Welcome

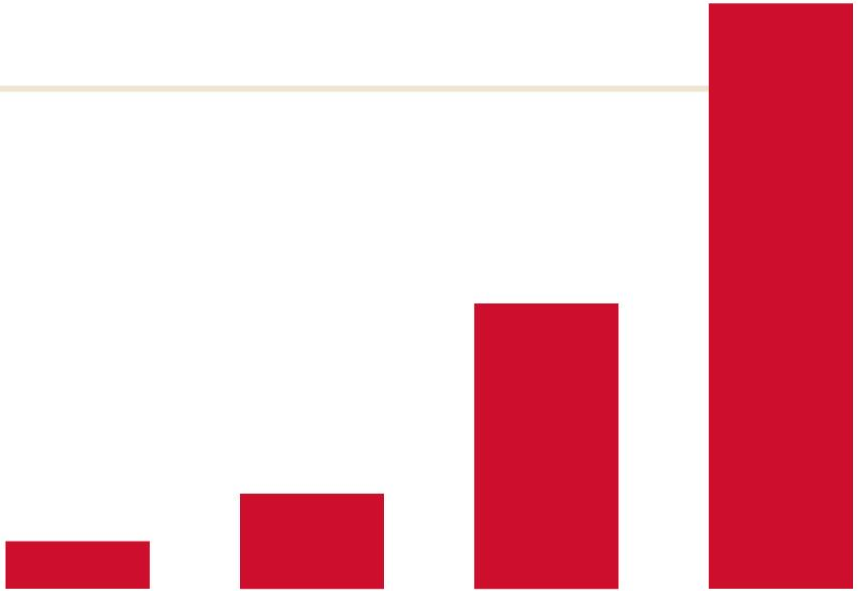
Kristy Herlitzka Production QA Manger
Jill Ball Regulatory Specialist

KWIK TRIP, INC.
CORRECTIVE AND PREVENTIVE ACTION PROGRAMS

Growth

1965

First Kwik Trip store opens in **Eau Claire, WI**



1983

50 stores

1986

100 stores

2000

300 stores

Today

675+ stores

KWIK TRIP INC.

Trade Names

Trade Names

Kwik Trip,™ Kwik Star®

Current Employment

24,000+ co-workers

KWIK TRIP INC.

Privately Owned

Kwik Trip is owned by four generations of the Zietlow Family

KWIK TRIP INC.

Priorities

People

Guests, Co-workers and the communities we serve

Food

Provide great quality, value and selection at good prices

Vertical Integration

Control Production, quality, delivery and efficiency

KWIK TRIP INC.

Our Mission

Mission Statement:

To serve our customers and community more effectively than anyone else by treating our customers, co-workers and suppliers as we, personally, would like to be treated, and to make a difference in someone's life.

- All co-workers know our mission statement
- Job interviews focus on the ability of the person to live the mission statement and core values

KWIK TRIP INC.

Kwik Trip, Inc. Manufactured Food Corrective Action Programs

- Dairy Plant – Milk and Flavored Milk – Bagged and Bottled
- Ice Cream Plant – Ice Cream, Frozen Yogurt,
- Beverage Plant –Bottled Water, Flavored Water, Orange Juice, etc.
- Ice Plant – Ice
- Bakery – Sweet Goods
- Bakery – Bread and Buns
- Kitchens – Pizza, Burritos, Sandwiches, Wraps, Parfaits, etc.

KWIK TRIP INC.

Sources that Initiate a CAPA

- Retail Concerns
- Vendor Concerns
- Production issues
- Internal Audits
- Third Party Audits
- Regulatory Inspections

Corrective & Preventative Action SOP

DOCUMENT ID	SOP # 10A Corrective/ Preventative Actions	**PAGE**	**1 of 1**
PLANT NAME:	Kwik Trip, Inc. Production Operations	**ISSUE DATE**	3/30/18
ADDRESS:	1626 Oak Street, La Crosse, WI 54602	**SUPERSEDES**	4/13/17

Co-workers, supervisors and management are responsible for completing corrective actions.

When issues occur with product, processes, or paperwork a corrective action is needed to document how the problem was fixed. Corrective and preventive actions must state how the deficiency was corrected, who is responsible and what will be done to prevent any future recurrence. Not all issues need a CAPA form filled out; a note in the CAPA/Comment box may be sufficient. For example, if a check on a production form was not done at the proper frequency or the information is illegible, a note explaining what happened in the CAPA box would be sufficient.

The CAPA process shall include investigation, action, review, and follow up to make sure the problem is corrected. Root cause analysis combined with corrective action helps to understand the cause of the deviation and prevent recurrence of a similar problem. Here are ways to approach a problem.

1. Define the problem
State the problem. Do not make assumptions or suggest ways to improve it.
Problem stated based on facts, not beliefs. Include what, when, where and impact of the problem.

2. Ask Why
Why #1 -Ask why did the problem occur? Why #2 – Why did the action in why #1 occur? Keep asking why until you can determine the root cause – which is what started the chain of events leading to the problem.

3. Root Cause/Corrective Action
Determine the Root Cause and how it can be prevented from happening again.
WHAT changes will be implemented? WHO is going to implement the change? WHEN will the changes be implemented?

4. Implement, Verify, Spread
Record what was changed, by whom and when the change was made
Verify that changes have eliminated the Root cause
Identify all areas where this solution could be reapplied to prevent similar incidents from occurring

All Regulatory and Third Party audit reports received by Kwik Trip, Inc. production facilities are to be forwarded to Production Quality Assurance. Production Quality Assurance will forward to the Director of Operations.

Quality Assurance will assist the appropriate production department personnel with the corrective action responses to the Regulatory or Third Party audit reports. The production departments should not respond directly to ensure a consistent response can be provided.

Records for Corrective Action
Each production facility is to maintain a file of all internal audits, third party audits, regulatory actions, visits, reports or other notifications received from any regulatory agency along with the corrective action. All information from the corrective action must be documented and kept on file via hard copy or stored electronically for a minimum of two years.

KWIK TRIP INC.

Retail Concerns

DOCUMENT ID	Kwik Trip Production Operations Customer Quality Concern Form	PAGE	1 of 1
PLANT NAME:	Kwik Trip, Inc. Production Operations	ISSUE DATE	5/1/17
ADDRESS:	1626 Oak Street, La Crosse, WI 54602	SUPERSEDES	2013

Submitted by:		KT production Dept.:	
Date of Report:		Date of Incident:	
Call ID #:		Product Description and Size	

Code Date/Sell By Date:

Description of the reported concern:

Comments after reviewing retention sample and/or returned product (include date reviewed):

Is nonconformance verified? *Explain* Yes ☐ No ☐

Is nonconformance valid? *Explain* Yes ☐ No ☐

If nonconformance is determined to be valid, the following sections must also be completed:
(A written response is required within 5 business days)

1. What was the immediate corrective action to this issue?
2. Explain the root cause of the issue.
3. What preventive actions will be taken?
4. Are there additional lot/codes of this product or any other product that may share this nonconformance?
5. *If yes to question 4:*
   Has the product been placed on Hold? Yes ☐ No ☐
   Has the product been Withdrawn or Recalled? Yes ☐ No ☐

Vendor Concerns

DOCUMENT ID	Kwik Trip Production Operations Vendor Concern Form	PAGE	1 of 1
PLANT NAME:	Kwik Trip, Inc. Production Operations	ISSUE DATE	5/1/17
ADDRESS:	1626 Oak Street, La Crosse, WI 54602	SUPERSEDES	2013

Vendor:		Item Description	
Date of Report:		Vendor Item #:	
Date of Incident:		KT Item #:	
Submitted by:		Lot/ Code:	
Email address:		Quantity:	
Pictures:	*N/A or See bottom of the report*	P.O.:	

Description of the reported concern:

Is there any remaining product in inventory? Is the product placed on Hold?

To be completed by Vendor:

It is requested that Corrective Action be taken for the nonconformance(s) noted above. A written response is required. Please return this completed form by email to the person noted above within five business days of the date of this report.

Name and position of person completing report:		Date:	
		Phone #:	

1. What was the immediate corrective action to this issue?

2. Explain the root cause of the issue.

3. What preventative actions have been implemented?

4. Are there additional lot/codes of this product or any other product that may share this nonconformance?

5. *If yes to question 5:*

Has the product been placed on Hold? **Yes** ☐ **No** ☐

Has the product been Withdrawn or Recalled? **Yes** ☐ **No** ☐

KWIK TRIP INC.

Production Issues

Document ID:	CAPA Form	PAGE	1 of 1
Plant Name:	Kwik Trip, Inc.	ISSUE DATE	10.17.16
Address:	1626 Oak Street; La Crosse, WI 54603	SUPERSEDES	10.7.16

Date:		*Category:		Reference #, *if applicable:*	
Owner:					
Issue/ Problem Statement :					

*Audit, Environmental, Concern, Documentation, Program, Training, Operator, Contractor or Other.

Immediate Corrective Action:			
Verified By:		Date:	

Root Cause:			
Verified By:		Date:	

Preventative Action:			
Verified By:		Date:	

Verification Action:			
Verified By:		Date:	

KWIK TRIP INC.

Internal Audits; Third Party Audits; Regulatory Inspections

Document ID:	CAPA Form	PAGE	1 of 1
Plant Name:	Kwik Trip, Inc.	ISSUE DATE	10.17.16
Address:	1626 Oak Street; La Crosse, WI 54603	SUPERSEDES	10.7.16

Date:		*Category:		Reference #, *if applicable:*	
Owner:					
Issue/ Problem Statement :					

*Audit, Environmental, Concern, Documentation, Program, Training, Operator, Contractor or Other.

Immediate Corrective Action:			
Verified By:		Date:	

Root Cause:			
Verified By:		Date:	

Preventative Action:			
Verified By:		Date:	

Verification Action:			
Verified By:		Date:	

KWIK TRIP INC.

Kwik Star, Kwik Trip Corrective Action Programs at Retail

- 95 Iowa Kwik Star Locations
- 171 Minnesota Kwik Trip Locations
- 400 Wisconsin Kwik Trip Locations

KWIK TRIP INC.

Sources that Initiate CAPA

- Internal Audits – Semi Annually
- Third Party Audits - Annually
- Guest Concerns – Direct
- Guest Concerns – Social Media
- Guest Concerns – 24/7 Hotline
- Retail Concerns – 24/7 Hotline
- Regulatory Inspections

Phase 1: Retail CAPA for Internal and Third Party Audits

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Kwik Trip, Inc.

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Brand Protection Services
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Charlotte NC 28226
704.544.1900

How to Enter Corrective Actions over the Internet

1. On the day after your audit you will receive an email that includes a link to take you directly to the Corrective Action Plan. You can access the system without the email link as well by typing https://foodsafety.steritech.com/login.html into your web browser.
2. You will need to enter your username and password. Both Username and Password are the same, the store number.
3. Follow the instructions for ENTERING A CORRECTIVE ACTION PLAN – instructions are on the Kwik Net under the RETAIL CENTER / FOOD SERVICE / FOOD SAFETY section

How to write SMART Corrective Action Plans

SMART Corrective Actions are: Specific, Measurable, Actionable, Realistic and Timely.

Specific: Is the goal detailed enough to be easily understood and completed?
Typical Example: Clean and repair the floors.
SMART Example: Clean floor tiles and grout nightly with degreaser. Replace broken tiles under ovens by May 20th.

Measurable: Is the goal written in terms that can easily be measured or evaluated?
Typical Example: Team members must complete food safety training.
SMART Example: All team members working in kitchen must complete the CBT food safety training module by May 30th. All other team members must complete the CBT food safety training module by June 30th.

Action Based: Is the goal written using active terms with the desired result included?
Typical Example: Mops will not be left in mop water after use.
SMART Example: Install mop rack on wall above mop sink by May 20th. At opening meeting on May 21st, train all employees that mops must be hung after use.

Realistic: Is the expected outcome and timeline realistic for the specific goal?
Typical Example: Replace damaged tile floor with epoxy floor throughout kitchen by next week.
SMART Example: Replace broken floor tiles by May 20th. Monitor damage weekly and replace or repair as needed. Get three estimates by end of August on costs for replacing entire kitchen floor with epoxy and submit as part of next year's budget meeting in October.

Timely: Is the goal written with an appropriate deadline?

KWIK TRIP INC.

Phase 2: New Retail Training CAPA for Internal and Third Party Audits

What is a CAPA?

Corrective **A**ction & **P**reventive **A**ction consists of improvements to an organization's processes taken to eliminate customer complaints, unacceptable levels of product non-conformance, issues identified during an internal audit.

It is usually a set of actions that laws or regulations require an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring nonperformance.

Such as:

- Error proofing
- Visible or Audible Alarms
- Process Redesign
- Product Redesign
- Training – Modification of existing training programs
- Improvement to maintenance schedules
- Improvements to surrounding environments

In some cases, a combination of such actions may be necessary to fully correct the problem and prevent it from happening again.

It must be systematically implemented and observed for its ability to eliminate further recurrence of such non-conformation.

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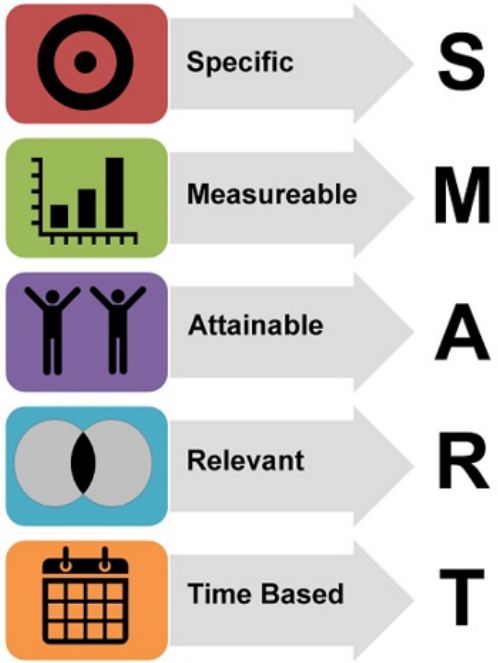
Phase 2: Retail CAPA for Internal and Third Party Audits

Corrective Action

The action taken to eliminate the error on the affected process or product; "the immediate fix".



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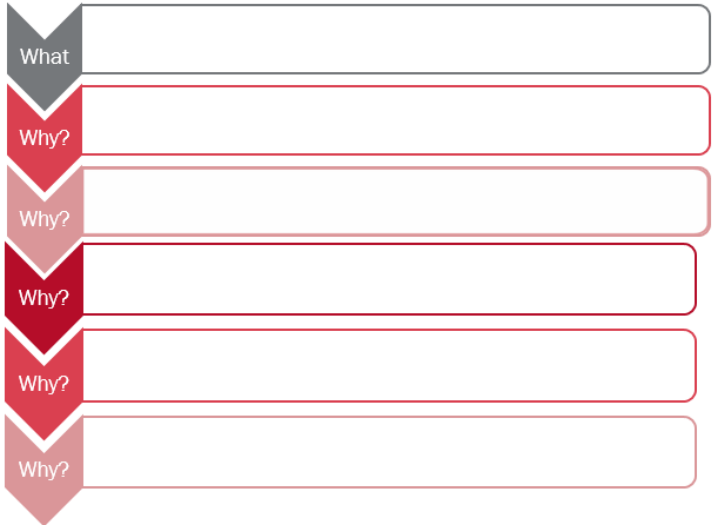
Phase 2: Retail CAPA for Internal and Third Party Audits

The Why's???

Keep asking why until you can determine the root cause – which is what started the chain of events leading to the problem.
The reason the problem happened should not be not enough time, not enough money or not enough manpower. These answers may be true, but they are out of our control.
Ask the question "why did the process fail?"
Remember: People do not fail, processes do!

What (problem): Ran through a red light.

- ***Why?*** – Late for work
- ***Why?*** – Woke up late
- ***Why?*** – Alarm clock didn't work
- ***Why?*** – Dead batteries
- ***Why?*** – Forgot to replace them



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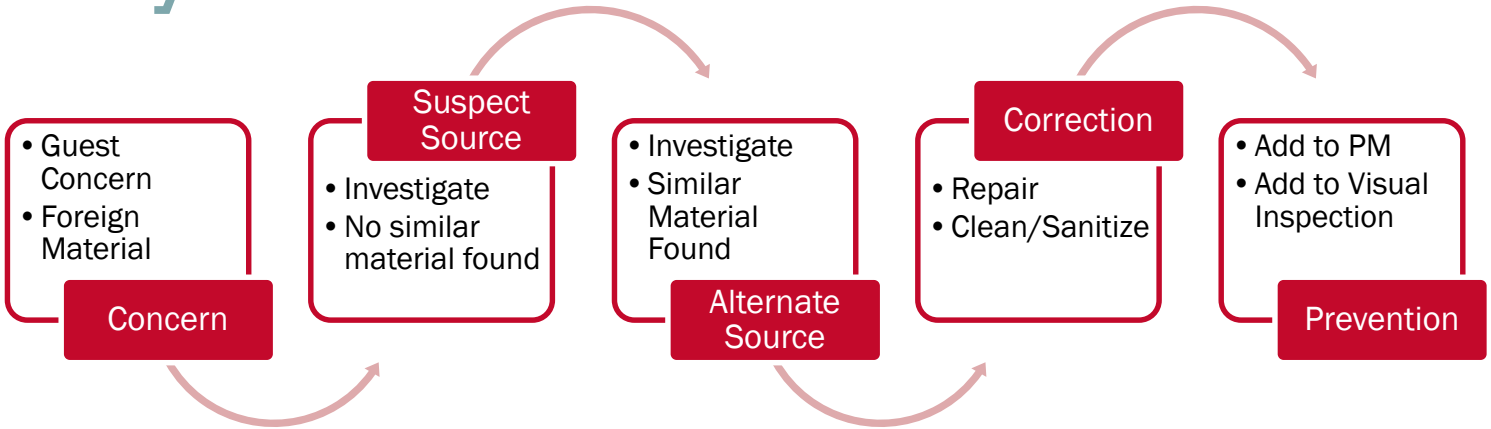
Example of a Root Cause Analysis



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QUESTIONS?

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