Product Safety Program Audits – An Often-Missed Opportunity

by Don Mays

(Published in ADK's 2020 Product Safety and Recall Directory)

Key Takeaways:

- Misplaced trust in raw material or component suppliers is often the root cause of unsafe or non-compliant finished products.
- The laboratory testing program is an often-forgotten part of a product safety audit.

Introduction

There is plenty of information available regarding best practices for designing and managing your product safety program. However, you might be hard-pressed to find much information on best practices for auditing that program. Regular audits are an important, but often missed, element of the product safety management process.

All pubic companies have their financial statements independently audited each year. Most private companies also go through annual audits of their accounting and financial records. But in a recent survey of ICPHSO attendees, only 43 percent of respondents reported that their company regularly audits their product safety program. Yet lapses in a product safety process can result in injuries to consumers, costly recalls, product liability lawsuits, and reputational damage to a company … all risks that perhaps the accountants didn't consider.

Far too often companies believe that ensuring compliance with all regulations and standards also ensures product safety. But studies have shown that the vast majority of products cited in CPSC recall announcements are fully compliant with regulations and standards. Clearly, compliance does not equal safety, and simply auditing the compliance program will fall far short of identifying more grievous risks.

Developing a robust product safety program is complex and beyond the scope of this article. But once designed and fully executed, it important to ensure that the tenets of the program are being followed religiously. While this article does not prescribe a one-size-fits-all approach to safety audits, it does layout some key considerations.

Essential audit elements

Product safety program audits start with a look at the design phase of any new product development. At that stage, there should have been a risk assessment using processes such as DFMEA (Design Failure Mode and Effects Analysis) or Fault Tree Analysis. There also should have been a human-factors evaluation to uncover risks that may not have been so easy to foresee.

Sourcing is the next critical area that requires very close scrutiny. Misplaced trust in raw material or component suppliers is often the root cause of unsafe or non-compliant finished products. The audit should review the level of due diligence exercised when selecting and on-boarding suppliers. Was there a deep dive check into the supplier's background? Were specifications clearly documented? Does the supplier have a robust QC program? Does the supplier outsource any part of the manufacturing process? Has a supplier scorecard system been implemented with documented and enforced consequences for poor performance? Is there QA testing conducted independently to qualify final acceptance, and ongoing testing to ensure continued compliance with specifications? Is there a traceability process to identify the history of each component used in each finished product? Those are a few of the questions that should be asked—and answered— to ensure supplier transparency and accountability, which are critical elements of a safety program.

Next is a close look at the factory and manufacturing process. The factory should have a robust QC program as well as QA program that sets low tolerances on off-spec production. There should be an effective stage-gate process that is executed with discipline. Factory workers should be empowered to stop production when potential safety hazards could enter into the product's manufacturing process. Storage and shipping processes for final production should also be reviewed to ensure there is no opportunity for hazards to be introduced post-production.

The laboratory testing program is an often forgotten part of a products safety audit. A recent ICPHSO survey revealed that only 30 percent of the respondents said their companies regularly audit their testing program. Yet audits are essential for uncovering lapses in test equipment calibration, test report errors, procedural errors, lab personnel incompetence and negligence, and even fraud. The media is filled with reports about falsified test results that have left companies and consumers at risk. The first question to ask is whether the lab being used is accredited to perform the desired tests and whether their personnel are qualified to conduct such testing. Auditors may also ask about the whistleblower policy for lab personnel to disclose ethical violations.

Once the above requirements have been satisfied, the audit should include a review of the documented data collection and warehousing procedures. Document repositories should be centralized, easily searchable, and accessible to stakeholders. Auditors should look at whether there is version control on documents as well as a process to make sure that documents can't be altered without administrative authority.

When the product reaches the marketplace, there should be a robust data collection and analysis process to promptly identify any emerging safety issues. The data collection process should be designed to assimilate data from both internal and external channels. Ideally, that process should be automated and not be relegated to a single person.

The audit should also look at the process by which safety issues are escalated to senior leadership. Often, a cross-functional product safety committee is established to prioritize issues and recommend any appropriate corrective actions. That committee should be empowered to serve as a SWAT team to resolve issue quickly.

When things go wrong, as they sometimes do, recalls are often the result. A safety program audit should look for recall preparedness—a documented process with stakeholder roles and responsibilities in the event that a recall should be required. The documented process

should include a communication strategy as well as a reverse logistics process for pulling back defective products.

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"When you don't have the time to do it right, when will you have the time to do it over?" -- John Wooden

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Audit teams

So who should conduct a product safety audit? While it could be conducted by either the Internal Audit team or outside auditing firms, what is most important is that the auditors be independent of the business function. They should be qualified product safety professionals who follow standard auditing principles such as those described by ISO 19011–2018. Ideally, audits should be done by a team of two or three people with a mix of backgrounds, such as engineering and law.

Audit results should be communicated to the highest level of a company with recommendations for any corrective actions with milestones and deadlines prescribed. It would also be ideal to have feedback loops implemented such that the effectiveness of prescribed corrective actions can be monitored.

While I haven't described all of the elements of a product safety program audit, I am hopeful that I have at least inspired some food for thought. While developing a disciplined product safety program may not be key objective a company, its importance always become paramount when faced with a safety crisis.

The views and opinions expressed here in this article are those of the author and do not represent the views or opinions of Samsung Electronics America.

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