

HANDBOOK FOR MANUFACTURING SAFER CONSUMER PRODUCTS



U.S. Consumer Product Safety Commission

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Acknowledgement

Product safety depends on purposeful planning and action. This publication provides guidance for industry in answering safety-related questions. The *Handbook for the Manufacturing of Safer Consumer Products* (Handbook) and its accompanying *Commentary for Implementation of the Handbook for the Manufacturing of Safer Consumer Products* (Commentary) were originally published in June 1975 and revised in May 1977. In consultation with senior staff members of the Consumer Product Safety Commission, Mr. John J. Riordan, an authority on product assurance technology and a consultant to the Commission, originally developed the Handbook and the supporting Commentary. This August 2005 edition of the Handbook and the Commentary were edited by Mr. Nicholas Marchica, Program Manager, Office of the Executive Director.

The Purpose of the Handbook and the Commentary

The underlying premise of the Handbook is that safety must be designed into and built into consumer products in the United States in conformance with the requirements of product safety systems planned, established, and implemented at the direction of executive management. The Handbook identifies the elements of a comprehensive system approach to manufacturing safe products.

This Handbook has been developed and provided as a public service by the U.S. Consumer Product Safety Commission (CPSC). The CPSC is the U.S. government agency responsible for the safety of consumer products in the United States. The CPSC fulfills this role through issuing mandatory product safety standards, as well as through working cooperatively with industry to develop numerous consensus (also called voluntary) safety standards. In addition, the Commission monitors consumer product-related injuries and deaths, and works with companies to recall defective products from the marketplace.

The Commentary was developed for use by persons in industry who are implementing or planning to implement the Handbook. The term "manufacturing" is used throughout this publication as inclusive of all operations from design through production and distribution.

Persons and organizations implementing the Handbook need background information regarding the rationale of its concepts as well as suggestions and ideas for its implementation. The Commentary is a response to that need. It is intended to help industry establish product safety systems as an integral part of manufacturing, thereby serving the interests of industry and the public.

Background-The Consumer Product Safety Problem

Congress wanted to protect consumers from unreasonable risks of injury from consumer products when it enacted the Consumer Product Safety Act (CPSA) Public Law 92-573: "The Congress finds that (1) an unacceptable number of consumer products which present unreasonable risks of injury are distributed in commerce; (2) complexities of consumer products and the diverse nature and abilities of consumers using them frequently result in an inability of users to anticipate risks and to safeguard themselves adequately; (3) the public should be protected against unreasonable risks of injury associated with consumer products."

While there is ample data demonstrating the magnitude of the product safety problem, there is far less data for isolating the root causes of product-related safety hazards. Conventionally, the causes of product safety hazards are classified as man-related, environmental and product-related. These categories, of course, overlap. It is difficult to disentangle one from the other. But irrespective of root causes, it can be said that manufacturers have the greatest potential and therefore the largest responsibility for reducing hazards. Manufacturers' potential for reducing product defects that raise consumer safety concerns exists in their capability to design and fabricate products that take account of human and environmental factors. On this subject, the National Commission on Product Safety¹ commented as follows:

". . . the greatest promise for reducing risks resides in energizing the manufacturer's

¹ "Final Report of the National Commission on Product Safety." June 1970.

ingenuity.

"We do not mean that manufacturers by themselves can do all that is needed to achieve an optimal safety record. We mean that with Government stimulation they can accomplish more for safety with less effort and expense than any other body—more than any other body—more than educators, the courts, regulatory agencies, or individual consumers.

"Manufacturers have it in their power to design, build, and market products in ways that will reduce if not eliminate most unreasonable and unnecessary hazards. Manufacturers are best able to take the longest strides to safety in the least time."

After observing "danger is a regrettable but unavoidable facet of life," the Commission goes on to conclude:

"Prospects for measurable reform of human behavior are distant. Similarly, there is little hope for an early improvement of the home environment. The limited power of conventional educational methods has been described by our witnesses.

"Consequently, while continuing to educate and seeking even better ways, there seems little choice but to concentrate on reducing unreasonable hazards by encouraging additional care in the design and manufacture of products.

"The law has tended in recent years to place full responsibility for injuries attributable to defective products upon the manufacturer.

"But beyond his liability for damages, a producer owes society-at-large the duty to assure that unnecessary risks of injury are eliminated. He is in the best position to know what are the safest designs, materials, construction methods, and modes of use. Before anyone else, he must explore the boundaries of potential danger from the use of his product. He must be in a position to advise the buyer competently how to use and how to maintain and repair the product."

How best can industry assume its responsibility for product safety? Substantially, this question was answered in a Report of April 1973, entitled "Safety in the Marketplace" prepared by the Sub-Council on Product Safety of the National Business Council for Consumer Affairs. After emphasizing the responsibility of manufacturers for assuring the safety of their products, the Sub-Council goes on to advise that product safety is ". . . best accomplished by a comprehensive systems approach." The Handbook was developed to translate the phrase "comprehensive systems approach" into specific actions that collectively constitute a system.

Handbook for Manufacturing Safer Consumer Products

INTRODUCTION

Manufacturers must assure the safety of consumer products. This is achieved through the design, production and distribution of the products they manufacture. It is best accomplished by a comprehensive systems approach to product safety, which includes every step from the creation of a product design to the ultimate use of the product by the consumer. The basic concepts for a comprehensive systems approach for the design, production and distribution of consumer products are discussed in this Handbook.

The substance of this Handbook reflects the following premises:

1. The practices in this Handbook are voluntary and serve the interests of manufacturers as well as consumers.
2. The safety of a product depends upon many factors. One factor is building safety into the product design. The circumstances under which products are used or misused by consumers is another factor. The ability of manufacturers to recognize and anticipate these factors is central to the effective design and production of safe products.
3. There are basic principles for manufacturing safe consumer products applicable to industry generally, despite the scope and diversity of manufacturing. The application of these principles must be commensurate with the character of the product, which includes the product's complexity and intended use.
4. Systems already exist in industry to assure quality, reliability and other product characteristics. Such systems ordinarily encompass many of the provisions of this Handbook. For many manufacturers, therefore, it is not necessary to create a new system to implement practices in this Handbook. Existing systems can be readily augmented.

SUMMARY

This Handbook identifies the essential elements of industrial systems for manufacturing safe consumer products. It is concerned with "what" not "how." Its provisions are presented in three sections. Section I, below, defines the purpose of the Handbook and its applicability. Section II relates to executive action. Section III discusses technical concepts.

SECTION I: PURPOSE AND APPLICABILITY

A. PURPOSE

The purpose of this Handbook is to provide guidelines to executive industrial management for establishing systems to prevent and detect safety hazards in consumer products. It is made available to manufacturers, retailers, importers and buyers by the CPSC staff to encourage self-regulation with the expectation that such activities will result in safer consumer products and fewer product related injuries.

B. APPLICABILITY

The provisions of this Handbook are intended for voluntary implementation by industry, except for those that are statutory by virtue of being established in product safety standards and rules, in accordance with the statutes governing the U.S. Consumer Product Safety Commission.

SECTION II: EXECUTIVE ACTION

A. PRODUCT SAFETY POLICY

The commitment of the manufacturer, retailer, importer or buyer is the first executive step to be taken in developing an industrial consumer product safety system. A clear, strong statement from senior management citing statutory and voluntary reasons for this commitment is needed. The policy should be explicit with respect to the primacy of product safety during design, production and distribution. This policy should also make clear that it applies not only to the internal operations but also to suppliers, including suppliers of products manufactured outside the U.S. Ordinarily such a statement is publicized widely within the organization as a platform for subsequent planning and action. It may also be widely publicized outside the organization.

B. ORGANIZATION

The organization and management arrangements by which safety requirements are executed are the prerogative of the manufacturer. Except in industrial activities of very limited size, responsibility and authority for implementing particular elements in this Handbook, and for meeting the requirements of standards, should be clearly assigned to specific persons at the executive level and to specific operating entities, such as the responsibility and authority for product recalls. While management determines organizational patterns, it is also management's responsibility to formalize its organizational decisions in writing and to make this information available to interested persons.

C. TRAINING

Training, to a degree commensurate with the complexity and sensitivity of work assignments, is an integral element of effective safety systems. This training may be formalized (e.g., scheduled classroom meetings or on-the-job training) and it also may be accomplished by publications, bulletins, posters or other media. Most personnel have need of information regarding regulatory safety requirements related to the products they help fabricate, distribute or service, including information regarding the influence of their work on product safety.

Safety training should be conducted at an appropriate level for the target audience. For example, training for senior executives should provide an overview of a company's responsibility for product safety as well as the benefits. It should include management tools needed to implement a product safety process and instill a safety culture within the company.

Training for persons responsible for making decisions to purchase products for a retailer (buyers) should include basic product safety requirements for their product area. They should be trained to be able to identify potential hazards and minimum test/certification requirements for the products they purchase.

Finally, product designers and engineers should have intensive and frequent training on known hazards, foreseeable use analysis, evaluation methods, safety standards, test methods and use of injury databases. Active participation in relevant voluntary standards development activities is an effective way to maintain knowledge of current safety issues.

Certificates (or similar forms of recognition) are advisable when training programs are successfully completed for highly specialized skills. Generally, product safety training should be viewed and implemented as an ongoing integral element and not as an "add on" or occasional event.

SECTION III: TECHNICAL GUIDANCE

A. DESIGN REVIEW

Design review is an examination of materials, configuration, packaging and labeling for purposes of identifying potential product hazards. Design review consists of:

1. Foreseeable Use Analysis: A foreseeable use analysis considers the potential ways that a consumer will interact with and/or operate a product. It is a critical step in designing a safe consumer product. Foreseeable use includes the use as intended by the manufacturer, and also use in ways that were not intended but can reasonably be expected to occur.

The effectiveness of a safe product design may be evaluated in various ways. For example, a proposed design may be measured against accepted product standards such as a set of industrial voluntary standards and/or regulatory standards. Additionally, it may be measured against a set of objectives for the product and even comparable products. The product evaluator must define product use environments and contexts as precisely as possible, as well as the kinds of people who will operate and/or interact with the product. The evaluator should define the age levels, physical and cognitive limitations of users, and contingencies that might occur including uses not intended by the manufacturer.

For example, one can predict that a snow blower may possibly be used by tired adults in demanding physical conditions of extreme cold, wet and poor visibility. Significantly, the consumer will likely have no training and only occasional experience. Any warning labels may be obstructed by snow, and instructions will likely not be with the machine. The user will probably be wearing heavy outdoor clothing and heavy gloves, which will make control manipulation difficult. Factors such as these should be taken into account when evaluating the safety of the product design.

An effective foreseeable use analysis will distinguish substantial safety hazards that involve risks of injury or impairment of health from product deficiencies. Systematic analysis tools, such as a Failure Modes and Effects Analysis (FMEA) or fault tree analysis are used by product designers to identify potential safety hazards. The FMEA is an approach that identifies the components of a design or the functions of a process and their potential consequences of a failure. Conversely, the fault tree analysis begins with the consequences and determines the sequence of events that led to them. A thorough review of injury data and existing safety studies is also an important step in the design review process.

2.Team Review: Results of these evaluations should be reviewed by a group of individuals that is chaired by a designated senior official. This group should include personnel responsible for quality assurance, consumer services, and compliance with standards and regulations. Manufacturers as well as buyers that do not have in-house expertise should consider using an accredited test laboratory to evaluate the safety of a product. Appropriate corrective action must be taken when product safety hazards are identified. Adequate records must be maintained showing the details of the hazard and subsequent corrective actions taken.

B. DOCUMENTATION AND CHANGE CONTROL

Changes in design, production and distribution must be subject to control, be made matters of record, and be incorporated into all documentation affecting the product. Supporting technical documentation (e.g., drawings, replacement parts data, production, inspection, testing and repair instructions, and operating handbooks) must be current with design. Obsolete documents and data are to be removed from all places where they might be used inadvertently.

C. PURCHASE PRODUCT CONTROL

Unless raw materials, parts and sub-assemblies are safe and reliable, it is unlikely that the end product into which they are assembled will be satisfactory. Product manufacturers must exercise control over suppliers to a degree consistent with the potential safety impact of the items they supply. This control encompasses the following action:

1. Preparation of purchase documents with clear and precise statements of design and safety requirements, including, as applicable, the provisions of this Handbook and review of applicable statutes, regulations, and consensus (voluntary) standards to make sure the materials to be used are in compliance with them (e.g., documentation and change control).
2. The selection of suppliers with proven ability to provide acceptable and safe products.
3. The examination of suppliers' facilities, operations, records and supplies to the extent necessary to verify conformance of supplies to contractual requirements.
4. Taking corrective action promptly when circumstances necessitate such action.
5. Effecting unequivocal understanding regarding the responsibilities of suppliers for reporting substantial consumer product hazards to the manufacturer and/or the U.S. Consumer Product Safety Commission, in accordance with Section 15 of Public Law 92-573, 15 U.S.C. § 2064.

D. PRODUCTION

While all production practices affect product safety, the following necessitate particular

attention:

1. *Materials*

Raw, semi-finished or finished materials must conform to configurations and conditions specified during product design. This requirement is accomplished for suppliers' material by actions described in "Purchase Product Control" (Paragraph C, Section III, above). For those materials modified or degraded by handling, storage and/or processing during production, periodic verification is necessary to assure that prescribed materials are being used. It is necessary that materials be identified and labeled by means of shop travelers, tags, stamps or other devices, to prevent mistaken utilization.

2. *Work Instructions*

Work operations affecting safety are to be described in writing, including inspection and testing procedures, except those that are so simple that guidance is unnecessary. These work instructions may exist in many forms including work orders, operation sheets, inspection logs, repair logs, test procedures, and process specifications. They may also specify (a) equipment to be used for particular operations, (b) traceability arrangements identifying the person(s) who performed each of the operations, and (c) forms for recording quantitative data such as test readings and dates accomplished.

3. *Facilities*

Different products, designs and fabrication processes necessitate varied levels of precision and accuracy of manufacturing equipment and tooling. The precision and accuracy of equipment and tooling must be commensurate with product requirements, i.e., equipment capable of consistently fabricating products to established tolerances.

4. *Production Processes*

Production processes need to be controlled to minimize variability in product performance and characteristics. To minimize the probability that these operations are resulting in hazardous defects, it is necessary to institute controls of equipment, methods and qualifications of personnel. Such controls consist of scheduled inspections of equipment, surveillance of compliance with procedures, and verification of competence of personnel. Records of the results of such inspection and surveillance are necessary to substantiate the state of control of these processes.

5. *Repair*

When a manufactured product is determined to be potentially hazardous, it may be discarded or repaired. In the event that the product is repaired, repair operations must be monitored to the same degree or more intensively than original production operations. For example, when it is determined that a component is unsafe, adequate precautions, including testing as required, must be taken to assure that the replacement component is effective in eliminating the safety hazard identified. Repair may require more skilled operators, more precise equipment and more closely controlled materials. Repair operations performed by distributors or other representatives of the manufacturer must be subject to the same controls as would apply to products repaired in the production facility. As with original production, repair practices are to be described in work instructions.

6. *Work Environment*

The fabrication of safe and reliable products is a function of many factors, including physical

working conditions. A satisfactory working and processing environment (e.g., good lighting and controlled temperature and humidity) are necessary prerequisites for the manufacture of safe products.

7. Handling and Storage

Raw and manufactured materials used in production are to be handled, packaged and stored under conditions that preclude damage and resultant safety hazards. For example, items such as special adhesives that have limited shelf life and require prescribed storage conditions must be identified in terms of their shelf-life limitations and should be monitored by periodic inspections to assure their continued effectiveness and safety. Precautions for handling, packaging and storage are normally prescribed in work instructions.

E. QUALITY

Quality assurance refers to a systematic process taken throughout manufacturing to prevent and detect product deficiencies and product safety hazards. Accepted quality management processes and systems such as those included in the ISO 9000 standard can be implemented by manufacturers of all sizes. A quality assurance system is specific to a manufacturer's operations and addresses product safety matters. The following elements of a quality system are selected for special emphasis due to their significant effect on product integrity and safety.

1. Inspection and Testing

It is imperative that consumer products be inspected and tested prior to distribution in order to verify their conformance to established requirements. When a product includes components or subassemblies that are not accessible for inspection and testing, good judgment dictates that inspection and testing be undertaken, as applicable, before such items are inaccessibly assembled into parent units. It is the manufacturer's responsibility to provide guidance for inspection and testing to the degree that operators are fully informed on how to conduct inspections and tests that are meaningful, objective and uniform, and on how to record and maintain results.

2. Statistical Methods

Except for critical characteristics or when pertinent standards require the inspection and testing of each unit of product, manufacturers may use statistical techniques for inspection, testing, calibration, process control and technical auditing. Sampling procedures should be in accordance with standard sampling tables, including related procedural precautions. If the manufacturer designs alternative sampling plans, documentation of the statistical characteristics and procedural details of such plans is needed.

3. Non-Conforming Material

In most manufacturing operations some material, for one reason or another, fails to conform to established requirements. Such non-conforming material is a potential hazard to safety because it can be easily and inadvertently assembled into end products. Therefore, it is necessary that non-conforming material be clearly labeled and segregated.

F. MEASUREMENT AND CALIBRATION

If not properly selected, calibrated and maintained, equipment and devices for measuring, inspecting, and testing could generate misleading information. The selection of inspection and

testing equipment with a sufficient degree of precision and accuracy, and their adequate calibration and maintenance, are central to the assurance of product integrity. Good calibration practice necessitates the use of verifiable or traceable measurement standards (e.g., standards traceable to the National Institute of Standards and Technology).

G. DISTRIBUTION

Distribution practices significantly influence the safety of consumer products. Accordingly, control over final packaging and shipping operations is necessary. This control includes the selection of adequate packaging materials, design of methods of packaging that preclude damage in shipment, and selection of shipping methods consistent with the physical properties of the product. Packaging and shipping techniques and practices are, of necessity, revised as experience dictates. In those instances where distributors or other organizations are involved in assembly or test operations prior to delivery to the consumer market, they must be provided with current and adequate assembly and test instructions. It is incumbent on the manufacturer to assure that these instructions are fully implemented, under direct management control.

H. CONSUMER SERVICE

Consumer service programs are of varied scope and magnitude, depending on manufacturers' policies and objectives. To assure product safety, these programs necessarily include four elements: (1) advising consumers through manuals or otherwise how products are to be assembled and operated to prevent safety hazards; (2) proactively informing consumers how and where to obtain product servicing, particularly for deficiencies or malfunctions that are potential causes of product safety hazards; (3) the establishment and maintenance of a records system that identifies products (e.g., serial number, model and date of manufacture) and identifies their location in the distribution system, including consumers; and (4) clear written procedures for company response to product defects that pose the risk of consumer injury, including clear recall procedures and policies.

I. RECORDS

An effective product safety system requires records in sufficient detail and format to permit timely detection of safety hazards and trends, and for effecting traceability of the assembly operations and components involved. For these purposes the following records are particularly necessary: (1) the results of inspections, tests and calibrations; (2) consumer complaints and comments and related actions; (3) actions taken to correct product and system deficiencies; (4) location of products within the production and distribution systems so that prompt and effective recall can be accomplished, if required; and (5) information required by regulations issued by the CPSC that appear in 16 Code of Federal Regulations Parts 1101 through 1702.

J. CORRECTIVE ACTION

To prevent potentially dangerous products from being delivered to consumers, it is necessary that manufacturers establish procedures to take prompt corrective action when appropriate. This action includes determination of hazard cause(s), prevention of their repetition, and removal of hazardous consumer products from production and distribution channels. Reporting procedures are necessary to keep executive management informed of product safety hazards and trends that might induce such hazards. Most importantly, arrangements must be provided for compliance with CPSC safety standards, and Section 15 (b) of the CPSA, which states, "Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such product "shall report to the CPSC products that contain "a defect which could create a substantial product hazard."

If the product is certified by an accredited laboratory, the manufacturer should also notify the laboratory.

K. AUDITS

Audits are planned, scheduled, and management-directed examinations of procedures and operations to determine whether they comply with (1) applicable CPSC laws and regulations, (2) relevant safety standards, (3) established company policies and directives, and (4) principles of this Handbook. Audits of particular functions and activities should be performed by persons other than those administratively responsible for such functions. Results should be recorded and distributed appropriately within the organization for the accomplishment of necessary improvements.

NOTE: As stated under paragraph II B. above, implementation of principles in this Handbook is the responsibility of executive management, and must include all levels of management and all employees. This responsibility is most effectively accomplished by an integrated program that implements all provisions of the Handbook that are applicable to particular consumer products.

Commentary for Implementation of the Handbook for Manufacturing Safer Consumer Products

For purposes of readability and convenience, this Commentary is structured as follows:

1. Statement of Handbook

Each section of the Handbook is quoted verbatim in italics.

2. Commentary

The quotation of the Handbook is followed by comments on the background and need for the guidance.

3. Application

This is a discussion of approaches and techniques for incorporating the guidance into day-to-day manufacturing operations. (In some instances a Handbook section is keyed to a related requirement of the CPSA.)

4. Effectiveness Evaluation

Questions are posed for the purpose of probing how effectively a section is applied and pinpointing needs for comprehensive and in-depth analyses and actions.

SECTION I. PURPOSE AND APPLICABILITY

A. PURPOSE: *The purpose of this Handbook is to provide guidelines to executive industrial management for establishing systems to prevent and detect safety hazards in consumer products. It is made available to industry by the CPSC staff to encourage self-regulation with the expectation that such activities will result in safer consumer products and fewer product related injuries.*

B. APPLICABILITY: *The provisions of this Handbook are intended for voluntary implementation by industry, except for those that are statutory by virtue of being established in product safety standards and rules, in accordance with the statutes governing the U.S. Consumer Product Safety Commission.*

Commentary

The above contains three key phrases: "executive industrial management," "self-regulation" and "voluntary implementation." The Handbook is addressed to executive management; as only management has the resources and authority to institute sustained actions to prevent and detect product safety hazards. If responsibility for implementing the Handbook is passed down the line to lower echelons of management, there is less likelihood that the manufacturer's product safety program will be successful. The CPSC incorporates the concept of executive responsibility as applied to the safety of products in Sections 20 and 21. The Handbook is not a mandatory standard imposed by government on industry.

Application

Once an industrial organization implements the Handbook, other follow-on decisions and actions become necessary. The effectiveness of the Handbook depends importantly on the coordinated implementation of all its provisions. In addition, management will need to determine the types of products to which the Handbook applies. For practical planning, operational and economic reasons, it is advisable to apply the provisions of the Handbook to all consumer products manufactured by an organization. This, of course, necessitates careful and comprehensive planning. This planning, however, will prevent costly *ad hoc* responses to problems. It is suggested that a *carte blanche* strategy for assuring consumer product safety is less expensive and more effective than piecemeal improvisations and corrective actions.

Effectiveness Evaluation

- (1) Has the Handbook been adopted?
- (2) Is the Handbook applied to all of the company's consumer products?
- (3) If not, what products are excluded? Why?
- (4) What problems have been encountered in implementing the Handbook?
- (5) Have these problems been resolved?

SECTION II. EXECUTIVE ACTION

A. PRODUCT SAFETY POLICY: *The commitment of the manufacturer is the first executive step to be taken in developing an industrial consumer product safety system. A clear, strong statement from senior management citing statutory and voluntary reasons for this commitment is needed. The policy should be explicit with respect to the primacy of product safety during design, production and distribution. This policy should also make clear that it applies not only to the internal operations but also to suppliers, including suppliers of products manufactured outside the U.S. Ordinarily such a statement is publicized widely within the organization as a platform for subsequent planning and action. It may also be widely publicized outside the organization.*

Commentary

To get anything done it is necessary to start out with some basic idea, fundamental concept or commitment in principle. In absence of such a clear mandate, administrators, employees and customers may not know the organization's product safety policy. An industrial organization's commitment to product safety should be made known within and outside the organization. This commitment, translated into words, is "policy." In short, a policy statement expresses an organization's point of view and degree of commitment to achieving product safety from which the different divisions and departments of an organization derive and develop product safety programs related to their own operations. The formulation of policy is an occasion for self-analysis.

Application

A policy statement must reflect the personality, problems, convictions, and needs of a particular organization. Each policy statement is unique. A product safety policy should encompass: (1) *Commitment*. This is a formal recognition of the imperative need for consumer product safety. The management expresses its intent to take prompt and practical actions to make sure its products are hazard-free. (2) *Reasons for this Commitment*. These reasons relate to social, legal, economic, regulatory, or other considerations. It may be helpful, in some instances, to stress particular factors reflecting the special interests and concerns of the organization. (3) *Individual Expectations*. Specific management expectations of all company employees, including reporting directives regarding how to remedy any issues that may affect the safety of products, should be included.

Effectiveness Evaluation

- (1) Does the organization have a policy?
- (2) Does the policy establish principles that provide a basis for action at operating levels?
- (3) Is the policy issued by an authoritative level of management such that the probability of implementation is maximized?
- (4) Is the policy adequately disseminated? To employees? To suppliers?

(5) Is the policy clear enough so that subordinates in the organization can refer to it as an authoritative statement of management intent?

B. ORGANIZATION: The organization and management arrangements by which safety requirements are executed are the prerogative of the manufacturer. Except in industrial activities of very limited size, responsibility and authority for implementing particular elements in this Handbook, and the requirements of safety standards, should be clearly assigned to specific persons at the executive level and to specific operating entities, such as the responsibility and authority for product recalls. While management determines organizational patterns, it is also management's responsibility to formalize its organizational decisions in writing and to make this information available to interested persons.

Commentary

Organization and management are the prerogative and responsibility of the manufacturer. An organizational structure accommodates management needs and promotes a spirit of harmony and cooperation among persons and activities involved in manufacture. Regardless of how an industrial organization is structured, responsibility for consumer product safety rests with senior executive management. Of necessity, authority and responsibility for the execution of various provisions of the Handbook is delegated throughout the organization. This delegation does not relieve management of its prime obligation to assure the safety of products delivered to consumers.

Application

Responsibility for implementing the principles of this Handbook must be assigned to specific persons and organizational entities. As a practical matter, the conventional elements of industrial organization (e.g., purchasing, design, production, quality control) can readily and logically assume these responsibilities. In thinking out how best to organize, a distinction can be made between line and staff responsibilities and authority. The manager for line activities (e.g., design, production) can be assigned responsibility for those provisions of the Handbook that fit their traditional roles. A staff coordinator might be assigned responsibility for making sure that all necessary actions to protect product safety have been taken and to evaluate the effectiveness of these actions. Clear responsibility and authority must be assigned for corrective actions including, as needed, suspension of production, or of distribution, or possibly recall, if necessary. The worst possible situations are those in which authority for taking action is not delegated and arrangements do not exist for communicating critically important information to upper-level management for its consideration and prompt action. Organizational decisions regarding product safety should be reduced to writing and appropriately attributed.

The question of "organization" raises the specter of added costs on the theory that a "new function" necessitates new people and new job titles. It is true that in some companies the implementation of the Handbook might require additional personnel. It would be ill advised, however, to assume that this is generally true or, if it is true, that added costs are

considerable. The provisions of the Handbook, even though related primarily to product safety, are common-sense measures necessary for economic management, apart from considerations of product safety. The implementation of the Handbook, properly planned, can serve the larger interests of efficiency and economy as well as enhance the probability that consumer products will be hazard-free.

Effectiveness Evaluation

- (1) Is information available regarding how the organization is structured to assure consumer product safety?
- (2) Does executive management have an assigned role?
- (3) Are specific persons or organizational entities assigned responsibility for implementation of particular provisions of the Handbook?
- (4) If the organization has a product safety manager or coordinator what are his responsibilities and authority? To whom does he report?
- (5) Does an arrangement exist for keeping senior management advised of safety-related product deficiencies?
- (6) Who is responsible for informing the Commission of product safety-related defects in accordance with Section 15 (b) of the CPSA? A senior executive? If not, to whom is this responsibility and authority delegated?

C. TRAINING: Training, to a degree commensurate with the complexity and sensitivity of work assignments, is an integral element of effective safety systems. This training may be formalized (e.g., scheduled classroom meetings or on-the-job training) and it also may be accomplished by publications, bulletins, posters or other media. Most personnel have need of information regarding regulatory safety requirements related to the products they help fabricate, distribute or service, including information regarding the influence of their work on product safety. Certificates (or similar forms of recognition) are advisable when training programs are successfully completed for highly specialized skills. Generally, product safety training should be viewed and implemented as an ongoing integral element and not as an "add on" or occasional event.

Commentary

The effectiveness of manufacturing operations that affect product safety (e.g., design, production, distribution) is a function of the knowledge and skills of personnel assigned to those functions. Training is an important factor in developing and implementing comprehensive safety systems programs. The basic purpose of such training is to broaden each person's understanding of the meaning and importance of product safety and to place in their hands specific tools and techniques to help them in executing their assigned tasks. Training programs are particularly important in organizations that in the past have not been formally concerned with product safety. In such organizations there might be resistance to new requirements and new ideas. If properly planned and executed, a training program will prevent or counteract such misunderstanding provided employees are informed of

substantive reasons for a product safety program and advised of how they fit into that program, including their job security.

Application

The format and content of training programs necessarily are dictated by the needs of the organization. There are many factors that determine training requirements, including the need for upgrading skills to keep the organization abreast of new technology. The complexity and magnitude of various operations, morale, the need for unifying personnel and activities as a working team—these and many other considerations have a bearing on how a training program will be structured. Such training may be conducted on the job, in formal class work, at special schools, or in periodic seminars. Under some circumstances, training may be accomplished by use of bulletins, posters or newsletters. There is no single pattern applicable to diverse industrial activities.

When programs are formalized, it is necessary that curricula be thoughtfully prepared. Employees should be consulted regarding their training needs. Instructors should be properly trained and achievement tests developed. Such testing may include practical demonstrations (e.g., the performance of pre-designed weld operations followed by dissection to evaluate the effectiveness of the trainees' welds). It may be advisable to recognize personnel trained to specific levels of competence by means of certificates or other special identifications.

It is suggested that training programs should encompass the following:

1. A review of the organization's product safety program and the relationship of each person's work to the program.
2. Statutory and regulatory requirements (e.g., 15 U.S.C. §2051-2084 and 16 Code of Federal Regulations Parts 1101 through 1702) and the relevant consensus (voluntary) safety standard requirements (ANSI, ASTM, UL, for example).
3. Specialized manufacturing techniques (e.g., heat treating, soldering).
4. Inspection and test procedures (e.g., sampling, non-destructive testing).
5. Record keeping and reporting.

There may be highly specialized training needs for professional and specialized technical personnel. For example, design review and hazard analysis merit particular attention because of their sizeable influence on product safety.

Effectiveness Evaluation

- (1) Is the responsibility for establishing training requirements clearly assigned?
- (2) Are provisions made for informing each person of his relationship to overall product safety?
- (3) Is training provided for professionals and specialized personnel?
- (4) Are training program curricula documented and are they adequate for the intended purpose?
- (5) Are tests conducted for those operations amenable to evaluation and are the test criteria adequate?
- (6) Are certificates provided where desirable?
- (7) Are the training programs followed-up to assure they are up to date?

SECTION III. TECHNICAL CONCEPTS

A. DESIGN REVIEW: *Design review is an examination of materials, configuration, packaging and labeling for purposes of identifying potential product hazards.*

Design review consists of:

1. Identification and evaluation of potential safety hazards against pre-established criteria appropriate to the product. It is particularly important that these criteria include objective projections of the conditions under which the product is used, including recognition of the age levels and physical limitations of users, and contingencies that might occur as a result of reasonably foreseeable misuse or abuse of the product. It is advisable that the criteria distinguish substantial safety hazards from product deficiencies that do not involve risks of injury or impairment of health.

2. Review of these evaluations by a group chaired by a designated senior official. This group should represent the areas of design, production, quality control and consumer service.

Appropriate corrective action must be taken when product safety hazards are identified. Adequate records must be maintained showing the details of the hazard and subsequent corrective actions taken.

Commentary

Design is the dominant influence on product safety. Product safety starts in the mind of the product designers. If all the elements of manufacturing were ranked in order of their potential effect on consumer product safety, the design function would lead the list. Additionally, design importantly affects subsequent decisions and practices related to materials, production, testing, processes, labeling, packaging and distribution.

Application

There are three fundamental concepts for assuring the overall effectiveness of a design review. First, the designer or the design organization must objectively review product design against safety criteria that take into account (a) possible hazards in the product itself (e.g., sharp edges), (b) hazards that could develop by reasons of user age levels (e.g., children) or the physical conditions of users, and (c) the circumstances under which the product is used (e.g., indoors, outdoors, in a play room, in wintry, moderate or tropical climates). It requires intensive planning, information resources and analytical skills.

Some manufacturers may choose to conduct design reviews for product safety separately from design reviews for other product characteristics. This has the advantage of isolating safety as a uniquely critical requirement that is not subject to "tradeoffs" as may be permitted for less critical design parameters. Other manufacturers may prefer to include safety with other parameters (e.g., producibility, reliability) while retaining safety as a requirement not subject to "tradeoff." Either arrangement can be effective provided the

overriding and dominant prerequisite for product safety is recognized in design review procedures.

Second, since it is rarely possible for a designer or a design organization to be completely knowledgeable of all the factors that enter into product safety, the Handbook proposes that before a design is released for production, it be reviewed by personnel responsible for quality assurance, consumer services, compliance with standards and regulations and other appropriate functions. This review must be conducted under the direction of a senior official of the company. It is assumed that design organizations are not omniscient and that many organizational elements should contribute to the decision making process by which a consumer product is evaluated for safety. For this reason it is incumbent on management to make sure that all concerned persons and activities have a chance to become involved and to speak their piece. However, the Handbook does not specify the organizational arrangements by which an interdisciplinary group conducts design review. This is a matter to be worked out by management as befits its needs and circumstances.

Section III A does, however, explicitly provide for senior management involvement in design review. Otherwise, the designer might well find himself critiquing his own decisions or possibly reacting defensively to the opinions of others. There must be inculcated into the design review process a perspective that exceeds that of the original design activity.

Third, design review could necessitate corrective action and the maintenance of records identifying hazard sources and hazards and actions taken to purge the product design to the degree necessary.

In developing criteria for design review it is suggested that a practical definition be drafted of what constitutes a substantial hazard for the product being reviewed. This definition should reflect engineering and legal considerations. Design review for product safety might be performed independently of design reviews for other product characteristics, or safety might be an element of a broader review inclusive of other characteristics. In either event it is useful to develop norms applicable as corporate policy to all product design reviews. This has the effect of establishing organization-wide and standard norms of judgment while highlighting the imperative and pervasive requirement for product safety. Otherwise different design review groups may find themselves overlapping and, inadvertently, in conflict by reason of using differing criteria. The following example indicates how such organization-wide guidance might be formulated:

Categories of Consumer Product Design Deficiencies

Category 1

Safety Hazards

Any condition of a consumer product that causes a substantial risk of injury or death to the public by reason of design, production or other defects or because of hazards resulting from interactions of the product with the user or the circumstances under which the product is used.

Category 2

Usability Deficiency

A. A condition that is not likely to cause personal injury or death but could cause the product to be non-useable in a product/man/environment context.

B. A condition that is not likely to cause personal injury or death but could reduce the usability or effectiveness of the product.

Category 3

Cosmetic Deficiency

A condition that does not affect personal safety or usability, but detracts from the appearance of the product.

Since this publication is addressed to consumer product safety, it is beyond its purpose to elaborate regarding risks, if any, that might be permitted for product characteristics covered by Category 2 and Category 3. Any condition that potentially could cause injury or death (Category 1) must be corrected. None can knowingly be tolerated.

The interpretation of the phrase "substantial risk" involves, to some degree, subjective judgment. As a practical matter, persons who are experienced in the design, production and servicing of consumer products can usually recognize a hazard, particularly when personal experience is supported by product performance and injury data derived from consumers. It is suggested that checklists be drafted to reduce to concrete terms the meaning of a "substantial product hazard," to expedite design review, and to make sure that key considerations have not been overlooked. It is not possible to prepare a generalized checklist for widely different types of products. Checklists for electrical products are quite different from those for chemical products. But a common logic applies to drafting such lists. The logic consists of identifying possible hazard sources (e.g., energy transfer, humidity) and resultant hazard (e.g., fire, corrosion). Hazards must be anticipated realistically with reference to the age and capabilities of users and the conditions of product utilization, including storage.

Effectiveness Evaluation

- (1) Does the organization have a design capability?
- (2) If not, who does design its products?
- (3) Does the design organization have a clearly assigned responsibility for performing product safety design review?
- (4) Does this responsibility include purchased materials?
- (5) Has the organization established an independent group representing functions in addition to design for conducting independent product safety design reviews? Who "chairs" the group? Is this person at an executive management level?
- (6) Is technical guidance (e.g., criteria, checklists, experience data) available to reviewers?
- (7) Are records kept of proposed design review changes? Of those implemented? Not implemented?

B. DOCUMENTATION AND CHANGE CONTROL: Changes in design, production and distribution must be subject to control, be made matters of record, and be incorporated into all documentation affecting the product. Supporting technical documentation (e.g., drawings, replacement parts data, production, inspection, testing and repair instructions, and operating handbooks) must be current with design. Obsolete documents and data are to be removed from all places where they might be used inadvertently.

Commentary

From an industrial point of view, modern technology has had the effect of accelerating the rate of design and other changes in consumer products. Industry has increasingly recognized the necessity for "change control" or "configuration control." The objective of change control is to make sure that changes in design, production or other processes affecting the safety of a product are calculated, and that these changes are incorporated into related documentation. The product must be protected (throughout its life) from casual, thoughtless, unauthorized, unrecorded change. Authorized changes must be promptly incorporated into related documents. These include blue prints, specifications, work orders, operation and process sheets, purchase orders, inspection checklists, test instructions, operating and repair handbooks, customer instruction and training data.

Design and other changes reflect many considerations—economic, technological, marketing and others. Changes affecting safety must be incorporated into the manufacturing system and into the documents that describe and support that system.

Application

Each manufacturer must tailor his change control program to satisfy his individual needs. There are, however, elements common to change control systems regardless of their scope and complexity. These may be classified as follows:

1. **Authority**. This assigns to specific persons or organizations the right to institute changes.
2. **Responsibility**. Those persons or organizations authorized to institute changes are also responsible for coordinating these changes and transmitting them to other interested persons and activities within the organization and, as necessary, with consumers. Responsibility must be assigned to appropriate persons and functions for action to incorporate changes into their operations and documents (e.g., production must act on a design change and revise production drawings accordingly).
3. **Classification of changes**. Not all changes are of equal importance. Changes that affect product safety must be underscored as mandatory, requiring immediate action. On the other hand, a purely cosmetic change might be treated as optional, to be implemented when convenient.

4. Affectivity. Each changed document should indicate affectivity in terms of dates, model and serial numbers, or similar identifications.

5. Physical marking. Products with configuration changes must be identified to distinguish them from similar products previously produced. This is necessary for traceability and other reasons. It is usually accomplished by marking or stamping. It should be kept in mind that caution should be exercised when locating identification on a product and in choosing the kind of instrument used for this purpose. A highly stressed part, for example, should not be stamped with a steel instrument in an area of maximum stress.

6. Distribution. Documentation must be made available at every location where needed. Obsolete documents should be removed to preclude their inadvertent use.

Effectiveness Evaluation

- (1) Is responsibility and authority for safety-related changes clearly assigned?
 - (2) Are provisions made to distinguish safety-changes from all others?
 - (3) Have arrangements been established for prompt and mandatory implementation of changes related to product safety?
 - (4) Is production documentation (e.g., process sheets) controlled to assure that it is current with design changes?
 - (5) Do products carry model, part and serial numbering or other forms of identification that permit traceability of configuration?
 - (6) Are arrangements adequate to assure that user manuals and safety instructions are current with design and other changes?
-

C. PURCHASE PRODUCT CONTROL: Unless raw materials, parts and sub-assemblies are safe and reliable, it is unlikely that the end product into which they are assembled will be satisfactory. Product manufacturers must exercise control over suppliers to a degree consistent with the potential safety impact of the items they supply. This control encompasses the following action:

- 6. Preparation of purchase documents with clear and precise statements of design and safety requirements, including, as applicable, the provisions of this Handbook and review of applicable statutes, regulations, and consensus (voluntary) standards to make sure the materials to be used are in compliance with them (e.g., documentation and change control).***
 - 7. The selection of suppliers with proven ability to provide acceptable and safe products.***
 - 8. The examination of suppliers' facilities, operations, records and supplies to the extent necessary to verify conformance of supplies to contractual requirements.***
 - 9. Taking corrective action promptly when circumstances necessitate such action.***
 - 1. Effecting unequivocal understanding regarding the responsibilities of suppliers for reporting substantial consumer product hazards to the manufacturer and/or the U.S. Consumer Product Safety Commission, in accordance with Section 15 of Public Law 92-573, 15 U.S.C. § 2064.***
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Commentary

Consumers are sensitive to the importance of purchasing products from sources that are reliable and have records of good performance. The Handbook proposes that manufacturers take at least the five actions quoted above to maximize the probability that purchased products are hazard-free. These actions are based on the premise that a supplier's facility is conceptually, for product safety planning purposes, an extension of the manufacturer's. Therefore, the provisions of the Handbook are applicable to the supplier to the extent that his product involves potential safety hazards. The manufacturer is responsible for the safety of the product he offers in the marketplace. Product safety hazards frequently have their roots in new materials, components and sub-assemblies that are assembled into consumer end-products without adequate controls.

Most large industrial organizations include specifications in their purchasing packages. However, purchase specifications may be incomplete, ambiguous or otherwise ineffective. If a manufacturer fails to explicitly specify product safety requirements for a product he plans to acquire and later assemble into an end-item, he may create a defective product. Manufacturers should inform their suppliers of testing, process control, labeling or other requirements that must be met as a condition of product acceptability and for payment, and manufacturers should verify that these requirements are met.

Application

A purchase instrument is incomplete unless it specifies product safety requirements. These requirements (e.g., performance, purity, inspection, testing, packaging and labeling) are determined by the nature of the product. The manufacturer may draft his own requirements or he may choose to use standards, if they cover product safety, issued by governmental or other standards-setting organizations. Before writing a standard, it is well to consult indices of standards available in most technical libraries. This might save time, money and hard work. Safety related consensus (voluntary) standards also must be implemented. Manufacturers may find it helpful to check the web sites of the relevant standard-setting bodies, such as UL, ANSI, and ASTM, for standards applicable to their products. If a consumer product safety standard has been promulgated by the U. S. Consumer Product Safety Commission, then its implementation is mandatory.

With a standard available, it is now necessary to find a qualified supplier. Ordinarily this involves reviewing records and other information regarding the supplier's past performance- assuming such information is available. While it is necessary to check past performance, it is not good practice to depend on it exclusively. Manufacturers should determine for themselves how well a product satisfies safety requirements. A wide range of options are available for making this determination. For some products incoming inspection and testing is adequate. For others it may be necessary for the manufacturer to make an on-site verification of the adequacy of the supplier's facilities to confirm the effectiveness of production, quality, control, inspection and testing operations.

It is understandable that when a manufacturer conducts on-site verification the supplier might consider such action an indication of the manufacturer's lack of confidence in him. Such a misunderstanding will not likely arise provided on-site verification is in accordance

with the manufacturer's established policy applicable, for example, to products that cannot be adequately verified for safety on receipt at the manufacturer's facility. Suppliers should keep in mind that on-site verification can be highly useful in preventing downstream problems and misunderstandings and in establishing person-to-person rapport with customer organizations.

Section 15 of the CPSA requires that manufacturers and others, i.e., distributors and retailers, report to the U. S. Consumer Product Safety Commission whenever they have information that a product fails to comply with an applicable consumer product safety rule or contains a defect that could create a substantial product hazard. This requirement applies regardless of whether or not an applicable product safety standard exists. It is therefore necessary that manufacturers have clear understandings with their suppliers regarding responsibility for submitting Section 15 reports. Otherwise the end-product manufacturer might assume that the supplier is responsible for such reporting and vice versa. If manufacturers and suppliers discuss this responsibility frankly and define their respective roles clearly, the possibility of a Section 15 report not being filed in a timely manner will be significantly reduced. This matter is of greatest importance because of its serious legal implications.

Effectiveness Evaluation

- (1) Does the organization have a policy and procedures for assuring the safety of items procured from suppliers?
- (2) Do purchase documents have explicit requirements for product safety?
- (3) In selecting suppliers does the organization have any criteria for considering past safety performance?
- (4) If purchased products cannot be inspected or tested on receipt, does the manufacturer have an arrangement for verifying product safety at supplier source?
- (5) Is there evidence that when products purchased from suppliers are unsatisfactory, suppliers are promptly advised?
- (6) In particular instances, have suppliers taken prompt corrective action when so advised?
- (7) Are suppliers obligated to report substantial hazards to end-product manufacturers?
- (8) Do arrangements exist between the end-product manufacturer and the supplier for submitting reports as required by Section 15 of the CPSA?

D. PRODUCTION: While all production practices affect product safety, the following necessitate particular attention:

1. Materials

Raw, semi-finished or finished materials must conform to configurations and conditions specified during product design. This requirement is accomplished for suppliers' material by actions described in "Purchase Product Control" (Paragraph C, Section III, above). For those materials modified or degraded by handling, storage and/or processing during production, periodic verification is necessary to assure that prescribed materials are being used. It is necessary that materials be identified and labeled by means of shop travelers, tags, stamps or other devices, to prevent mistaken utilization.

2. Work Instructions

Work operations affecting safety are to be described in writing, including inspection and testing procedures, except those that are so simple that guidance is unnecessary. These work instructions may exist in many forms including work orders, operation sheets, inspection logs, repair logs, test procedures, and process specifications. They may also specify (a) equipment to be used for particular operations, (b) traceability arrangements identifying the person(s) who performed each of the operations, and (c) forms for recording quantitative data such as test readings and dates accomplished.

3. Facilities

Different products, designs and fabrication processes necessitate varied levels of precision and accuracy of manufacturing equipment and tooling. The precision and accuracy of equipment and tooling must be commensurate with product requirements, i.e., equipment capable of consistently fabricating products to established tolerances.

4. Production Processes

Production processes (e.g., welding, soldering, molding, heat-treating, bonding) generate product characteristics whose acceptability is difficult to evaluate. To minimize the probability that these operations are resulting in hazardous defects, it is necessary to institute controls of equipment, methods and qualifications of personnel. Such controls consist of scheduled inspections of equipment, surveillance of compliance with procedures, and verification of competence of personnel. Records of the results of such inspection and surveillance are necessary to substantiate the state of control of these processes.

5. Repair

When a manufactured product is determined to be potentially hazardous, it may be discarded or repaired. In the event that the product is repaired, repair operations must be monitored to the same degree or more intensively than original production operations. For example, when it is determined that a component is unsafe, adequate precautions, including testing as required, must be taken to assure that the replacement component is effective in eliminating the safety hazard identified. Repair may require more skilled operators, more precise equipment and more closely controlled materials. Repair operations performed by distributors or other representatives of the manufacturer must be subject to the same controls as would apply to products repaired in the production facility. As with original production, repair practices are to be described in work instructions.

6. Work Environment

The fabrication of safe and reliable products is a function of many factors, including physical working conditions. A satisfactory working and processing environment (e.g., good lighting and controlled temperature and humidity) are necessary prerequisites for the manufacture of safe products.

7. Handling and Storage

Raw and manufactured materials used in production are to be handled, packaged and stored under conditions that preclude damage and resultant safety hazards. For

example, items such as special adhesives that have limited shelf life and require prescribed storage conditions must be identified in terms of their shelf-life limitations and should be monitored by periodic inspections to assure their continued effectiveness and safety. Precautions for handling, packaging and storage are normally prescribed in work instructions.

Commentary

The essence of production is to assure that the final product retains intact all of the safety characteristics designed into it. If design safety is degraded in the transition from design to production, unsafe products—with all their ramifications—will be a safety problem for both the producer and consumer. Assuming the integrity of design, the paramount production consideration from a product safety perspective is to prevent the degradation of designed-in safety.

Production is treated extensively in the literature. Each industry has its own production techniques, its own special processes and its own production problems. These comments point out a few aspects of production that merit particular consideration because of their direct and substantive impact on product safety.

Application

The subjects mentioned in Paragraph III D of the Handbook as requiring "particular attention" are addressed in many textbooks. What follows are suggestions and reminders to relate these topics to product safety. The pertinence of any single topic to a particular manufacturer depends on the size and scope of his manufacturing organization and the characteristics of the products being manufactured.

Materials

The word "materials" is used herein as inclusive of raw materials, semi-finished and finished items. Thus the term applies to bar, stock, components, sub-assemblies, and major assemblies that are incorporated into larger products, e.g., the pump of a washing machine. When implementing the "materials" provision of the Handbook, it is helpful to keep in mind that its primary purpose is to prevent "wrong" materials from being assembled into consumer products. The word "wrong" covers two situations: (1) Material that is assumed to be in conformance with design requirements but is not. Such non-conformance may be due to various causes, including deficient change control, incomplete processing, or deterioration. To prevent such degradation regardless of causes, it is necessary to verify periodically that such material conforms to design requirements. (2) Another situation arises when material is mistakenly used in production. As a preventive measure, clear identification and labeling of raw, finished and semi-finished material is essential. Materials that look alike but are different should be segregated and stored separately. Proven labeling and identification standards, established by recognized standards-setting organizations, should be used. Finally, it is advisable to establish a plan for periodically checking items at various staging and storage points to make sure the products match labels or other forms of product identification.

Work Instructions

These are descriptions, written or otherwise documented, of how specific production jobs are to be accomplished. Work instructions cover a broad range of practical and necessary detail, e.g., identification of equipment and tools to be used, the proper sequence for doing a job, how to set up and adjust machines, how to recognize "out of control" trends, storage points, and required tests and inspections. These instructions must be revised as design, production practices, materials and other features of manufacturing change.

It is not necessary to develop work instructions for every production operation. This would generate excessive paper work and would be costly without advantage. Ordinarily decisions regarding the need for work instructions are made at the time of production planning. In making these decisions a good rule of thumb is that work instructions are needed when reasonable judgment indicates that in their absence work would not be properly performed with the possible consequence of causing a product safety hazard. For example, a widely used consumer product was determined to be hazardous due to the unexpected fracture of a metal component. The cause of this defect was traced to heat treating operations. Without going into details, this hazard could have been prevented had the operators been provided specific detailed guidance regarding quenching, tempering, pickling and aging. This assumes, of course, that operators will meticulously comply with instructions given them.

Work instructions are the means by which management makes sure that selected production operations are executed in accordance with explicit guidance. This makes possible precise product replication and thereby the retention of safety characteristics originally designed into the product.

Facilities

Once a product has been designed and approved for production, the safety characteristics designed into the product must be retained during production. Production facilities (e.g., machine tools, gages, jigs, fixtures, testing and process control devices) must be capable of operating to specified tolerances and that capability must be retained by adequate maintenance.

There are some precautions that should be taken to prevent production problems that might be costly and adverse to product safety. The first is to make sure that design, production engineering and production functions consult intensively before final product configuration is determined. In this way the production activity can prepare itself to meet established tolerances. The second is to verify the tolerance holding capability of equipment, tooling, inspection and testing devices prior to production. To attempt to manufacture products with facilities that are not commensurate with design requirements is asking for trouble. Either the design must be adjusted to be compatible with production facilities or new equipment must be acquired to make it possible to fabricate safe products consistently. If neither is practical, production should not be initiated. If production is attempted, it could have serious legal and economic consequences.

Production Processes

The term "production processes" as used in this section refers primarily to those processes such as heat treating, bonding, welding, soldering, electroplating and conformal coating, which are not normally capable of being evaluated on the basis of visual or simple

mechanical inspections. These processes usually require (1) work instructions that describe the operations in detail; (2) specialized equipment; and (3) skilled personnel. These factors should be tested in preliminary operations and records maintained to provide a basis for evaluating their adequacy. The latter two (i.e., personnel and equipment) should ordinarily be tested and certified in accordance with prescribed criteria. Provisions should be made for retest and recertification at pre-determined intervals to assure that the personnel skills and equipment performance have not deteriorated.

In addition, such processes generally require the following kinds of controls:

1. Initial check of set-up prior to use (e.g., spot weld machine).
2. Non-destructive and/or destructive tests of samples that simulate the production articles (e.g., X-ray and dissection of structural welds).
3. Frequent periodic inspections of conditions and material throughout the performance of the process (e.g., flow soldering).
4. Statistical control charts to spot trends towards unsafe conditions (e.g., heat treating and hardness testing).

When "out-of-control" conditions or safety-related defects are detected, the process should be terminated and not reinstated until causes have been determined and the problems corrected. Further, those items that have been processed subsequent to the last time the particular process was proven valid, should be reassessed to determine whether they are suitable for further use, as is, or whether rescreening, rework or scrapping is necessary.

Repair

As used herein, the term "repair" refers to those operations performed on a product that makes that product safe and acceptable for use without regard to whether it was found unsafe or unusable during production or was returned from distribution channels. In this sense, all the controls required for original production are applicable to repair operations, i.e., control of: (1) design of repair (unless the product is being returned to original design configuration), (2) documentation and changes thereto, (3) purchased products used in the repair, (4) materials, (5) work instructions, (6) facilities, (7) production processes, (8) work environment, (9) handling and storage, (10) quality control, (11) measurement and calibration, (12) records, (13) corrective action and (14) audits.

In establishing controls peculiar to repair operations, certain requirements must be highlighted including:

1. Identification of material to be repaired by use of withholds or repair tags that are designed to preclude erroneous distribution of the unrepaired product.
2. Segregated storage of the product to be repaired for the reason stated above. It is sometimes advisable also to provide segregated areas for repair operations requiring special skills or environments.
3. Detailed description of the repair procedure, the location where it should be accomplished, and any other special instructions (e.g., test procedures).
4. Clear and permanently recorded identification on the products and/or accompanying work documents to indicate whether the repair has been completed. Where alternative-repair methods or techniques are used, the identification should reflect differences.
5. Records including such details as serial numbers, dates of original production, quantities, conditions found, repair schemes used, technicians responsible for repair, inspectors responsible for acceptance.

When repairs are to be accomplished by distributors, retailers, or third parties, provisions should be made to assure that the aforementioned controls, where pertinent, are implemented and that the quantitative and qualitative data needed by the manufacturer is fed back to them.

Work Environment

The term "work environment" involves two effects. The first relates to the effect of environment on personnel. Any condition that distracts personnel from effective performance of assigned operations is unfavorable to both product and human safety. (The latter subject is beyond the scope of this Commentary. Attention is invited, however, to Public Law 91-596 pertaining to occupational safety.) The second relates to the effect of the work environment directly on work operations. For example, in many industries it is essential to control humidity, dust, and other environmental variables that directly or indirectly affect the integrity of the operation (e. g., electroplating).

With respect to personnel, it is suggested that checklists be prepared for implementation by designated persons, specifying minimum environmental conditions for various locations within the production areas. Such checklists should include requirements for lighting, cleanliness, temperature, and space (e.g., clearances between machines, walls, and walkways). These checklists should also cover vibration and noise control, storing and stacking of materials (to make sure that they do not obstruct personnel movement) and arrangements for the orderly flow of materials. Most of these considerations are normal in a well-ordered manufacturing organization. However, unless formal procedures exist to assure the adequacy of the work environment, unfavorable conditions will emerge with negative effects on efficiency and product safety.

It is advisable to incorporate into the audit plan, discussed under "Audit" below, provisions for confirming or negating the presumption that the work environment conforms to organizational policies and with federal, state and local statutes.

With respect to the impact of the environment on work operations, the restrictions and controls should be provided in the appropriate work instructions and process plans. The detailed requirements are of the type described in Section III D under Production Processes.

Handling and Storage

This relates to handling and storage of materials and products from receipt in the manufacturer's facility through final acceptance prior to shipping to customers. Improper handling or inadequate storage of materials, parts or subassemblies during the production operations can result in undetected damage that can later pose a safety hazard.

The controls for handling and storage involve the following actions:

1. Design of adequate protective materials, equipment and facilities for parts and assemblies to assure protection during processing, movement and storage. These involve such items as barrier materials, special carts and controlled environmental atmospheres where required.
2. Appropriately described precautions in work instructions to preclude error, including such items as specific shelf life limitations and special identifications.
3. Implementation of good handling and storage practices on the part of personnel involved

via training and supervision.

4. Audits of handling and storage controls to assure their initial adequacy and continued compliance.
5. Prompt corrective action to preclude safety hazards when deficiencies are detected.

Although these actions cannot preclude the accidental type of mishandling, they can minimize the frequency of their occurrence and the severity of their effect.

Effectiveness Evaluations

Materials

- (1) Are material identification procedures adequate to preclude misuse?
- (2) Are similar but not interchangeable materials sufficiently segregated?
- (3) Are materials adequately and properly identified?
- (4) Are sufficient inspections and audits of identification and segregation provided?

Work Instructions

- (1) Are work instructions provided for operations when needed?
- (2) Do work instructions provide necessary and sufficient detail (e.g., sequence of operations, special tools, set-up directions)?
- (3) Are work instructions controlled adequately to reflect applicable design and process changes?
- (4) Are they distributed and utilized as intended?

Facilities

- (1) Are facilities analyzed for adequacy as part of the preproduction planning?
- (2) Are they sufficiently and properly tested to verify their capability to produce within specified tolerances?
- (3) Are they upgraded concurrent with design or process change when needed?
- (4) Are they maintained and checked adequately to consistently assure safe products?

Production Processes

- (1) Are adequate work directions provided for the "special" production processes involved?
- (2) Is proper equipment available?
- (3) Are sufficiently skilled personnel provided?
- (4) Are equipment and personnel certified and recertified for those processes requiring certification?
- (5) Are adequate records maintained?
- (6) Are the processes sufficiently inspected and controlled?
- (7) Is adequate action prescribed when "out of control" conditions are detected?

Repair

- (1) Are the controls provided for original production also implemented for repair operations as applicable?
- (2) Are adequate work instructions provided for repair items?
- (3) Are storage and repair activities adequately segregated from other areas?
- (4) Are records sufficient?
- (5) Are directions for repair and reporting by distributors, retailers or third parties adequate?

Work Environment

- (1) Are work environment controls (e.g., humidity, temperature and dust limitations) provided?
- (2) Do they cover all those variables that affect product safety?
- (3) Do they also adequately cover the elements that could distract personnel from proper performance necessary to assure safe products?
- (4) Are appropriate checklists provided?
- (5) Are they implemented sufficiently?
- (6) Are audits performed to verify compliance with federal, state and local statutes?

Handling and Storage

- (1) Are adequate protective materials, equipment and facilities provided for handling and storage of parts and assemblies?
- (2) Do work instructions identify appropriate precautions including identification of items such as shelf life limitations?
- (3) Are audits accomplished?
- (4) Is corrective action taken as warranted?

E. QUALITY CONTROL: Quality control refers generically to actions taken throughout manufacturing to prevent and detect product deficiencies and product safety hazards. These actions include verification of compliance of manufacturing operations with the guidance of this Handbook. The following elements of a quality control program are selected for special emphasis due to their significant effect on product integrity and safety.

1. Inspection and Testing

It is imperative that consumer products be inspected and tested prior to distribution in order to verify their conformance to established requirements. When a product includes components or subassemblies that are not accessible for inspection and testing, good judgment dictates that inspection and testing be undertaken, as applicable, before such items are inaccessibly assembled into parent units. It is the manufacturer's responsibility to provide guidance for inspection and testing to the degree that operators are fully informed on how to conduct inspections and tests that are meaningful, objective and uniform, and on how to record and maintain results.

2. Statistical Methods

Except for critical characteristics or when pertinent standards require the inspection and testing of each unit of product, manufacturers may use statistical techniques for inspection, testing, calibration, process control and technical auditing. Sampling procedures should be in accordance with standard sampling tables, including related procedural precautions. If the manufacturer designs alternative sampling plans, documentation of the statistical characteristics and procedural details of such plans is needed.

3. Non-Conforming Material

In most manufacturing operations some material, for one reason or another, fails to

conform to established requirements. Such non-conforming material is a potential hazard to safety because it can be easily and inadvertently assembled into end products. Therefore, it is necessary that non-conforming material be clearly labeled and segregated.

Commentary

“Quality control” is the function of industrial management whereby calculated actions are taken to assure that manufactured products conform to design requirements and to user needs. At one time the terms “quality control” and “statistical quality control” were considered synonymous because statistical techniques were considered the major tools of quality control. Over time, quality control has taken on a larger meaning to include whatever actions are necessary to assure that products conform to design and other requirements and perform to the satisfaction of consumers. Thus, the quality control function often includes participation in design review, development and administration of defect reporting systems, preparation of specifications and standards, design of inspection and test procedures, calibration of measuring instruments and many other activities. The concept of an “assurance function” is based on the recognition that purposeful and deliberate planning and action is necessary by management to assure that products conform to established requirements and satisfy user needs. The components of this planning and action constitute a “quality control program.”

Conceptually, product safety is a product characteristic along with reliability and other characteristics. Thus product safety may be considered a characteristic to be “assured” within the scope of a quality control program. In practice, however, this may not be advisable. For good reasons a manufacturer may choose to treat product safety as a separate subject because of its effect on human well-being, not to mention liability and other considerations. These observations underlay a viewpoint expressed repeatedly in this Handbook, i.e., each management must structure its organization to fit its needs and obligations. That is its prerogative. Thus, the various concepts of the Handbook may be assigned to different functions for implementation with coordination being effected by a “Quality Control Manager” or “Quality and Safety Assurance Coordinator” or a “Safety Assurance Manager” or by other arrangements and related titles. Of central importance are (1) establishment of a formal program for manufacturing safe products in accordance with the Handbook, (2) delegation of responsibilities for implementation of requirements of the program, (3) coordination of product safety actions and evaluation of effectiveness, and (4) direction of the program by senior management.

Application

Regardless of how control and assurance functions are organized and designated, the following aspects of quality control programs merit particular attention because of their day-to-day relationship to product safety.

Inspection and Testing

The purpose of inspection and testing is to assure that products perform their intended functions safely. “Inspection” is used herein to include any procedure by which a product is compared with a requirement. This may include visual examination, testing with

appropriate instruments, measuring or other forms of evaluation including mere counting. The basic planning principles that apply to inspection (i.e., examination visually or by relatively simple measuring devices) also apply to testing (i.e., examination of a product by scientific methods and instruments to a degree not practical or possible by "inspection").

To be effective and uniform an inspection program for product safety should be reduced to writing and should encompass, at least, the following elements.

(1) *Identification of the Product to Be Inspected.*

Identify what is to be inspected. The "Unit of Product" is the item that is classified as "safe" or "unsafe" (acceptable or non-acceptable) on the basis of inspection. A "Unit of Product" might be almost anything (e.g., a nut and bolt, a nut or bolt, a toaster and cord, a cord or toaster, a washer with wringer, a washer without wringer, a package of bleach or solely the package, etc.). The reason the identification of the "Unit of Product" is important is that it is difficult to rationally plan subsequent inspection procedures unless what is to be inspected is identified.

(2) *Requirements.*

It is necessary to establish requirements for inspection. Not all characteristics of a product equally affect safety. What characteristics must be inspected? To what tolerances? It may be advantageous to isolate these characteristics into groups, i.e., those safety-related from those that are not. The latter may be further categorized (e.g., as major, minor, cosmetic). Such categorization helps to resolve problems related to sampling as discussed below.

(3) *Methods.*

It is important that the inspection plan specify exactly how an inspection will be conducted and the gauges, tools or instruments to be used. If an inspection operation is particularly critical to product safety, the inspection plan may require that it be performed by designated specialized or certified personnel.

(4) *Quantity to be Inspected.*

It may be necessary, as a safety measure; to inspect each and every unit of product for specified characteristics. Or, it may be appropriate to inspect a sampling of production using statistical methods.

In summary, then, an inspection plan must identify the thing being inspected, it must translate requirements into inspection of explicitly specified characteristics or properties, it must describe methods and specify the number of Units of Product to be inspected, i.e., all units or a sample. The foregoing is essential for the effective inspection of consumer products.

Statistical Methods

Statistical sampling methods are used to develop a sampling plan to ensure production quality. This means that random samples are drawn from a lot or batch and inspected for specific characteristics: Each Unit of Product is classified as acceptable or unacceptable, safe or unsafe, for that characteristic (or for a group of characteristics of equal criticality). If the unacceptable number of Units of Product in the sample equals or exceeds a pre-set rejection number (as provided in the sampling plan), the total lot is rejected.

All sampling inherently involves risk. Most standard sampling plans identify risks by operating characteristic (OC) curves. These curves show the probability that an unsafe lot will be accepted at various levels of defectiveness (e.g., 1%, 5% defective). It is suggested that sampling plans for product safety protection be examined closely for "consumer risk" as distinct from "producer risk" before being specified in an inspection plan.

For those characteristics which can only be inspected or tested by destructive means and for those which are not potential safety hazards, sampling inspection and test may be conducted to explicitly defined risks as documented by OC curves provided in standard sampling plans, or calculated for plans specially devised by the manufacturer. It should be kept in mind that sampling plans involve disciplines that must be respected, for example, samples must be randomly selected, records maintained, and decision rules with respect to non-conformance rigidly followed. The mechanics of sampling are as important as determination of sample sizes and rejection numbers.

Non-Conforming Material

It is quite easy to inadvertently mix products that do not conform to safety requirements with those that do. For this reason, the Handbook suggests that a definite arrangement be made to prevent such potentially dangerous mixing. This is best accomplished by marking "bad" products with "loud" tags or other devices, and by setting aside areas for segregating what is "bad" from what is "good." Further, it is necessary to make sure that the disposition of non-conforming products is in accordance with policies, procedures and controls prescribed by senior management.

Effectiveness Evaluation

- (1) Are quality control actions instituted throughout manufacturing to prevent and detect product deficiencies and safety hazards?
 - (2) Are inspections and tests conducted in accordance with written plans?
 - (3) Do these plans contain explicit inspection and test instructions?
 - (4) Are inspections and tests accomplished in the manufacturing flow before potential safety hazards become inaccessible for detections?
 - (5) Are sampling plans adequately defined and described? Are OC curves known?
 - (6) Are the risks acceptable for the applications?
 - (7) Is 100% inspection and testing required for characteristics that are potential safety hazards?
 - (8) Are the disciplines required for scientific sampling enforced, e.g., random selection, strict compliance with decision rules, records of results?
 - (9) Are non-conforming products distinctly identified?
 - (10) Are they segregated from conforming products?
 - (11) Are the dispositions of non-conforming products accomplished as prescribed?
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F. MEASUREMENT AND CALIBRATION: If not properly selected, calibrated and maintained, equipment and devices for measuring, inspecting, and testing could generate misleading information. The selection of inspection and testing equipment with a sufficient degree of precision and accuracy, and their adequate calibration and maintenance, are central to the assurance of product integrity. Good calibration practice necessitates the use of verifiable or traceable measurement standards (e.g., standards traceable to the National Institute of Standards and Technology).

Commentary

The word "accurate" refers to the degree that a measurement instrument yields the true value of quantity. Measuring instruments that report different results when repeatedly used lack precision. The term "precision" refers to the reproducibility of a measurement. Thus, "precision" is synonymous with "consistency" or "repeatability". Accuracy and precision are the prime prerequisites for reliable measuring instruments.

In engineering and production, calibration is a formalized procedure for comparing a measuring instrument with a reference standard of a known and higher accuracy for purposes of adjusting the measuring instrument in the event that it is determined to be inaccurate. A reference standard may be a device, an instrument, or a material.

Measurement and calibration are of central importance in protecting safety and other product characteristics. There is no single arrangement applicable to many manufacturers by which the accuracy and precision of measuring instruments is assured. What is important is that these needs are recognized and arrangements, appropriate to the product and organization, exist to assure that measuring instruments are not yielding misinformation and thereby degrading product safety.

Application

At the outset it is necessary to select measuring and test equipment commensurate with the tolerance requirements of the product being measured or tested. The measuring device should have the capability of measuring to accuracy greater than a tolerance specified for the product being measured.

Assuming that adequate measurement instruments are available, it is necessary to establish a calibration discipline to protect their accuracy and precision. The severity of this discipline is a function of the tolerance requirements of the consumer product. Regardless of severity or magnitude, effective calibration discipline usually incorporates the following characteristics:

1. Environmental Control

Both measuring instruments and standards must be subject to environmental controls to a degree compatible with their functions. These controls include temperature, humidity and vibration. It is also necessary to protect some measurement and calibration equipment against dust, radio frequency interference, and similar extraneous and unfavorable influences.

2. Availability and Traceability of Standards

Calibration capability presumes the availability of necessary reference standards. The accuracy and precision of these reference standards must be established and maintained. Ordinarily this is accomplished by "traceability," that is, accuracy is directly or indirectly traceable to recognized standards, e.g., those of the National Institute of Standards and Technology. This also can be accomplished in other ways, for example, through the use of independent reproducible standards. The latter are standards based on accepted and permanent physical constants such as the wavelength of orange red light emitted by Krypton 86.

3. Calibration Procedures

These procedures describe how a particular calibration is effected. As already mentioned, the purpose of this procedure is to compare the device or instrument being calibrated with a "standard," that is, a reference instrument with higher levels of accuracy.

4. Intervals

Measuring instruments ordinarily are to some degree unstable. Every day wear and tear degrades their accuracy and precision. Therefore, instruments must be calibrated at fixed time intervals. These intervals may be changed depending on how often the measuring instrument is used or as a result of analysis of conditions affecting stability.

5. Labeling

All instruments and standards should carry labels or their equivalent that as a minimum identify the standard or instrument by serial number (or otherwise) and show the scheduled date for its next calibration.

6. Records

The results of calibration must be recorded. This data is the basis for planning calibration intervals and possibly for tracing causes of product deficiencies related to measurement.

7. Control of Supplier Calibration

Whatever calibration practices are appropriate for the manufacturer's operations apply also to his suppliers.

8. Special Actions

Frequently it is advisable to issue special guidance to protect instruments that are particularly fragile and sensitive or costly. This may, for example, involve restricting usage of the instrument to persons of known or technical proficiency. It may be advisable to seal the instrument to prevent tampering or adjustment by unauthorized persons.

This brief discussion of calibration may suggest the need for expensive investments in instruments and technical personnel. This may be true when an organization completely lacks a calibration capability or is about to produce products of greater complexity than those manufactured in the past. Under such circumstances a manufacturer can use outside calibration services that are widely available.

Effectiveness Evaluation

- (1) Is policy for controlling measurement and calibration instruments clearly defined?
- (2) Does it include an adequate minimum ratio of instrument and reference standard accuracy to tolerances?
- (3) Do detail procedures adequately identify responsibilities, calibration and inspection intervals records, and recalibration due dates?
- (4) Are reference standards used which are traceable to a valid source?
- (5) Are protective provisions adequate?
- (6) Are arrangements made to assure that suppliers comply with calibration requirements?

G. DISTRIBUTION: Distribution practices significantly influence the safety of consumer products. Accordingly, control over final packaging and shipping operations is necessary. This control includes the selection of adequate packaging materials, design of methods of packaging that preclude damage in shipment, and selection of shipping methods consistent with the physical properties of the product. Packaging and shipping techniques and practices are, of necessity, revised as experience dictates. In those instances where distributors or other organizations are involved in assembly or test operations prior to delivery to the consumer market, they must be provided with current and adequate assembly and test instructions. It is incumbent on the manufacturer to assure that these instructions are fully implemented, under direct management control.

Commentary

From the moment products leave a shipping dock until acquired by consumers they are exposed to numerous contingencies that can affect their safety or usability. Whether they survive this transition without degradation of their inherent safety characteristics depends on many factors, including packaging, handling, storage, shipping, assembly and testing by distributors or retailers, and assembly and handling by consumers. A comprehensive systems plan for product safety must include purposeful arrangements to minimize the

probability of product degradation on its journey from the manufacturer to the consumer. It is not unusual for manufacturers to meticulously control in-plant operations, such as production, while tolerating distribution practices that potentially negate qualities designed-in and built into the product before shipment.

Application

There are some basic positive actions that can be taken to minimize degradation of the built-in safety. These include:

1. *Proper packaging.* Packaging methods and materials should be prescribed during the original design. Conceptually package design is an integral element of the product. In addition to more elementary considerations (e.g., materials and construction of packaging) proper packaging should provide for protection against predictable deterioration (e.g., use of desiccants, labels with shelf-life data, and precautions specifying environmental requirements for both short and long term storage).
2. *Handling.* In most industries there are handling practices that are known to cause damage that could result in a product safety hazard (e.g., use of slings or certain kinds of grappling devices). While all contingencies cannot be anticipated, as stated previously, risks of safety-related damage can be reduced. For example, it is useful (particularly for new products) to examine, on site, handling practices to exclude or modify those that clearly are adverse to product usability and safety. As is true in other areas of industry, there is room for "inventiveness" in product handling, including more sensitive recognition of human factors.
3. *Assembly and test instructions.* To assure the adequacy of the assembly and test guidance supplied to distributors, it is advisable to validate distributor assembly and test procedures by assembling and testing a product exactly as described in the accompanying documentation. It may be desirable to repeat such simulated tests at periodic intervals to assure that guidance is current with the design configuration and that the packaging list did not omit any needed components.
4. *Safety hazard reporting provisions.* Easy-to-use reporting forms should be available to distributors, retailers and consumers so that they can advise the manufacturer of safety-related product deficiencies induced by inadequate packing, incomplete instructions or rough handling.

In light of increasing demands for preventing product-related safety hazards, regardless of cause, it is advantageous to re-examine traditional distribution practices in a product safety context.

Effectiveness Evaluation

- (1) Are packaging procedures defined in sufficient detail?
- (2) Are the packaging and handling precautions clear and sufficiently disseminated?
- (3) Are assembly and test instructions adequate?
- (4) Are they validated against the product?
- (5) Do they include guidance for reporting hazards?

H. CONSUMER SERVICE: Consumer service programs are of varied scope and magnitude, depending on manufacturers' policies and objectives. To assure product safety, these programs necessarily include four elements: (1) advising consumers through manuals or otherwise how products are to be assembled and operated to prevent safety hazards; (2) proactively informing consumers how and where to obtain product servicing, particularly for deficiencies or malfunctions that are potential causes of product safety hazards; (3) the establishment and maintenance of a records system that identifies products (e.g., serial number, model and date of manufacture) and identifies their location in the distribution system, including consumers; and (4) clear written procedures for company response to product defects that pose the risk of consumer injury, including clear recall procedures and policies.

Commentary

The term "consumer service" encompasses a broad spectrum of activities. These comments are limited to one facet of consumer service—its impact on consumer product safety. Consumer service programs apply to a wide range of products: throwaway items; lifetime equipment; end products and components; simple and complex; portable and non-portable. These may or may not be covered by warranties and are serviced in many ways. Consumer service programs represent a complex matrix of product types and services with varying potential for product safety.

Application

Despite the range and variety of consumer products, there are some principles applicable, in a safety context, to most products. In applying the consumer service provisions of the Handbook, attention is invited to three considerations: (1) the importance of planning, (2) the need for providing adequate information to consumers, and (3) the necessity, in many instances, for providing person-to-person assistance when information in manuals or similar printed form is not adequate for assuring safe use or application of purchased products.

Planning. Consumer service must be planned. Consumer service programs that are not properly planned serve neither the interests of manufacturers nor consumers. At a very minimum, planning must take account of (a) the problems the consumer is likely to encounter in using the product (e.g., the availability of replacement parts), and (b) experience data regarding the incidence of injuries associated with the product or with other products in the same general category. Among other sources of information, the National Electronic Injury Surveillance System (NEISS) of the U. S. Consumer Product Safety Commission should be consulted.

Information needs of consumers. Keeping in mind the thousands of consumer products to be found on the marketplace, it is difficult to be specific on consumer need for safety-

related information. There are three categories of information needed by users of most products. These are:

1. Identification of the product. This means that the product should be properly labeled and that the labeling includes any precautions necessary to prevent reasonable foreseeable misuse or abuse of the product.
2. Channels for reporting safety-related deficiencies to manufacturers.
3. Guidance for assembling, installing, using and maintaining the product. Manufacturers may want to consult the “Manufacturers Guide to Developing Consumer Product Instructions” available on the Commission website at www.cpsc.gov.

Person-to-person assistance. If manufacturers erroneously presume that consumers have greater technical sophistication and accessibility to tools than they really have, then assembly and operational guidance, as provided in manuals, is inadequate. Person-to-person assistance is needed to prevent safety hazards. This assistance should be an integral and routine element of consumer service. Depending on the character of the product, such assistance might include help in original assembly, installation, hands-on training, and in continuing maintenance.

There is a wide range of options open to manufacturers for rendering this assistance. Local technical representatives of the manufacturer can directly service products. The manufacturer might delegate this role to distributors or to third party service organizations. These services are as important to the consumer as the product itself and should be provided for in the purchase contract if safety is at stake. In effect, the consumer buys safety protection. The cost of such protection plus the acquisition cost of the product itself adds up to the cost of safe product ownership.

Effectiveness Evaluation

- (1) Does the manufacturer include consumer service in purchase contracts? Does the distributor?
- (2) Does the manufacturer provide consumer guidance in the form of manuals or other publications for assembly, installation and maintenance?
- (3) Are such documents adequate?
- (4) Are they difficult for consumers to understand?
- (5) Are these publications updated?
- (6) Do manuals and similar documents provide adequate consumer guidance?
- (7) If not, is personal assistance provided? By whom?
- (8) Does the manufacturer or distributor provide training and demonstration to consumers in safe product utilization?
- (9) Can the manufacturer trace a product back to the time and place of its manufacture?
- (10) Does the product conform to consumer product standards issued by the U. S. Consumer Product Safety Commission and to relevant voluntary (consensus) safety standards issued by standard setting bodies such as ASTM, ANSI, and UL?
- (11) Are there channels for customers to report hazards directly, or through distributors, to manufacturers?

I. RECORDS: *An effective product safety system requires records in sufficient detail and format to permit timely detection of safety hazards and trends, and for effecting traceability of the assembly operations and components involved. For these purposes the following records are particularly necessary: (1) the results of inspections, tests and calibrations; (2) consumer complaints and comments and related actions; (3) actions taken to correct product and system deficiencies; (4) location of products within the production and distribution systems so that prompt and effective recall can be accomplished, if required; and (5) information required by regulations issued by the CPSC that appear in 16 Code of Federal Regulations Parts 1101 through 1702.*

Commentary

The prudent manufacturer will recognize the need for adequate records. For reasons of efficiency, self-protection and protection for consumers, records are an integral requirement for efficient manufacturing, akin to drawings, specifications, plant layout and similar essential documentation.

The challenge to management is to identify record keeping needs for substantiating product safety and to prevent record keeping that serves no useful purpose. As manufacturing methods and products change, it is to be expected that record keeping practices will also change. Thus, record keeping is a dynamic function. If it is considered an incidental and static aspect of manufacturing, records may soon become both costly and irrelevant.

Paragraph 16(b) of Public Law 92-573 states:

“Every person who is a manufacturer, private labeler, or distributor of a consumer product shall establish and maintain such records, make such reports, and provide such information as the Commission may, by rule, reasonably require for the purposes of implementing this Act, or to determine compliance with rules or orders prescribed under this Act. Upon request of an officer or employee duly designated by the Commission, every such manufacturer, private labeler, or distributor shall permit the inspection of appropriate books, records, and papers relevant to determining whether such manufacturer, private labeler, or distributor has acted or is acting in compliance with this Act and rules under this Act.”

This provision, as others in Public Law 92-573, reflects the paramount demand and needs of the public for protection against hazardous products.

Application

In establishing a records system, it is necessary to define objectives. In a product safety context, record keeping has five objectives. The first is to demonstrate the products have been properly inspected and tested for safety before being released into distribution channels. The second is to indicate responsiveness to consumer complaints and, when necessary, to substantiate corrective actions that have been taken. The third purpose is to

substantiate that manufacturing operations are and have been under control in accordance with the concepts of this Handbook. The fourth is to maintain a capability to locate hazardous products wherever they may be positioned in the production and distribution system so that prompt corrective action, including product recall, can be readily accomplished if necessary. Lastly, records are needed to make sure that the organization is in compliance with the provisions of Section 16(b) of Public Law 92-573 quoted above. Records satisfying these objectives provide an excellent source of information should defense be needed against an alleged violation of P.L. 92-573.

With respect to the need for a capability to locate products within the production and distribution system, it may be impractical to maintain records identifying all owners of a particular consumer product. However, a reasonable effort in that direction can be made by requesting distributors or retailers to maintain such records or by inclusion in product packages of self addressed mailing cards by which consumers can, if they choose, identify themselves. It is not the purpose of these comments to explore all the techniques by which product identification and location record keeping can be maintained. The burden of this paragraph is to suggest that while there are practical limitations to developing complete and accurate records of product location, there are arrangements by which reasonably complete records can be established and maintained. Finally, in implementing the records provision of this Handbook, attention is invited to those paragraphs that specify guidance for record keeping. It is suggested that the reader review those ideas as inputs when planning record keeping procedures.

Effectiveness Evaluation

- (1) Does the organization have an overall record keeping system for product safety?
- (2) Are data available documenting the results of product tests and inspections related to safety?
- (3) Is it possible to locate products in distribution system?
- (4) Are records of suppliers accessible when they apply to product safety?
- (5) Are consumer complaints made matters of record?
- (6) Are these complaints analyzed to detect trends and to isolate causes of complaints that are substantive?
- (7) Are significant changes in manufacturing processes or in product design documented?

J. CORRECTIVE ACTION: To prevent potentially dangerous products from being delivered to consumers, it is necessary that manufacturers establish procedures to take prompt corrective action when appropriate. This action includes determination of hazard cause(s), prevention of their repetition, and removal of hazardous consumer products from production and distribution channels. Reporting procedures are necessary to keep executive management informed of product safety hazards and trends that might induce such hazards. Most importantly, arrangements must be provided for compliance with CPSC safety standards, and Section 15 (b) of the CPSA, which states, "Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such

product. . ." report to the CPSC products that contain "a defect which could create a substantial product hazard."

Commentary

The very concept of a "system" for manufacturing safe consumer products implies a complete and closed loop that provides for reaction to data feedback from all sources involved in the manufacturing program, including consumer and distribution channels. A mechanism for corrective action is the link that closes the system. An effective corrective action plan is characterized by, at least, the following: (1) an arrangement for reporting product safety hazards to executive management; (2) prompt reaction to reported product safety hazards; (3) a comprehensive range of actions (i.e., corrective action should not be an *ad hoc* reaction to a particular product hazard); (4) accurate and complete record keeping; and (5) the requirements of the CPSA and 16 C.F.R. part 1115.

Experience has shown that unless a formal policy for corrective action is implemented, the tendency exists to only pursue and correct the obvious, in an unorganized and incomplete manner. It has also been demonstrated that few aspects of the safety system are more important or have more substantive effect on the safety and integrity of the product, as well as the economics involved, than this component.

Application

The causes of product safety hazards have their roots throughout the manufacturing and distribution system. Indications of a safety problem may come from such diverse sources as production, test, inspection, distribution operations, consumers or even from the press or the government itself. A corrective action mechanism, therefore, must include most sectors of an organization, since almost every operation potentially impacts product safety.

The elements of a corrective action program generally include:

1. *Reporting* - Responsibility for originating reports of safety hazards must be clearly established within the manufacturer's facilities as well as within distribution channels.
2. *Promptness* - As a minimum, a single internal reporting point at the executive level must be established so that appropriate management action can be taken without delay and with sufficient authority.
3. *Comprehensiveness* - The range of necessary actions include:
 - a. Prevention of continued distribution of products with known or suspected hazards.
 - b. A detailed investigation of the primary cause of the hazard as well as the cause of the breakdown of the manufacturing operations. As an example, if a report of a hazard is generated from consumer reports, the investigation must include a determination as to why the deficiency was not detected in production, inspection or test, and why it was not anticipated in design review, or why it was not detected at the supplier's facility, if a supplier was involved.

In most cases, the determination of cause is linked to an assignment of organizational responsibility and sometimes to individual responsibility. Analysis of responsibilities for safety hazards may lead to a number of indications including management or supervisory deficiencies, needs for increased or improved training, and possibly needs for personnel reassignment.

c. A repair plan formulated as described in Section III, Paragraph D5 above to eliminate the hazards.

d. Action to prevent similar breakdown of the system's capability for anticipating and/or detecting like hazards in the future. This may involve correction of such factors as procedures, equipment, inspection and test operations.

4. *Records*

The completeness and accuracy of records may provide the basis for determining the need for corrective actions. In this regard, trends may be revealed in production operations, which are precursors to the identification of actual hazards. As an example, if the records of hardness of a component which is required to be heat treated to a particular minimum strength indicate deterioration to a point close to the minimum, the corrective action program, starting with an investigation of cause, could well preclude a much more serious condition from materializing. Similarly, the recognition of early trends in distributor or consumer reports could accomplish the same objectives.

5. *Responsiveness*

The program must be responsive to the requirements of the CPSA and 16 C.F.R. part 1115.

Effectiveness Evaluation

- (1) Is the corrective action program, including reporting responsibility, clearly defined?
- (2) Does it provide for sufficiently prompt response to safety hazards?
- (3) Does the action prescribed adequately cover detection, correction and future prevention?
- (4) Are necessary and sufficient records and reports provided?
- (5) Is sufficient follow-up provided to assure the effectiveness of planned actions?

K. AUDITS: Audits are planned, scheduled, and management-directed examinations of procedures and operations to determine whether they comply with (1) applicable CPSC laws and regulations, (2) relevant safety standards, (3) established company policies and directives, and (4) principles of this Handbook. Audits of particular functions and activities should be performed by persons other than those administratively responsible for such functions. Results should be recorded and distributed appropriately within the organization for the accomplishment of necessary improvements.

Commentary

It is to be expected that management is often hard pressed to keep informed of the status of programs and activities under its control. In part, this is due to the complexity and specialization that surrounds many manufacturing operations. It is not necessary for a top-level manager to be specialized in every area of manufacturing in order to assess the status and effectiveness of a particular function. The concept of management audit came about as a response to the need of management to inform itself on the status of corporate functions and activities in a technical rather than financial perspective.

Application

An audit is a planned review to determine whether management directed policies and programs have been executed and to ascertain the effectiveness of their execution. Since the purpose of audits is to prevent oversights, their results should be discussed frankly with responsible persons as a basis for affirming that operations are satisfactory or for giving visibility to safety-related deficiencies that need correction. An audit is not an investigation. If it is so viewed, a climate of secretiveness and possibly hostility might easily be created. In a certain sense, an audit is not unlike an annual physical examination. The person examined is considered to be healthy. In the event the examination reveals deficiencies, that person is so advised. This is the underlying concept of a management audit.

There are at least five elements in typical auditing plans: (1) the identification of the functions to be audited, (2) the audit plan for each function, (3) audit schedules, (4) arrangements for reporting results, and (5) consultations and corrective action. For each function there must be a specialized audit procedure. For example, an audit plan for purchasing practices would include an analysis of a scientifically chosen sample of standards or purchase descriptions to determine the adequacy of the product safety provisions; a random sample of incoming inspection records to determine how well suppliers conform to established standards; and review of scrap, rework and repair records to detect trends or correct problems. High scrap and repair rates are danger signals. Larger functions (e.g., production) necessitate more comprehensive audit plans. In general, these plans should be directed towards sensitive points that serve as indicators that all is well or not well.

Effectiveness Evaluation

- (1) Does the organization have a management product safety audit plan?
- (2) Is it directed by a senior executive?
- (3) Does the plan include audits of all functions affecting product safety?
- (4) Are these plans implemented on a scheduled basis?
- (5) Are results recorded?
- (6) Is effective corrective action taken?
- (7) Are responsible personnel advised of audit results, including corrective actions?