

Product Safety Program Audits

Risk Control from Liberty Mutual Insurance



Highlights:

- Goals of conducting an audit
- Types and scope of audits
- Preparing and conducting the audit
- Management
- Research and development/ engineering and other departments
- Quality control

Performing a formal program audit is a systematic approach for evaluating the continuing effectiveness of your product safety program.

Goals of conducting an audit should include determining if your:

- Product safety program is meeting the organization's needs and goals.
- Product risks are clearly defined and well controlled.
- Manufacturing and quality control procedures are sufficient.
- Instruction manuals and warnings are properly prepared and communicated.
- Product safety program adequately addresses specific areas such as recalls, record retention, product safety design review, regulations, etc.
- Overall program fulfills the primary intent of reducing liability risk to the organization.

Types and Scope of Audits

Product safety audits can vary according to the audit's intended goals, how often they are conducted and who completes them. Some companies conduct audits on a regular basis, often to benchmark progress each time; while others may perform them on a less frequent, as-needed basis.

Depending on the audit's objectives, the focus may be on one specific operation or department, or a specific aspect of product safety. Other situations may call for performing an audit that evaluates a wide range of company operations. Whatever your objective, it is important that the purpose and scope of the audit be clearly determined before it is designed and conducted.

The magnitude and type of audit will help determine how many individuals and departments should take part. Auditors should possess an understanding of the various technical areas that will be studied.

Individuals who could serve well as auditors include:

- A product safety coordinator
- Product safety committee member(s)
- Employee teams
- Design and manufacturing engineers
- Outside consultants (those specializing in product liability and quality functions)

Preparing for the Audit

It is important that the auditors are well prepared to conduct the evaluation. This will help ensure that the audit is successful, that outcomes and findings are reliable, and that the auditors receive cooperation from other individuals involved in the process.

Before conducting the product safety program audit the auditors should be familiar with the following:

- The goals of the audit.
- Present company product safety program content and methods.
- Technical information concerning the products being evaluated.

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- Actual and potential sources of accidents and injuries from use of your products.
 - Applicable federal, state and local regulations, as well as association practices.
 - Applicable consumer and consensus standards, national and international.

Using an audit guide or template can help ensure consistency and help reduce the possibility of oversights by ensuring the evaluation of critical items. Each portion should be designed and tailored to properly assess the specific operation or department. Complete the audit with observations and impressions gained through personal interviews, reviewing records, literature, manuals, policies, procedures, etc.

Conducting the Audit

Auditors should meet with the operation/department managers to review, discuss and clarify responses, along with ideas concerning potential corrective actions. A formal report should then be prepared and reviewed, in draft form, with your legal department. The report should include an executive summary, objective findings and recommendations; and elaborate on current strengths versus opportunities for improvement. Items should be prioritized, indicating those that are most critical and any that require additional study.

The following lists identify those items to evaluate during the audit.

Management

- Corporate product safety guidelines.
- Scope and range of product safety coordinator function and defined duties.
- Evidence of management and employees training concerning their product safety responsibilities.
- Meeting minutes and bylaws of your product safety committee.
- Methods and protocol for your record retention policy.
- Recall, withdrawal and product retrofit processes; including evidence of past critiques and plan testing.
- Process flow charts demonstrating effective lines of product safety communication between departments.
- Reports of action taken responding and correcting previous product liability related accident and injuries — including investigations and reports of all types.

Research and Development/Engineering

- Product safety design reviews.
- Applicable safety codes, regulations and industry standards.
- New and revised regulations as products evolve and improve will need to stay current with updated standards.
- Documents verifying assessments that demonstrate how products are designed to meet ergonomic and human factor principles. This also includes analysis of Intended product uses and likely misuses that are identified and evaluated.
- Adequate, reliable safeguarding — including logic used to design into product.
- Quality control records are used to identify and correct product safety problems related to manufacturing defects.
- Safety warning labels and instructions meet applicable codes and standards.
- Instruction, operation and maintenance manuals address how to safely use, maintain and dispose of the product.

Manufacturing

- Production methods demonstrate GMPs used within the industry — evidence of evolving improvements for efficiency, safety and reliability. Packaging, storage and transporting of goods and finished products have specific written processes, time and safety tested.
- Training records demonstrate consistent employee competency in correct SOPs.
- Quality control records audited to reflect areas needing improvement.
- Product identifications mark company name, location and manufacturing date (and Julian dates where applicable).
- Records maintained of component supplier materials, service providers, installers and design consultants both foreign and domestic are traceable to those providers.

Marketing Department

- Advertising and sales literature (hard copy and e-commerce information) accurately depicts product use and limitations.
- Publications are technically correct and have been reviewed by legal counsel and subject matter experts equipped and skilled to approve.
- Photographs and diagrams illustrate the safe use of the product — no puffery noted.
- Sales professionals demonstrate competency with training records highlighting product use and product liability communications.
- Records retained (hard copy or e-commerce registrations) kept on first purchasers.

Purchasing

- Records demonstrate legal review of purchase orders, hold-harmless agreements, supplier and/or service provider contracts.
- Quality control records show where engineering specifications are met or are deficient, including course of action, timelines and responsible parties.
- Written procedure that shows how suppliers and providers are selected and audited.
- Procedure specifies how supplier parts and materials are to be packaged and shipped, and that supporting documents are due upon receipt to accept shipments.

Quality Control

- Documented quality control program and metrics are in effect.
- Testing criteria for critical raw, in-process and finished materials.
- Defect verification and isolation methods: how are manufacturing flaws checked at each production and testing stage?
- Written SOP for correcting deficiencies.
- Records of test equipment maintenance, calibration and certification.
- Procedures dictate how products are packed and stored.
- Process in place to isolate items received or those needing rework to avoid re-introduction to production floor — process to destroy or return discrepant materials.
- Returns, complaints and warranty information are reviewed for recurring product safety problems.
- Production team or product safety team minutes isolate corrective actions taken in response to complaints, defects and returns.

Distributors/Dealers

- Reports of customer accidents and complaints are promptly reported to the supplier, provider or OEM.
- Communications regarding known or suspect product hazards and recalls provided to the distributors and dealers.
- Contracts denoting terms and conditions of relationships are required and obtained from distributors, dealers and providers.
- Certificates of Insurance on hand for all supply chain players with evidence of additional insured coverage on your company's behalf, in place before services are accepted.

Service Installation

- Records of field service calls (e.g., installations, setup, on-call visits, scheduled PM) document all inspections, tests and findings, with customer sign-off.
- Customer-refused repairs are documented in writing, with a copy is left with the customer.
- Unsafe operating practices or modifications documented (with photos where necessary) and a copy is left with the customer.

Records Management

- In writing, procedure lays out all records retention, purging cycles and functions of department coordinator, with legal oversight.
- Records included are all product evolution and design, material specification conformance, audit results, claim response and action taken, and recalls (examples contained in the preceding sections of this audit process).
- Complete documentation under regulatory scrutiny, including those required by CPSC, FDA, USDA, and ISO. All such standards are within jurisdiction of product type, use and market.

Summary

Important information concerning the effectiveness of your product safety program can be obtained by conducting an audit. It can help you verify whether your present program is capable of identifying and controlling product safety exposures, and should help specify any deficient areas in need of improvement or additional study.

Sample audit guides are available from your Risk Control Consultant. They can be tailored to meet your organization's particular audit needs.

Bear in mind that any audit is only as good as the follow-up and correction of those opportunities discovered during the audit itself.

Resources

The Bureau of National Affairs, Inc., Product Safety & Liability Reporter.

U.S. Consumer Product Safety Commission, Regulations.

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