Effective QC Implementation

Food Safety & Food Quality

- Why?
  - Consumer Trust/Brand Recognition
  - Continuous Improvement

Food Safety & Food Quality

- Why?
  - Continuous Improvement
    - Third Party Audits
    - Customer Audits
    - Global Food Safety Initiative (GFSI)
      - http://www.mygfsi.com/

Food Safety & Food Quality

- Why?
  - Regulatory
    - Food Safety Modernization Act (FSMA)
      - January 2011
      - http://www.fda.gov/Food/GuidanceRegulation/FSMA/
      - Re-Proposed Rules – September 29, 2014
    - Reminder: It is time to renew your facility registration with the FDA (October 01 – December 31)

- Commitment
  - Critical that the entire company is committed to Food Safety and Food Quality
  - Culture of FSQ
    - Part of Something Bigger
    - Be Persistent
    - Make it Personal – Food is Personal

- Commitment
  - Mission, Values, FSQ Statement
    - Documented
    - Display it Prominently
    - Signed by President/COO
    - Reviewed Annually
    - Communicated

- Training Program:
  - Make it Personal
    - Everyone Eats (employees, family, friends, etc.)
    - Statistics and “real-life instances” that employees can relate to.
    - http://www.stopfoodborneillness.org/
  - Intentional and Unintentional Failures

  - Guest Trainers/Speakers (internal or external)
  - Interactive Training (Questions, Prizes, etc.)

- Training Program:
  - Written Policy
    - What? - Training is provided
    - Who? – Responsible for training
    - When? – Frequency (New Hire, Annual, Changes, Start of Shift, Corrective Action / Preventative Action, etc.)
  - Training Register

Employee Name

Training	Trainer	Date Completed	In House	Outside
Internal Auditor	Thom Trusky	05/19/2014	X	

• Training Program: Effectiveness

Document Number: GN-08 **Revision**: E	**CONTROLLED DOCUMENT**

Training:	**Date:**	**Duration:**
Instructor (s):		

PRINTED NAME	**SIGNATURE**	**TRAINEE IS COMPETENT TO CARRY OUT TRAINING PROVIDED** *(To be completed by instructor only)*
		Yes ☐ No ☐
		Yes ☐ No ☐
		Yes ☐ No ☐
		Yes ☐ No ☐

• Training Program: Effectiveness

Food Safety and Food Quality Training Exam

Name:

Date:

Circle or fill in the correct answer.

1. The _____ _____ _____ _____ is legislation designed to improve capacity to prevent food safety problems. The legislation is also designed to detect and respond to food safety problems, expanding the authority of the FDA and adds focus to HACCP and risk based controls.

A. First In First Out
B. Food Safety Modernization Act
C. Internal Audit
D. British Retail Consortium

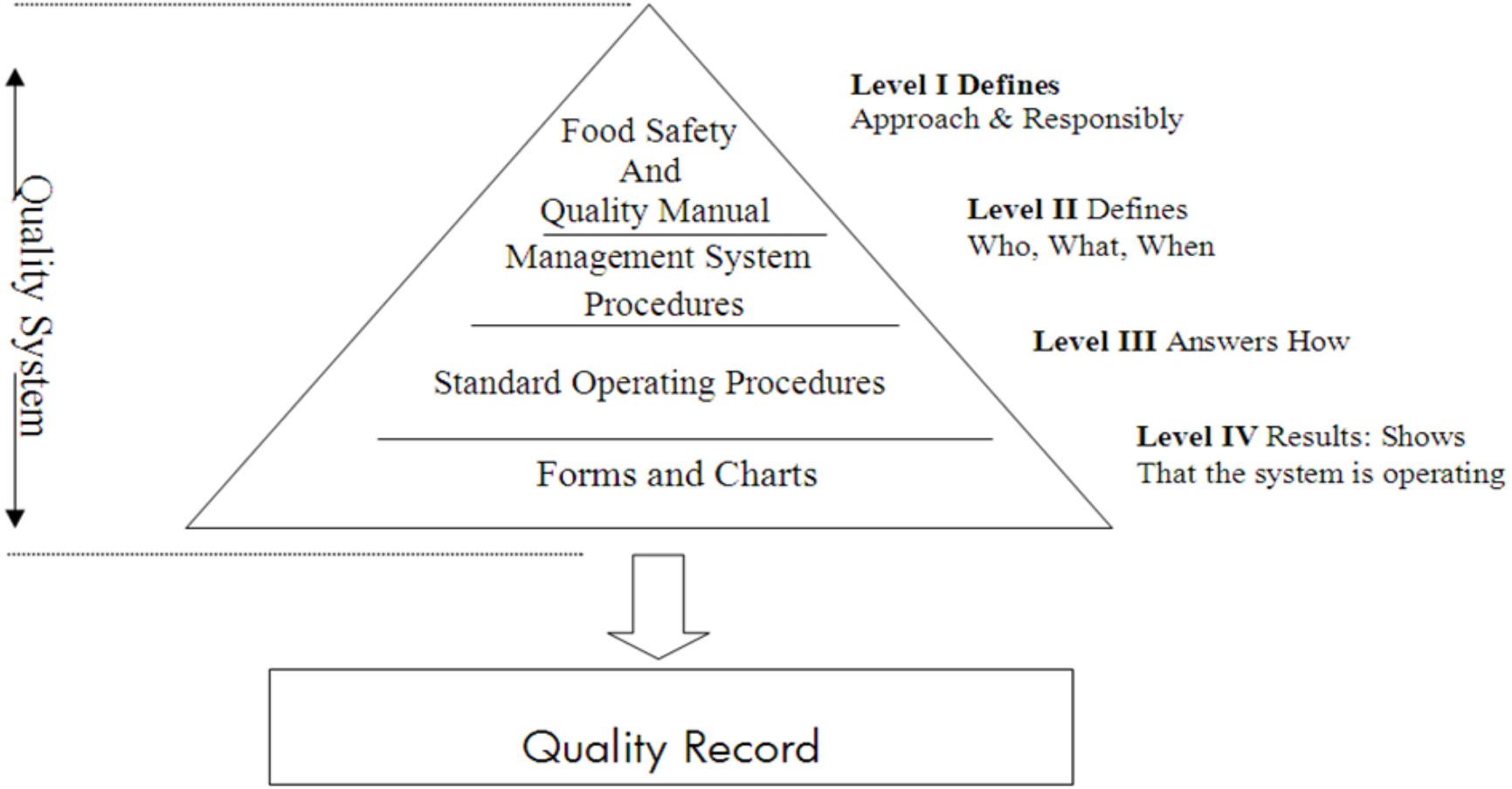
2. Name two of the twelve hazards of HARP-C (Hazard Analysis Risk- Based Preventative Controls).

1 _____
2 _____

3. Name three items we check or require on all inbound deliveries of raw materials.

1 _____
2 _____
3 _____

• Document and Record Control



- Document and Record Control
  - System to Ensure Most Current Version
    - Document / Record Number
    - Revision Level
      - Document Revision (request, review, approval)
    - Training for Employees
      - Why?
      - Legible, Signed/Initialed, Dated
      - Corrections?
      - Approved Writing Utensils – potential contamination?

Food Safety & Quality Management System Procedure

System Procedure:
Subject:
Revision:
Effective Date:

CONTROLLED DOCUMENT

1.0 PURPOSE

This procedure defines the responsibility and methods for..

2.0 SCOPE

This procedure applies to...

3.0 REFERENCES/EXHIBITS

4.0 DEFINITIONS

Etc....

5.0 PROCEDURE

Procedure Sequence	Responsibility /Authority	Method / Activity
5.1	Line Leaders, Area supervisors and managers	Initiate new or changed documentation via a documentation change notices (Form – What ever the number is)

Revision	Date changed	Changed By-Title	What was changed
A	May 29, 2009	Keith Lee	Format Change

DOCUMENT CHANGE REQUEST

CONTROLLED DOCUMENT

Change Requested By- Include Title

Date:

Document Type:
☐ **Record** ☐ **SOP** ☐ **Policy** ☐ **Other**

Type of Action Requested:
☐ New Document ☐ Cancellation/Disposal
☐ Revision to an existing document

Document Number	**Revision Level**	**Document Title**
	_____	

Department Approval (Review and Approval)

Note requested changes: ***Complete only if revising an existing document***

☐ **Approved**	Signature:	Date:
☐ **Not Approved**	Reason:	

Document Control – Revision Final Release

☐ **Change Implemented**
☐ **Revision Level updated on document**
☐ **Revision Log updated on document**
☐ **Document Register updated**
☐ **Email sent to staff**

New Revision Level:
Date:
DCC Initials:

Document Control – Cancellation/Disposal

☐ **Change Implemented**
☐ **Hard Copies destroyed**
☐ **Removed from Document Control database**
☐ **Removed from Document Register**
☐ **Email sent to staff**

Date:

CONTROLLED DOCUMENT
CCP ID: XYZ

Critical Control Point Log

Date Code:____________

Action Code	Product	2.0 mm F Test Card	2.0 mm NF Test Card	2.0 mm SS Test Card	Time	Monitored By	Comments
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		
		Pass ☐ Fail ☐	Pass ☐ Fail ☐	Pass ☐ Fail ☐	: a.m. p.m.		

Action Code Legend: **SR** = Start of Run **AP** = Active Production **LD** = Line Down **ER** = End of Run **CO** = Change Over **SCW** = Stop, Call, Wait **FSV** = Food Safety Verification **MC** = Maintenance Calibration

Follow **STOP, CALL, WAIT** for any failure or rejection that may occur. All rejections shall be recorded on the **Process Deviation Log**.

Pass=When performing line test and product is kicked out by the reject arm.

Fail= When performing line test and product continues through detection and not kicked out by the reject arm.

Note: When performing line test always allow product to kick out. Never pick product up before passing by the reject arm.

• Document and Record Control Register

CODE CLAUSE #	DOCUMENT AND DOCUMENT#	LOCATION	RESPONSIBILITY	REVISION
2.2.1.1	Document Control Procedure P-2.2.1.1-01	G:\FilesandDocuments\CGC\CGC\BakingPowder\Document Control SQF Modules 2 and 11\2.2 Document Control and Records	Food Safety and Quality Department	F
2.2.2.1	Document Control Records Procedure P-2.2.2.1-01	G:\FilesandDocuments\CGC\CGC\BakingPowder\Document Control SQF Modules 2 and 11\2.2 Document Control and Records	Food Safety and Quality Department	E
2.2.2.2	Documentation of Verification and Recordkeeping P-2.2.2.2	G:\FilesandDocuments\CGC\CGC\BakingPowder\Document Control SQF Modules 2 and 11\2.2 Document Control and Records	Food Safety and Quality Department	A

If following a specific audit scheme, using the same code numbers may be beneficial.

- Food Safety and Quality Programs

- FSMA
- HACCP

• Food Safety and Quality Programs

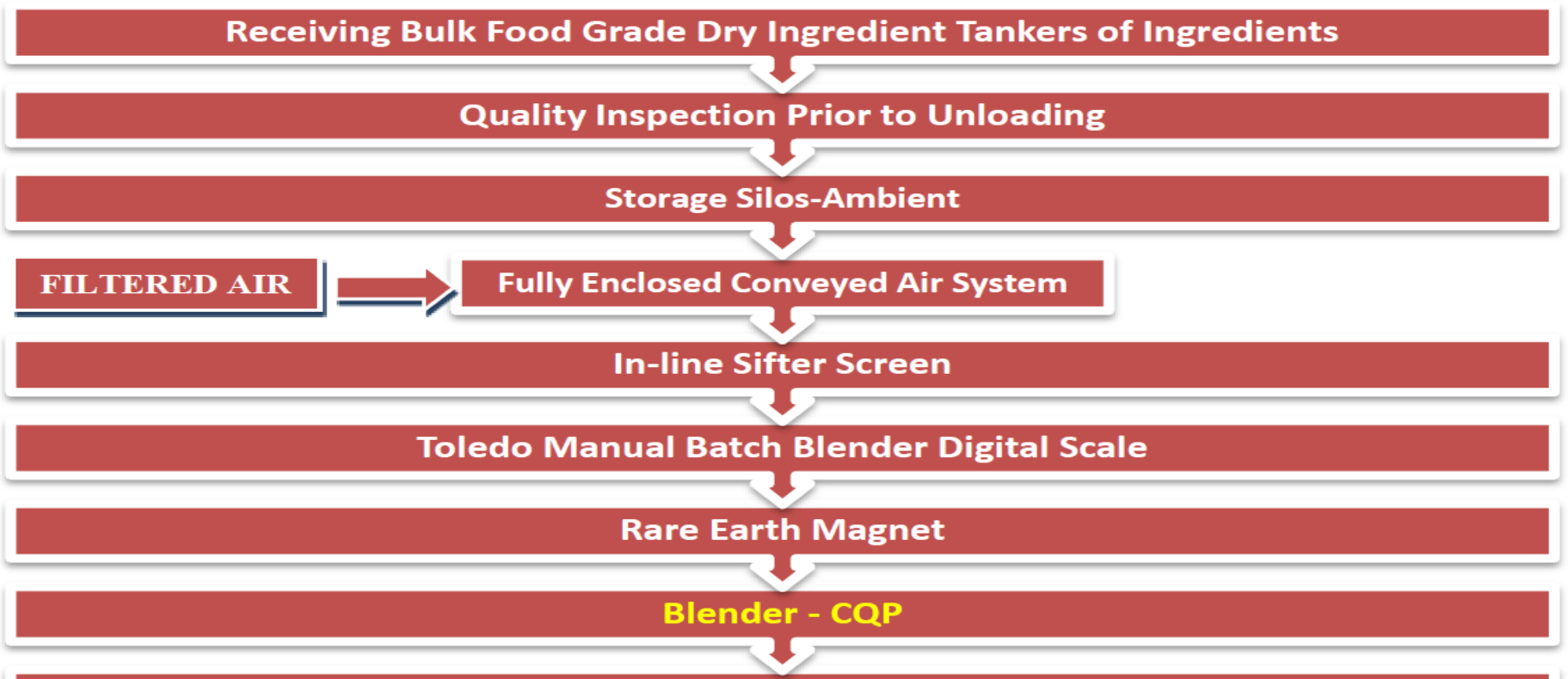
- Hazard Analysis Risk-Based Preventative Controls (HARP-C)
  - 12 Hazards of HARP-C
    - Biological
    - Chemical
    - Physical
    - Radiological
    - Natural Toxins
    - Pesticides
    - Drug Residues
    - Decomposition
    - Parasites
    - Allergens
    - Unapproved Additives
    - Intentional
    - Radiological
    - Intentional – Infinite Possibilities – Food Defense & Crisis Management/BCP

- Food Safety and Quality Programs
  - Food Quality Plan (Process Flow, Hazard Analysis, Finished Product Profile)

Quality Process Flow

System Procedure:
Subject:
Revision: E

CONTROLLED DOCUMENT



Food Safety and Quality Programs

- Preventative Controls
  - Sanitation
  - Training
  - Environmental Monitoring
  - Allergen Control
  - Recall Plan
  - cGMP's
  - Supplier Verification

- Require:
  - Monitoring Records
  - Verification
  - Validation
  - Corrective Actions

- # Cleaning and Sanitation
  - Documented Program
  - Documented Training
  - Documented Task Completion
  - Verification/Validation of Effectiveness

CONTROLLED DOCUMENT

Daily Cleaning Log Sheet – Custodian (Building 3) **Month/Year: _____**

Day of the Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Cleaning																															
Restrooms- 1st Floor																															
Restrooms- 3rd Floor																															
Restrooms- 4th Floor																															
Empty All Trash Receptacles																															
Men's Locker Room																															
Women's Locker Room																															
Vestibules (entrances)																															
Break Room																															
Stock hairnets, shoe covers, gloves, etc.																															
Weekly																															
All Offices																															
Lab																															
Floor Scrubber																															
Elevators																															
As Needed																															
Maintenance Sink																															
Parking Lot -																															
Supervisor Verification																															

Initial = Complete X = No Work Needed **Signature: _____ Initials: _____**

- Allergen Control Program
  - Documented Program
    - Even if facility does not process allergens
  - Program Considerations:
    - Identification of Allergen(s) Upon Receipt
      - Labeling, Color Coding, etc.
    - Storage of Allergen Containing Materials
      - Separate, Like-above-like
    - Utensils (scoops, brooms, brushes, totes, etc.)
    - Batching/Weighing Tables
    - Blending Order
    - Cleaning & Sanitation
    - Label Verification

- Traceability & Recall Program
  - Documented Program
    - Must be able to trace one back & one forward
      - Raw Materials (including product contact packaging)
      - Point of 1st Distribution
    - Recall Team with Defined Responsibilities
      - Tracing Product
      - Draft Communication
        - » Press Releases
        - » Product Information
        - » Customer Contact
        - » Legal Contact

    - Traceability – Manual and/or Electronic

- Supplier Verification
  - Direct Impact on Finished Product FSQ
    - Documented Program
      - Supplier Questionnaires
        - » Most Recent 3rd Party Audit
        - » Certificate of Liability Insurance
        - » Continuing Guarantee
        - » Questions Related to FSQ
          - Updated at Defined Frequency
          - Complete and Review Prior to Approval
      - Supplier Scorecard
      - Site Visits
        - » Audit Facility
        - » Build Partnership

- Internal Audits
  - Annual Full System Audit
    - Cross-functional Team
    - Internal Audit Training
  - Monthly Facility Audits
    - Involve all Team Members
      - Conduct Training Prior to Audit
      - Audit
      - Record Findings and complete CAPA

Corrective Action Form

CONTROLLED DOCUMENT

Document Number: FS-167 Revision: C

Date:		**Due Date:**	
Issued by:		**Approved by:**	
Corrective Action assigned to:		**Department:**	
Team Member(s) selected to assist:		**Department:**	

Description of Non-Conformance

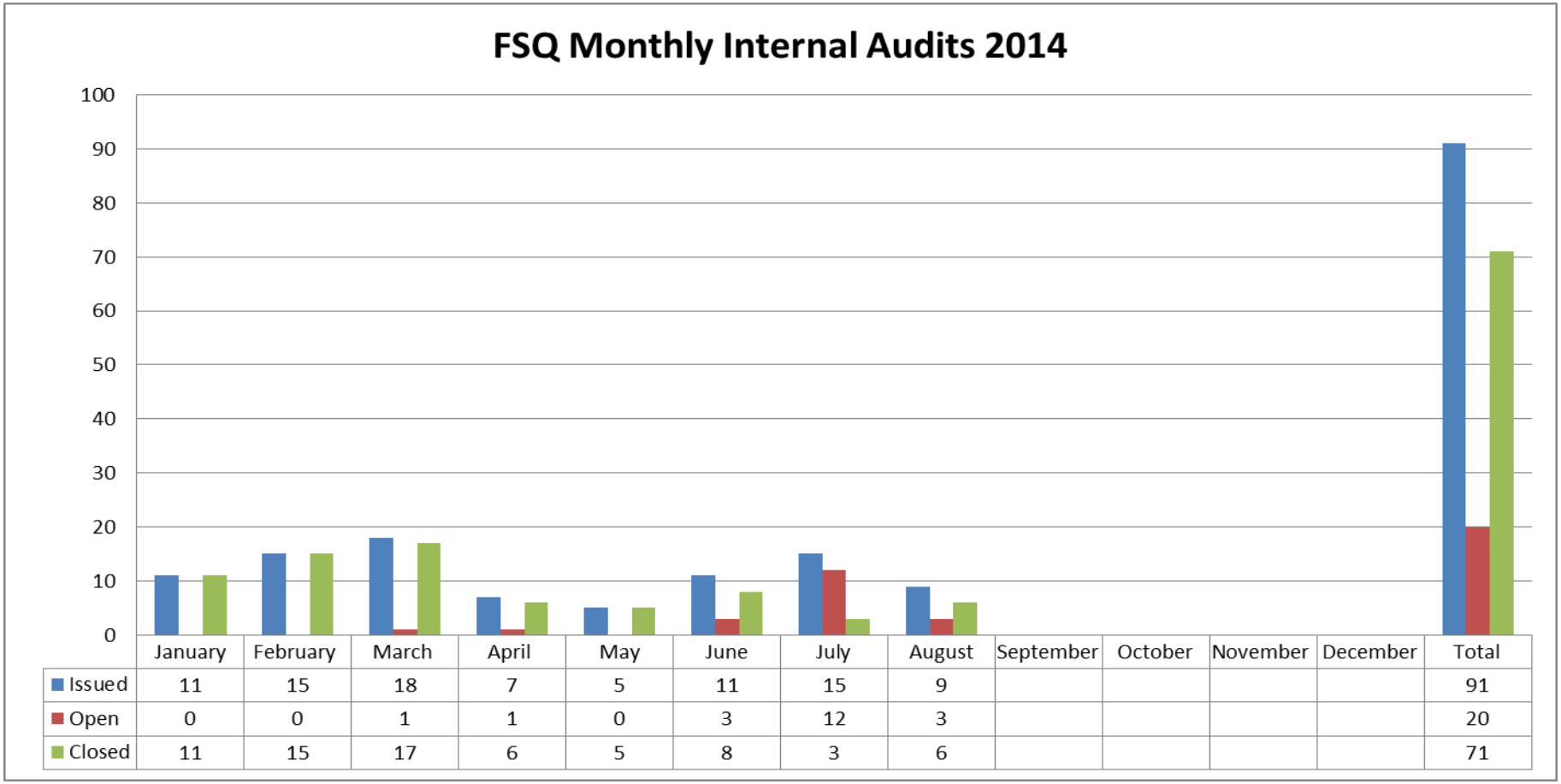
Before Picture(if applicable)	**After Picture(if applicable)**

Root Cause		
Description of action taken to correct issue:	**Completed by**	**Date Completed**
Description of verification activities(s) used to verify effectiveness:	**Completed by**	**Date Completed**
Preventive Measure		
	To be completed by:	**Target Date:**

To be completed by a Quality member:

Closed by:		**Date Closed:**	

- Internal Audits



	January	February	March	April	May	June	July	August	September	October	November	December	Total
Issued	11	15	18	7	5	11	15	9					91
Open	0	0	1	1	0	3	12	3					20
Closed	11	15	17	6	5	8	3	6					71

- Verification vs. Validation
  - Documentation as objective evidence that your FSQ programs are effective.

Verification →

Validation →

Food Safety/Food Quality/Pre-Req. Monitoring for Year 2014

	Validation Schedule				
	Audit frequency: Annually or when major changes are made.				
Element, Function or Area	Audit Date	Validation Method	Auditor	Judgement	CA Issued
Validation	**10/1/2014**	Review of Internal Audits, Verifications, and:	KHL		0
Training					
Personnel Practices					
Clothing	**10/1/2014**	Review of Customer Complaints	KHL		0
Jewelry & Personal Effects					
Visitors					
Personnel Processing Practices					
Calibration of Equipment					
Management of Pests/Vermin					
Premises & Equipment Maint.					
Cleaning and Sanitation					
Monitoring Water					
Control of Physical Contaminants					
Supplier Approval	**10/1/2014**	Review of Questionnaires, Scorecard, Audits	KHL		
Transport/Delivery					
Waste Management					
Allergen Control					
Food Safety Plan		Review of Customer Complaints			
Food Quality Plan					

* Note: The actual audit plan may be readjusted according to the status and importance of the audit activity.

Judgement Criteria

Suitable and effective = 

Suitable but NOT effective = 

NOT Suitable and NOT effective = 

Signature:

Date:

Additional FSQ Programs

- Food Defense
  - Visitors, Site Security, Shipping and Receiving
- Identity Preserved Foods
  - Non-GMO, Organic, Kosher, Halal
- Customer Complaints
  - Resolution, Tracking, Trending
- New Product Development
  - From Concept to Finished Product
- Label Approval
  - Creation, Review, Inbound, In-Process
- HOLD/Non-Conforming Product
  - Identification, Storage, Authority to Release
- Exterior Grounds
- Integrated Pest Management


STOP

- Effective Food Safety & Food Quality System
  - Make it Personal – Culture of FSQ
  - Audit Ready - Everyday
  - Document, Document, Document
    - Objective Evidence
  - Involve Team Members
    - Lean, Process Improvements