

Auditing (CQA) Fundamentals

Case Study B

Scenario: Organization being audited by customer

A. Background

The Cookie Factory Inc.

B-01

Category: Batch food processing, protected formulation

The Cookie Factory has been in business for 25 years. Mr. Baker (founder) sells three different kinds of cookies to distributors and private label customers for resale. One private label customer (Mall Mart) is 40% of the production volume. Mall Mart supplies the master print with their logo for the package art work. The Cookie Factory has 152 employees in their Blue Barn township facility.

Raw materials are purchased from local distributors who hold the materials at their warehouse in town until The Cookie Factory needs them. Food ingredients are checked and stored in a separate area that meets all local and federal regulations. The feed ingredients include powdered eggs, powdered milk, flour, sugar, leavening, vanilla, mint and code B material. Mr. Baker orders code B material himself. Code B is a special ingredient that Mr. Baker keeps secret. Other materials such as machine parts and lubricants are stored in a separate area. Each day the master chef fills out a recipe and gives the recipe to the production foreman. Sometimes there are minor changes in the recipe to reflect the quality and source of the raw ingredients. The recipe is placed on a bulletin board in the factory area (the previous day's recipe is returned to the master chef). The cookie makers refer to the master recipe and ensure that the necessary ingredients are secured from receiving and inspection.

There are 4 production lines with one cookie maker each. Each cookie maker has an assistant who uses a pushcart to collect the necessary ingredients. The cookie maker weighs out the ingredients on a 0-200 pound Toledo scale for large ingredients and a small electronic balance for the less than 10-pound additions. The cookie maker adds the ingredients per the recipe order and sets the mixing time and speed. The finished dough is dumped on to a moving belt. The belt takes the cookie dough through an oven with a microwave booster.

The baked cookies come off the end of the belt ready to be packaged. The packaging operator visually inspects the belt for broken, deformed or over-baked cookies. Rejected cookies are placed in a weigh bin. High reject rates result in a corrective action request. A sample is taken at beginning and end of each batch and taken to the laboratory for tasting. The cookies are gently coaxed into a cylinder (containing one dozen cookies) and sealed to maintain freshness. The cylinders are placed into boxes and taken to storage by a fork truck operator.

B. Cookie Factory Detailed System Audit Schedule - Issue 3. Audit 40517CFI

Item - Element	Area/ Function	Contact	Auditor	Date/ Time
DAY ONE				Oct. 27th
Auditor Team Meeting	Conference Room		ALL	7:30-8:30AM
Opening Meeting	Conference Room	Selected by Quality-Productivity Manager	ALL	8:30-9:30AM
7.4 Purchasing	Purchasing process	Dennis Power	RH	10-11:00AM
7.1, 7.2, 7.5	Order to Scheduling process	Jim Cable	RH	11- Noon
	Working Lunch			
7.1, 7.2, 7.5	Continue: Order to Scheduling process	Diane Draft	RH	1-2
5.2, 7.2, 8.1, 8.2.1, 8.4, 8.5	Customer Satisfaction process	Asa Bowen	RH	2-4PM
5.6, record of Steering Committee		Tom Stern	RH	3:30-4:30 PM
6, 7.6, 8.3, 8.5	Maintenance process	Bob Port Dave Beam	PC	10AM-12 Noon
	Working Lunch			
6, 7.5.2	Cookie process, master chef and maker certification	QP Mgr. and Operations Mgr.	PC	1-2PM
7.5.1, 7.5.3, 7.5.4, 7.5.5, 7.6. 8.2.3, 8.3	Cookie process	Operations Mgr and production personnel.	PC	2-4:30PM
4.2	Audit Quality Manual & Procedures		PC	Open Time
DAY TWO				Oct. 28th
4, 5.1-5.5.5 QMS	Adm. processes	Joe Fender	RH	8:30-9:00AM
4.2 Doc & Records	Documentation processes	Gayle Bowline	RH	10:-11AM
8.1, 8.4	Data Analysis process	QP Manger	RH	11-Noon
8.2.4	Testing	Janet Anchor	PC	8:30-10:00AM
8.2.2	Internal auditing process	QP Manager	PC	10-11AM
6.0	Adm., HR, training processes	Helen Waters	PC	11-Noon
Prepare Report	Conf Room		Audit Team	1:00-3:00PM
Exit Meeting	Conf Room	Auditee Personnel	ALL	3:00-4:00PM

Assignments: RH – Rachel Hook. PC: Paul Casting

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C. Audit Plan

AUDIT PLAN - 9/10/20XX	
Audited Organization:	Cookie Factory, Inc., Blue Barn Township
Auditing Organization:	Mall Mart Supplier Quality Assurance Department
Purpose:	Verify conformance and effectiveness of the quality system using ISO 9001 (ANSI/ISO/ASQ Q9001-20XX) quality system standards and to report any nonconformance(s) to ISO 9001 requirements.
Scope of the Audit:	The Cookie Factory facility production units plus support activities for Mall Mart Cookies. The audit includes all departments that support the production of Mall Mart cookies that are responsible for meeting ISO 9001 requirements. The areas of interest include the: Purchasing, Quality Assurance, Laboratory, Packing and Distribution, Order entry, Scheduling, Production, and Training departments.
Requirements:	As specified in ANSI/ISO/ASQ Q9001, Mall Mart specifications and existing Cookie Factory Company policies and procedures.
Applicable Documents :	The Quality (policy) Manual(s) Unit procedures that address the requirements. Other regulatory (FDA) requirements and industry standards
Schedule:	October 27, 20XX 7:30am..... Orientation for auditors (such as safety or environment) 8:30am..... Opening Meeting (for auditees) 9:00am..... Tour\ Review documents 10:00am-4:00pm... Interviews 4:00pm-5:00pm Audit team meeting October 28, 20XX 8:00am-8:30am.....Daily Briefing with Cookie Factory coordinator 8:30am-1:00pm..... Interviews continued 1:00-3:00pm.... Audit Team meeting, prepare report 3:00- 4:00pm.....Exit Meeting
Team Members:	Rachel Hook; Lead Auditor, ASQ CQA Paul Casting; ASQ CQA
Approved Rachel Hook, Mall Mart	Approved: Cookie Factory, Inc.