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Product Design Reviews

Product design reviews are standardized, formal, documented, systematic, and critical evaluations of product designs that are performed at various stages of product development. The purpose of these reviews is to identify any problem areas that may exist in the design or design process and to initiate corrective action to address these areas. Design reviews are important control measures for ensuring that designs meet their intended objectives.

Product design reviews are critical for product safety management and product liability prevention. Safety reviews can identify potential hazards that may exist in a product or process; ensure that safeguards have been provided and are adequate; and establish controls for producing the product according to specifications. In litigation, they can also be used as evidence that the company acted reasonably in designing the product.

Product design reviews are important from an economic perspective. The product design phase time in a product's life cycle is the time when product changes can be made easiest and least expensively. Once a product is in production and out in commerce, it becomes substantially more expensive to make changes. One author cites a product safety incident where the cost of correcting a product already in the marketplace was over 16,000 times the cost of addressing the problem at an early stage in product development.[6]

This report provides an overview of the product design review process and issues that should be considered when developing a review process. For information on legal issues associated with design defects, see *Design Defects* on Hanover's Risk Solutions website.

Product Development Process

Although specific processes will vary from company to company, new product development generally goes through five basic stages. They are:

- Concept development
- System level design
- Detailed design
- Testing and refinement
- Production ramp-up

Traditionally, organizations performed these activities in a sequential manner. Newer design models have been developed that overlap these stages to reduce the amount of time it takes to get a product to market.

Concept Development

In the concept development phase, the organization identifies the needs of the intended market for the product, establishes target specifications for what the product has to do, generates and evaluates alternative product concepts, selects a single concept for further development, refines the product, and establishes a development schedule. The organization will also analyze competitive products and perform an economic analysis of the project. The output of this phase will

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be documented in a development plan that includes the details of the selected concept, the product specification, a detailed development schedule, and a listing of the resources necessary to complete the project.

System-Level Design

In the system-level design phase, the organization generates the product architecture, defines the major subsystems and interfaces, refines the design for performance and manufacturability, identifies suppliers of key components, defines the product assembly scheme, and identifies service issues. The output for this phase usually includes the functional specifications for each of the product's subsystems and the process flow for the final assembly process.

Detailed Design

In the detailed design phase, the organization develops the complete specifications for all of the unique parts in the products, defines production processes and quality assurance procedures, and begins procurement of long lead-time production equipment. The output from this stage will be the control documentation that will be used to produce the product.

Testing and Refinement

In the testing and refinement phase, the organization constructs and evaluates preproduction versions of the product. The testing may address both individual subsystems of the product as well as the complete product. The goals of this stage are to determine whether the product will work as designed, satisfy customer needs, and meet reliability criteria, and to identify any necessary changes for the final product.

Production Ramp-up

In the production ramp-up phase, the organization builds the product using the intended production system. The purpose of the ramp-up is to train the work force and work out any remaining problems in the production process. The product may be sent to selected customers for final evaluation under actual use conditions. At some point after this, the product is launched and made available for widespread distribution.

Safety Reviews

Organizations should include formal safety reviews at set intervals during the development process. These reviews should be in addition to any informal safety reviews that are performed by the design team during the development of the design.

Objectives of Review

A design safety review has several key objectives. These include:

- To identify and correct hazards to prevent injury and illness
- To ensure that the product complies with applicable product safety regulations
- To ensure that the product conforms to any relevant, voluntary product safety standards
- To resolve outstanding safety- and health-related issues
- To contain project cost by reducing redesign and rework

Timing of Design Reviews

Design reviews may be performed at several different stages during the design process. The timing of these reviews may be based upon arbitrary points in the development process (e.g., every two weeks, at set milestones in product development, or when design specifications have been developed).

Typical milestones where formal design reviews may occur include:

- When target specifications have been developed
- When a conceptual design has been created
- When the product architecture has been developed
- When detailed design specifications have been completed
- Prior to production ramp-up

Scope of the Review

In general, the scope of a design safety review should be to identify and address any product safety concerns that arise from a proposed product design. The specific scope of an individual review meeting will vary depending upon the design culture of the organization and the timing of the review.

Culture

In organizations that follow traditional, serial design processes, the work of product designers and design reviewers is carried out in separate sequential steps. The designer prepares a design that is then formally reviewed from the ground up for safety by independent reviewers. In concurrent design processes, the designers conduct safety analyses during the design process and the formal design review involves the checking of the analyses already performed by the designers. There are advantages and disadvantages to each method.[5]

Timing of the Review

Design reviews performed early on in the concept phase of the design, before specifications are developed, will involve reviews of information on similar products produced by organizations or competitors and identifying potential product hazards involved with a design concept. As the design progresses, more information will become available about the proposed product and the review will focus more on the particular characteristics and specifications of the proposed product and its manufacturing process. At the end of the design process, reviewers will have a physical prototype or first-made product to evaluate, as well as initial results of product safety tests. Appendix A lists types of review activities that may take place at various stages in the development of the product.

Length of Review

Several factors will affect the amount of time required to perform a design review. These include:

- The complexity of the product
- The scope of the analysis
- The originality of the design
- The availability of data
- The formality of the analysis

Cost of Not Performing Reviews

One author provides the following example to illustrate the cost of not performing design reviews.[6] The example was derived from the experience of a major office equipment manufacturer in correcting the cost of a product defect. The company estimated that it would cost $35 to have corrected the defect during a design review. The cost for correction increased to $177 if the defect had been corrected after the design review, but before part procurement. The cost increased to $368 to correct the defect after procurement, but before assembly. It jumped to $17,000 for correction after assembly, but before shipping. Once the product was in the field, the cost of correcting the problem was estimated to be $590,000. The field correction ended up being 16,500 times the price of the correction at the design review stage.

Performing Design Reviews

The following section provides general recommendations for performing design reviews.

Process

The organization should develop a formalized policy and procedure for performing design reviews. The policy should identify the purpose of the review and why the organization is performing the design review. A senior company official should sign off on the policy to demonstrate management commitment to the project.

The procedures should include specific process measures for holding responsible persons accountable for completing the review. Measurement tools should be aligned with other project measures, such as scheduling and cost goals. This joint accountability is important to ensure that all the participants of the product development team work together.

Participants

A multidisciplinary team should perform the design review. The people for the review should represent the key functional areas in the company. The people should have differing backgrounds and experience so that the product may be looked at from multiple viewpoints. Also, they should not have participated in the development of the product. That way, the product can be reviewed with a new and unbiased viewpoint. Not all participants may be required for every review. If the design is being performed for a client, a representative from the client should be invited to participate.

The head of the team should be a senior official in the organization. Senior management involvement is essential for demonstrating that the proceedings have high priority and for assuring that a rigorous review is performed. Also, the senior manager may be used to reduce interdepartmental conflicts or defensive reactions to opinions.

At least one participant should have specific training and knowledge in safety engineering principles. Organizations should not assume that engineers or designers routinely possess these skills. A survey of mechanical engineers performed in the early 1990s identified that, although many design engineers recognize the value of safety on good product design, many engineers are either unaware of or have not been trained in, formal safety analysis techniques.[1] The majority of the respondents had not taken a single course in safety in college or attended any lectures or seminars specifically addressing product safety.

Guidance Document

A guidance document should be developed that identifies the procedures the participants should follow at each stage of the design review process and instructions for performing the procedures. The document may also include any standardized analysis tools that the reviewers will use when performing the review.

Checklists are often recommended for performing reviews. Such tools are helpful for expediting design reviews of repetitive design tasks or where variations in design are very small. They are also useful for making sure that key considerations have not been overlooked. Also, the creation of a checklist for a new product requires the checklist designer to complete a hazard analysis in order to create the checklist.

Checklists do have limitations and should not be used as a replacement for a formal safety analysis. The most important limitations are their completeness, currency, and applicability. If the checklist is not complete, the user may miss a potentially significant hazard. If the checklist is not current, the user may not be evaluating the product against the current state-of-the-art. If there are too many, or too significant, differences between the product being reviewed and the product it was designed for, the checklist may not provide an accurate review of the hazards present.

Corrective Action

All possible product hazards that are identified during the review process should be categorized according to the type and degree of hazard. The hazards should then be corrected to the degree of risk acceptable to the company.

Hazard Categorization

Hazards should be categorized according to their expected frequency of occurrence and the likelihood of severity. The criteria used may be qualitative (e.g., high probability, medium probability, or low probability of failure) or quantitative (e.g., one in one million, one in one thousand, or one in ten). These criteria can be used to rank the priority of identified hazards and be used when identifying possible corrective action measures.

Hazard Elimination and Control

Product safety practitioners have established a preferred hierarchy for corrective actions using system safety principles. In general, this

hierarchy consists of four basic options. In order of preference these are:

- Eliminate the hazard through design
- Protect or guard against the hazard
- Warn users about the hazard
- Train users to avoid the hazard

In cases where the identified hazard is so extreme, too expensive to fix, or beyond the risk tolerance of the organization, the organization may choose to end product development.

Factors Affecting Decisions

Corrective action decisions may be affected by internal and external factors. These include making trade-offs between the risk posed by the hazard and the utility or cost. The decisions made by a company will depend upon the risk tolerance of the company. Decisions made regarding trade-offs in corrective action should be documented to provide a record of the organization's rationale for the decision.

Third Party Reviews

There are several nationally recognized testing laboratories (NRTL) that provide product safety assessment services. These services can range from initial design reviews, to the testing of prototypes to verify that a design meets a particular safety standard. The organization may even certify that a design meets a particular safety standard.

Product manufacturers should consider using a third party reviewer as an external check on the soundness of the design. The reviewer can provide a more impartial assessment of the product since there is no emotional attachment to the product design. Certification of the design can provide a marketing advantage. Also, a third party certification may be useful should the design later be challenged.

The review should be documented and any hazards identified by the review addressed in a timely manner.

Documentation

The product design review process should be documented to provide a record that the examination occurred and the issues covered by the review. The documentation should include information on the follow-up actions that occur.

Recordkeeping serves several different functions. It is important for litigation defense because it provides a factual record that the review did occur, indicates the thoroughness of the review, and states the reason for design choices. This is important to show that the manufacturer acted in a reasonably prudent manner and to help defend against arguments that the product could have been made safer with a reasonable alternative design. (See Design Defects, on Hanover's Risk Solutions website for additional information on the legal aspects of product defects.) Also, it provides design organizations with a history as to why certain designs were approved or rejected and the concerns posed by the design in case the product is revisited in the future.

Specific documentation that should be maintained includes:

- Design drawings and specifications
- Copies of voluntary standards and regulations applicable to the design
- Minutes of formal design review meetings
- Hazard analyses and corrective actions
- Test results
- Assessments of alternative designs
- Correspondence with clients and third party reviewers

In most cases, not all documentation will be positive. However, negative documentation should not simply be discarded; otherwise, it has the potential to become a "smoking gun." Instead, the negative comments should be addressed contemporaneously in writing by someone in authority and included in the product file.

Evaluating Design Review Effectiveness

Design review is a demanding and complex task. The following are general questions that may be used to evaluate a design review.

- Are design safety reviews required for all new product designs?
- Does the design organization have a clearly assigned responsibility for performing product safety design reviews?
- Are design safety goals incorporated in the performance objectives of designers and engineers?
- How much training is provided annually to participants on the safety-related aspects of product design?
- Has the organization established an independent group representing functions in addition to design for conducting product safety reviews?
- Does a senior executive chair the review group?
- Is technical guidance available to reviewers?
- Are records kept of all proposed design review changes?
- Are records kept which explain why a design change was or was not accepted?

References

1. B. Main and J. Frantz. "How Design Engineers Address Safety: What the Safety Community Should Know." *Professional Safety.* 39.2 (1994) pp. 33-38.
2. K. Ulrich and S. Epplinger. *Product Design and Development.* New York: McGraw Hill, 1995.
3. National Safety Council (NSC). *Product Management Guidelines, Second Edition.* Chicago, IL: NSC, 1997.
4. P. Adams. "Establishing a Safe Design Process." *Professional Safety.* 44.11 (1999) pp. 29-32.
5. P. Clemens. "System Safety in Design Practice: Two Work Models Compared." *Professional Safety.* 44.11 (1999) pp. 33-35.
6. R. Goodden. *Product Liability Prevention: A Strategic Guide.* Milwaukee, WI: Quality Press, 2000.
7. T. Ichida. *Product Design Review.* Portland, OR: Productivity Press, 1996.
8. U.S. Consumer Product Safety Commission (CPSC). *Handbook & Standard for Manufacturing Safer Consumer Products.* Washington, DC: CPSC, 1975.
9. W. Hammer. *Product Safety Management and Engineering Second Edition.* Des Plaines, IL: American Society of Safety Engineers, 1993.

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Appendix A: Design Review Activities at Various Stages of Product Development

The following lists provide descriptions of activities that may occur at various stages of new product development. They are adapted from Figure 12-2 of *Product Safety Management and Engineering*, Second Edition. Consult the reference directly for a more comprehensive listing of activities.

Concept Phase Activities

Concept phase review activities include ensuring that the product developer has:

- Reviewed similar products for safety concerns
- Performed a preliminary hazard analysis on the proposed and accepted design concept
- Reviewed and taken into account any applicable safety standards and regulations when developing the preliminary design specification
- Established additional requirements for safety concerns not addressed by standards and regulations
- Determined basic criteria for evaluating components and external suppliers
- Initiated a means for monitoring safety concerns during product design

Design Phase Activities

Design phase review activities include ensuring that the product developer has:

- Conducted safety tests on all materials, components, and devices to be used in the product
- Evaluated test results to determine feasibility of design
- Identified safety-critical materials, components, and procedures
- Established procedures for coordinating activities between groups responsible for various design activities
- Established procedures for reporting design problems
- Reviewed the effect proposed design changes have on product safety
- Documented analyses, test results, and corrective actions taken to address each safety concern
- Conducted all activities required by mandatory regulation and standard

Pre-Production Activities

Pre-production review activities include ensuring that the product developer has:

- Developed and tested a prototype of the product
- Evaluated the prototype test results for safety concerns
- Addressed any safety concerns raised by prototype testing
- Documented any changes made to the design
- Ensured that changes are distributed to appropriate people
- Performed a safety analysis of the final product design
- Documented the results of this analysis
- Reviewed all advertising materials, dealer training materials, warnings, and instructions for safety content
- Trained field service and dealer personnel on safety-related subjects
- Made production and quality personnel aware of safety-critical items

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