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BASIC ELEMENTS OF PRODUCT SAFETY ENGINEERING

PRODUCT SAFETY AND PUBLIC EXPECTATION

“Manufacturers have a responsibility to produce products that satisfy the safety expectations of society” (American National Standards Institute, *Guidelines for Organizing a Product Safety Program*, 1978). “The public does have special expectations of technical people. Engineers, designers, and other technically trained people do have special responsibilities to the rest of society with respect to personal safety. Society invests in the training and professional development of technical people. Concomitantly, society invests with the professions and their institutions certain trusts, among them a trust that the professions will watch over the well being of society, including its safety. Professional responsibility is based on the belief that the power conferred by expertise entails a fiduciary relationship to society.” (William W. Lowrance, *Of Acceptable Risk*, 1976.)

BASIC ELEMENTS OF PRODUCT SAFETY MANAGEMENT AND ENGINEERING

Product safety engineering involves the application of the principles of safety engineering to the design and marketing of products. Basic elements of product safety programming are designed to identify and evaluate potential product hazards for systematic control using the techniques of safety management and safety engineering. Generally, basic elements of product safety programming include (but are not limited to):

- A clear, explicit, and documented statement of product safety policy.
- A clear, explicit, and documented assignment of individual responsibility for the conduct of product safety activity.

- A clear, explicit, and documented product safety program plan outlining the specific steps, procedures, and techniques to be followed on conducting product safety activity during the product design and marketing processes to achieve product safety goals.
- As a starting point, a documented search for authoritative literature and relevant standards relating to a potential safety concerns associated with the product to be designed or marketed.
- The conduct of explicit and documented activity giving attention to the systematic discovery or identification of reasonably anticipated potential product or system hazards, followed by an evaluation of those hazards in terms of associated risk factors (likely loss event probability and severity).
- The documented use of the core concepts and principles of safety management and safety engineering, and the cardinal rules of hazard control, to reasonably eliminate or minimize unacceptable product hazards (though, in order of preference and effectiveness, use of design, safeguarding, or warning means).

To summarize, an effective product safety program must (a) formally declare to all personnel that product safety is important, (b) assign responsibility to specific individuals (or heads of departments) to assure product safety during the product design, manufacturing, and marketing process, (c) establish specific activity to identify and evaluate potential product hazards based on reasonably foreseeable conditions of product use, (d) utilize reasonably well established and available safety standards and guidelines to design hazards out of products “on the drawing board,” (e) add components or devices to products to safeguard the remaining hazards, and following this, (f) provide

adequate product warnings and instructions that address hazards that must remain part of the product design (cannot be reasonably eliminated or controlled through design means) or are inherent to product use.

The basic elements of product safety management and engineering have been generally presented in various authoritative texts, beginning with the historic general safety engineering literature and, since the mid-1960's, expressly designated *product* safety literature and recommended *product* safety standards.

Two standards regarding the basic elements of product safety programs published in the 1970's are *Guidelines for Organizing a Product Safety Program*, published by the American National Standards Institute (ANSI) in 1972 (revised in 1978) and *Handbook & Standards for Manufacturing Safer Consumer Products* (1977), a publication of the Consumer Product Safety Commission (CPSC).

While these publications were first directed toward manufacturers of consumer products, the recommended basic elements of product safety programming contained within these standards were quickly embraced by the general product safety literature as applying to the manufacture of any product, whether consumer or industrial (see for example, Roger Brauer's *Safety and Health for Engineers*, Van Nostrand Reinhold, 1990). Accordingly, such references expressly state that product safety programs should appropriately include the following:

1. Policy Statement: A widely publicized explicit formal statement, as a matter of record, regarding top management's commitment to state-of-the-art product safety and the preeminent importance of product safety during product (system) design, production, and distribution.

2. Organization, Staffing, and Program Planning: Specific assignment of product safety responsibility and authority should be clearly established beginning at the executive level and reflected in various position descriptions and performance appraisals. Specific procedures should be developed for each element of the product safety program. Department plans should encompass product safety as it would relate to design, purchasing of parts, manufacture, marketing, use, service, and disposal. Means should

be established to provide administrative surveillance and technical product safety assistance and guidance to various operating departments.

3. Communications and Training: Appropriate training should be conducted to ensure that those participating in the product safety program know what their responsibility and role is and have the appropriate skills to properly carry out their contribution to product safety activity. An adequate and current reference library of applicable texts, periodicals, and related safety standards should be maintained.

4. Design Review: Design review involves the formal examination of product materials, components, configurations, packaging, and labeling (instructions and warnings) to identify, evaluate, and control potential product hazards. Hazard identification and evaluation criteria should include objective estimations of the conditions under which the product will be used, including such things as the age levels and physical limitations of users, and potentialities that might occur as a result of reasonably foreseeable product misuse. Comparisons should be made to applicable authoritative guidelines and standards.

Adequate laboratory and field-tests, addressing normal use and reasonably foreseeable misuse, should be conducted to verify product safety design factors throughout the product's useful life and disposal. Hazard analysis should be conducted using currently accepted techniques. Appropriate corrective action must be taken when product safety hazards are identified. Findings (details regarding potential hazards) and decisions (regarding corrective actions) should be documented.

Group design reviews should be chaired by a designated senior official having overall product safety authority over all participating departments.

5. Documentation and Change Control: Documentation and change control involves the documentation of design decisions and the technical basis or reasons for those decisions. After all reasonable design changes have been made, remaining hazards and the required actions that users must follow to protect themselves from danger (for later production of adequate product warnings and instructions) should be clearly identified in these documents.

6. Purchase Product Control: Purchase product control involves control over purchase procedures and decisions to include steps to ensure that safe materials, components, and finished products (free of hazards that will ultimately affect the overall safety of products sold in the marketplace) are obtained from suppliers, including the following: (a) preparation or purchase documents with clear and precise statements regarding safety requirements (adherence to state-of-the-art product safety techniques), (b) selection of suppliers with proven ability to provide safe products, and (c) the unequivocal understanding regarding the responsibilities of suppliers to declare and report substantial product hazards.

7. Production Control: Production control involves the control of production processes to assure product safety. Special concerns should include assurance that (a) raw materials, semi-finished, or finished materials conform to required specifications, (b) work instructions affecting product safety are described in writing, including inspection and test procedures, (c) the precision and accuracy of equipment and tooling meet established production tolerances and quality (including appropriate equipment tests and inspections), (d) out-of-spec parts or finished products are properly handled, (e) work environments enhance products safety, and (f) finished work is safely handled and stored to preclude damage and the introduction of safety hazards.

8. Quality Control: This step includes proper and adequate product sampling, inspection, testing, and repair or segregation of non-conforming (unsafe) products to remove unsafe products from the production process.

9. Distribution: This step includes the design and selection of proper packaging and product distribution methods to prevent hazards from being introduced during the shipping and handling process. This also includes the provision, where necessary, of current and adequate product assembly and test instructions.

10. Customer Service: Customer service includes the development of various manuals and warnings notices (including product labels) that provide (a) adequate product assembly and test instructions, (b) safe operating and maintenance instructions, and (c) adequate warnings concerning specific product hazards. Service after-the-sale includes the provision of up-dated product hazard information to previous product buyers (current users).

11. Records: An effective product safety program requires the (pro-active) compiling and keeping of records in sufficient detail and format to permit timely detection of safety hazards and trends. This includes the maintenance of records related to (a) safe product design, (b) production quality control (results of tests and inspections), (c) consumer complaints, comments, or accidents, (d) actions taken to correct product deficiencies, and (e) the tracking of products within the production and distribution (and Ownership) chain to facilitate potential product recall (or issuance of updated product warnings).

12. Audits: This involves the planned formal examination of product safety procedures and operations to ensure that the overall product safety program (established policies and procedures) is being properly implemented.