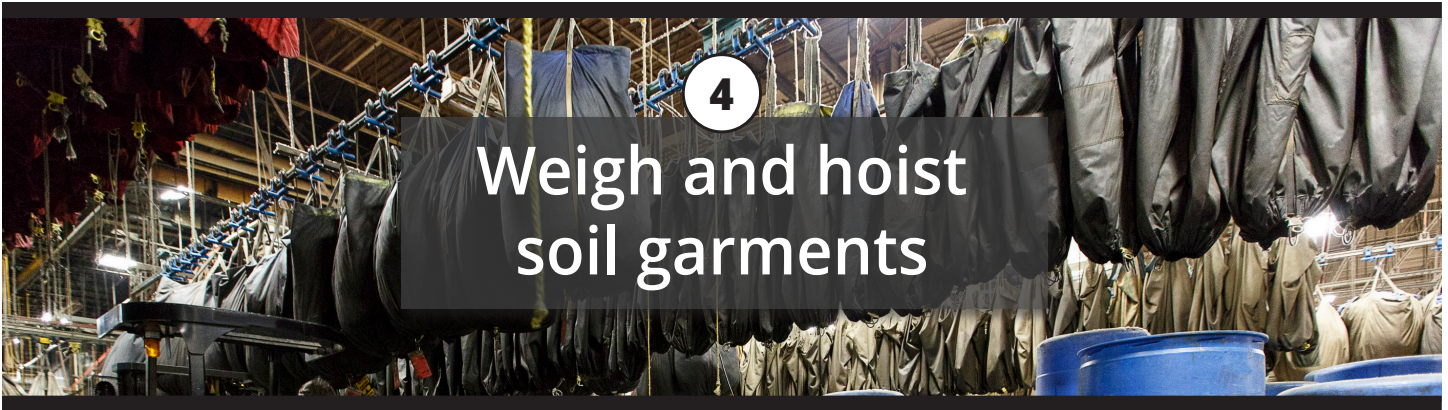
 **Physical Hazards**
■ Soiled garments

 **Microbial Hazards**
■ Soiled garments

 **Chemical Hazards**
■ None



Chit
Production
13 years at ITU AbsorbTech



4

Weigh and hoist soil garments

DESCRIPTION

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

- Equipment and gauges calibration list
- Soil garment sorting
- Hoist Inspection
- Safe Sling Practices and Methods
- 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
- ISO 14001-2004 employee training matrix
- ISO 14001-2004 certification of registration
- Scheduled external HACCP audit with chemical vendor - ECOLAB
- Customer onsite audits

POTENTIAL HAZARDS



Physical Hazards

- Soiled garments
- Inaccurate weighing of soiled garments



Microbial Hazards

- Soiled garments



Chemical Hazards

- None



Bob

Plant Manager

27 years at ITU AbsorbTech



5

Transport garments to washer

DESCRIPTION

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

CONTROLS

- Hoist Inspections
- Safe Sling Practices and Methods
- Trolley and Sling Inspection
- Cart repair identification

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Quarterly monorail inspections
- Monthly Sonic Aire delinting

VALIDATION

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

POTENTIAL HAZARDS



Physical Hazards

- None



Microbial Hazards

- None



Chemical Hazards

- None



Lorenzo

Production

18 years at ITU AbsorbTech

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DESCRIPTION

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 Fahrenheit 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

POTENTIAL HAZARDS



Physical Hazards

- None



Microbial Hazards

- Incorrect wash formula selected



Chemical Hazards

- Laundry chemicals used in wash process

garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label. Specific work instructions are utilized for employee training and tracked by our ISO 14001-2004 certification program.

- Washer Specific Work Instructions
- Air Operating Permit
- Wastewater Discharge Permit
- Chemical tank inspection- bulk tanks
- Chemical tank inspection- day tanks
- Change chemical drums

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

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

VALIDATION

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



Jose
Production
14 years at ITU AbsorbTech



DESCRIPTION

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. Specific work instructions are utilized for employee training and tracked by our ISO 14001-2004 certification program.

- Safe Sling Practices and Methods
- Trolley and Sling Inspection
- Washer Specific Work Instructions
- 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

- ISO 14001-2004 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



Physical Hazards

- None



Microbial Hazards

- None



Chemical Hazards

- None



Dry garments by appropriate drying formulas

CRITICAL CONTROL POINT #3

DESCRIPTION

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 Fahrenheit. Drying times vary based on garment being dried.

CONTROLS

All hard surfaces of dryers and carts where garments contact are regularly disinfected to minimize microbial cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label. Specific work instructions are utilized for employee training and tracked by our ISO 14001-2004 certification program.

- Safe Sling Practices and Methods
- Trolley and Sling Inspection
- Dryer Specific Work Instructions
- CEPR 5.1.1 Attachment 2b –Equipment and Gauges Calibration List (New Berlin)
- Air Operating Permit
- Proper Personal Protective Equipment (PPE)

POTENTIAL HAZARDS



Physical Hazards

- None



Microbial Hazards

- Incorrect dryer formula selected



Chemical Hazards

- None



Zoua

Production

19 years at ITU AbsorbTech

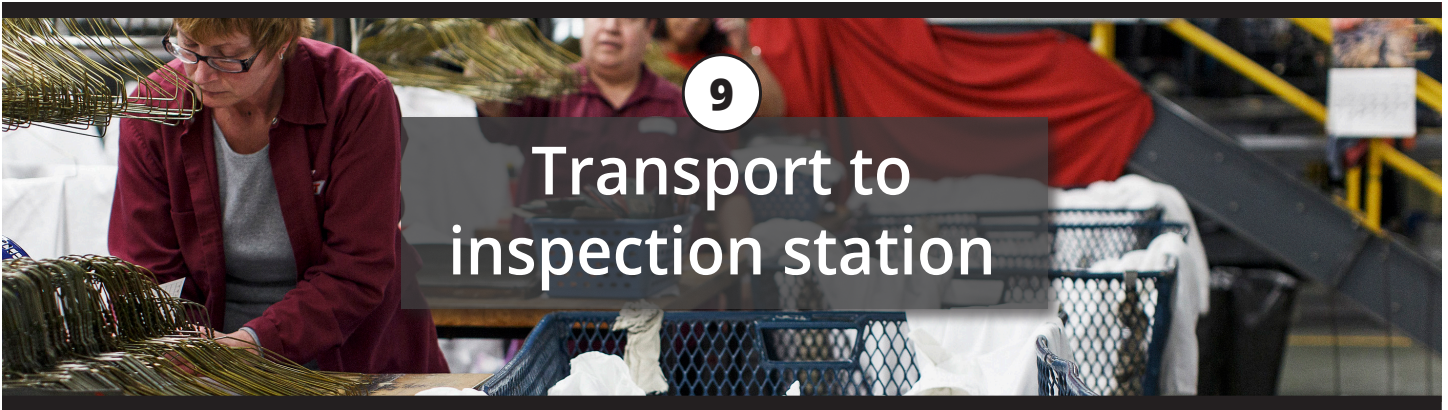
PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

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

VALIDATION

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



9 Transport to inspection station

DESCRIPTION

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



Physical Hazards

- None



Microbial Hazards

- Transportation carts
- Employee handling of clean garments



Chemical Hazards

- None



Robin

Production
2 years at ITU AbsorbTech



Garment inspection

CRITICAL CONTROL POINT #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 microbial cross-contamination of clean garments on soiled surfaces utilizing an EPA registered hard surface disinfectant, following proper concentration and contact time per label.

- Tunnel start-up and shutdown
- 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

POTENTIAL HAZARDS



Physical Hazards

- None



Microbial Hazards

- Table tops
- Employee handling of clean garments



Chemical Hazards

- None



Bobby

Production
3 years at ITU AbsorbTech

-
- Monthly Sonic Aire delinting
 - Quarterly steam tunnel inspection
 - Annual steam tunnel inspections

VALIDATION

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



DESCRIPTION

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 microbial 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



Physical Hazards

- None



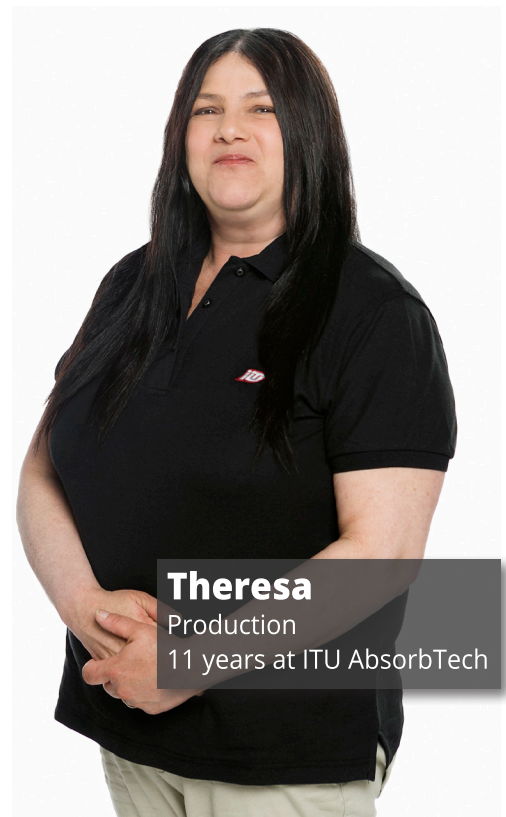
Microbial Hazards

- Table tops
- Employee handling of clean garments



Chemical Hazards

- None



Theresa

Production

11 years at ITU AbsorbTech



CRITICAL CONTROL POINT #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

- Tunnel start-up and shutdown
- Steam tunnel operators

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

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

VALIDATION

- Monitored monthly by a trained ECOLAB Specialist who provides a written service report regarding the steam tunnel performance
- ISO 14001-2004 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



Physical Hazards

- None



Microbial Hazards

- Steam tunnel equipment operation



Chemical Hazards

- None



DESCRIPTION

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

VALIDATION

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

POTENTIAL HAZARDS



Physical Hazards

- None



Microbial Hazards

- None



Chemical Hazards

- None



Jasan

Production

6 years at ITU AbsorbTech



14

Garment goes to no read line

DESCRIPTION

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

POTENTIAL HAZARDS

-  **Physical Hazards**
 - None
-  **Microbial Hazards**
 - Table tops
 - Employee handling of clean garments
-  **Chemical Hazards**
 - None



Mike
Plant Manager
13 years at ITU AbsorbTech



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Garments wrapped & stored for delivery

CRITICAL CONTROL POINT #6

DESCRIPTION

Final inspection of the clean garments is performed by the operator per the Corporate Garment Quality Specifications. The clean garments are wrapped appropriately to minimize microbial cross-contamination and are now ready for delivery back to the customer site. Specific work instructions are utilized for employee training and tracked by our ISO 14001-2004 certification program.

CONTROLS

- Designated lined clean only garment carts or tubes for transportation
- Garment Sort Work Instructions
- Proper Personal Protective Equipment (PPE)

PREVENTATIVE MAINTENANCE

(per internal standard operating practices)

- Weekly sort room inspections
- Monthly sort room inspections

VALIDATION

- ISO 14001-2004 employee training matrix
- 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



Physical Hazards

- Clean storage area



Microbial Hazards

- Table tops
- Employee handling of clean garments



Chemical Hazards

- None



DESCRIPTION

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

VALIDATION

- Auditing of Routes (Route Manager and Dock Auditor)
- ISO 14001-2004 employee training matrix
- Scheduled internal HACCP audit
- Scheduled external HACCP audit with chemical vendor - ECOLAB
- Customer onsite audits

POTENTIAL HAZARDS



Physical Hazards

- Vehicle properly aligned with dock
- Vehicle



Microbial Hazards

- Employee handling of clean garments



Chemical Hazards

- None



Jeff

Route Manager
13 years at ITU AbsorbTech



17

Garments delivered to customer site

DESCRIPTION

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 (Route Manager and Dock Auditor)
- Scheduled internal HACCP audit
- Customer onsite audits

POTENTIAL HAZARDS



Physical Hazards

- Contamination at customer site



Microbial Hazards

- Contamination at customer site
- Cross contamination from other soil products
- Employee handling of clean garments



Chemical Hazards

- In house cleaning chemicals at customer site



Training

DESCRIPTION

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



Jerry
Corporate Safety Manager
22 years at ITU AbsorbTech



Pest Control

DESCRIPTION

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

VALIDATION

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



Corrective Actions

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. Form 2 - Multiple Whys or Corporate Root Cause Analysis 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.

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Review Date: 10/09/15
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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
- l. 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
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Review Date: 10/09/15
Printed 11/28/16

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

Corrective / Preventive Action Subject					Facility	
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			
3. Describe the incident or concern. Clearly describe what happened to ensure all matters of concern are adequately addressed. Use additional space if needed. Attach additional documentation when available.						
4. Related Aspect? If yes, list below or indicate None			5. Related Regulation? If yes, list below or indicate None			
6. MS Team Review Date:			7. Investigation: interviewees, reports received, photographs, other - attach available documents			
8. RCA completed? Yes. List RCA method used.					No RCA - why not?	
9. Identified Root Cause(s) from 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 titles in detail as applicable; list attachments and save in corresponding Attachment folder.			Responsibility	Notes	Target Date	Completion Date
11. What is the expected result?						
12. Post Corrective / Preventive Action Measurement Effectiveness Review Date:						
13. Did actions taken address identified root cause(s)?			Yes		No**	
14. Were action(s) taken effective?			Yes		No**	
15. Actions/solutions communicated?			Yes		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.						

Issue Date: 11/05/12

Review Date: 08/04/14

Revision Date: 08/04/14

ITU AbsorbTech
HACCP System Record
Form 2 - RCA Multiple Whys

RCA# _____

Statement of Nonconformity / Requirement Reference

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WHY?

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WHY?

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WHY?

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WHY?

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WHY?

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ROOT CAUSE

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ITUAbsorbTech Internal HACCP Audit

Company Name	ITUAbsorbTech
Company Address	2700 S. 160th street
	New Berlin, WI
	53151
Telephone Number	262-782-1950
Fax Number	262-782-1802
Contact Name	Robert Beyer
Contact Email	RBeyer@ITUAbsorbTech.com
Contact Phone #	262-827-3581

Date of Audit	1/13/2017
Start Time	7:00am
End Time	2:00pm

	Name	Signature
Audited By:	Robert Beyer	
Accompanied By:	Scott Hill	

Summary of Audit

Overall HACCP program is on the right track. The HACCP booklet is well done. cleaning chemicals located throughout facility. Areas of opportunity: 1. Finalize employee HACCP training program 2. consider implementing garment cart liners for clean garment cages 3. Consider a standardized report for test results to share with customers 4. Consider posting signs throughout the plant identifying critical control point areas 5. Consider posting your HACCP team members and HACCP information in the production area

ITU AbsorbTech Internal HACCP Audit

1.0 HACCP System		
Description	Audit Findings	Pass
1.1 HACCP Manual/System Implemented	Program in the implementation step with a manual/system in place. Consider posting in the production area your HACCP team members and HACCP information	yes
1.2 Documented Work Instruction and Procedures	Work instructions in place for those identified in the HACCP process booklet	yes
1.3 Personnel Training and Records	No HACCP training has been performed; training materials are being developed in our AbsorbU training. Consider identifying the CCP areas in the plant.	NO
1.4 Customer Complaint Handling	Customer: Devon Chocolates requested our HACCP program information and email confirms satisfaction. <i>(see hard copy of email dated 12/8/16)</i>	yes
1.5 Non Conforming Findings	None noted to date; the first corrective actions will be implemented as a result our internal HACCP audit	yes
1.6 Corrective Action Procedures	Procedure in place and documents available as needed <i>(see HACCP booklet hard copy)</i>	yes
1.7 HACCP Flow Diagram	HACCP flow diagram in place with critical control points identified <i>(see HACCP booklet hard copy)</i>	yes
2.0 FACTORY PREMISES AND LOCATION		
Description	Audit Findings	Pass
2.1 Condition of Perimeter/Yard	Perimeter is free from debris	yes
2.2 General Condition of Buildings	Outside building has no open gaps that could allow pest entrance.	yes
2.3 Condition of Floors	aisles have been recently painted and those awaiting painting has had any loose materials removed	yes
2.4 Condition of Walls	Clean	yes
2.5 Condition of Ceilings	Clean	yes
2.6 Condition of Doors	Doors in good condition. Two doors scheduled for replacement in 2017; employee entrance and double doors by shirt press. <i>(see 2017 capital hard copy)</i>	yes
2.7 Condition of Windows	No cracks observed. Have window checks documented on quarterly SPCC record <i>(see 4th quarter quarterly inspection hard copy)</i>	yes
2.8 Segregation of Operations	No issues noted. Washroom segregated from rest of facility	yes
2.9 General Cleanliness/Housekeeping	Condition of facility is acceptable. No observable OSHA or HACCP violations	yes
2.10 Documented Cleaning Procedures	Table tops are documented on weekly 6S checklist <i>(see steam tunnel Jan. 2017 6S checklist hard copy)</i>	yes
2.11 Cleaning Records	6S checklists are posted throughout the facility. Have one (1) employee on staff for cleaning office area <i>(see steam tunnel Jan. 2017 6S checklist hard copy)</i>	yes

ITU AbsorbTech Internal HACCP Audit

3.0 PERSONAL HYGIENE		
Description	Audit Findings	Pass
3.1 Condition of Locker Rooms	Clean and acceptable	yes
3.2 Conditions of Bathrooms	Clean and acceptable	yes
3.3 Wearing of PPE	PPE being worn when handling soiled garments	yes
3.4 Handwashing Facilities	Wash stations throughout the plant and in the office area	yes
3.5 Use of Handwashing Facilities	Employees were observed using the wash facilities	yes
3.6 Restrictions on Smoking	Facility is a smoke free environment	yes
3.7 Hygiene Training	No "official" HACCP training has been performed; training materials are being developed in AbsorbU	NO
4.0 INFESTATION CONTROL		
Description	Audit Findings	Pass
4.1 Pest Control Contractor	Currently using Batzner Pest Management	yes
4.2 Pest Control Documentation/ Records	Monthly reports given to maintenance manager	yes
4.3 Insect Control/Evidence	None observed.	yes
4.4 Rodent Control/Evidence	Pest control stations throughout the facility	yes
4.5 Bird Control/Evidence	None observed	yes
4.6 Waste Disposal	Utilizes Waste Management for waste disposal. Compactor located outside. Dumpsters throughout facility	yes
5.0 RAW MATERIALS CONTROL		
Description	Audit Findings	Pass
5.1 Approved 14001 Contractor Log	ISO 14001 certified. Up-to-date contractor log on file (see 14001 certification hard copy)(see entire contractor program hard copy)	yes
5.2 Storage of Chemicals	Wash chemicals and waste water chemicals are stored in drums of bulk tanks	yes
5.3 Segregation of Chemicals	Wash chemicals in boiler room and wastewater chemicals in treatment room	yes
5.4 Control of Chemical Usage/traceability	Monthly inventory completed by ECOLAB (see 11/29/16 ECOLAB report hard copy for washroom and wastewater)	yes
5.5 Storage/Inspection of Packaging	No leaks observed. Training conducted for personnel on spill situations	yes

6.0 PROCESSING		
Description	Audit Findings	Pass
6.1 Equipment PM records	Weekly, Bi-weekly, monthly, quarterly, 6 month and yearly PM's in place. Moving PM's to electronic system (emaintenance) <i>(see steam tunnel daily and weekly PM hard copies dated 1/9/16)</i>	yes
6.2 Cleanliness of Equipment	Equipment clean	yes
6.3 Process Control Charts/Records	Utilization of Ultrax by management team along with visual controls for washroom in place. Monthly review by ECOLAB for our washfloor and wastewater operation. Work instruction training tracked through 14001 training matrix or AbsorbU	yes
6.4 Calibration of Instruments	14001 equipment calibration log completed for 2016 <i>(see calibration log for 2016)</i>	yes
6.5 Contamination Risk During Processing and Packing	None observed	yes
6.6 Operator Hygiene Practices During Processing and Packing	Operators observed wearing gloves when handling soiled product	yes
7.0 PRODUCT QUALITY VALIDATION		
Description	Audit Findings	Pass
7.1 Laboratory Facilities Used for HACCP Testing	Monthly testing performed by ECOLAB in their lab	yes
7.2 Laboratory Facilities HACCP Test Results	All lab results were passing. Consider the implementation of a standard report to share test results with customers. <i>(see ECOLAB results dated 11/10/16 and 12/15/16)</i>	yes
7.3 Internal ATP HACCP Testing performed	Weekly ATP testing being performed by garment supervisor	yes
7.4 Internal ATP HACCP Testing Results	All ATP test result are passing. Consider the implementation of a standard report to share test results	yes
7.5 Microbiological HACCP Analysis Schedule/Records	Currently monthly tests being performed by ECOLAB and internal tracking with ATP tester being done per weekly schedule	yes
8.0 PACKED PRODUCT STORAGE AND DISTRIBUTION		
Description	Audit Findings	Pass
8.1 Location of Finished Goods	Clean garments are stored in warehouse in cages or tubs. Consider the addition of garment liners for clean garment cages.	yes
8.2 Stacking of Cleaned Product	No garments are double stacked	yes
8.3 Condition/Control of Transport Equipment	Garment transportation equipment in operational condition	yes
8.4 Cleanliness of vehicles, schedule and	Trucks are swent out daily	