Guidance on the Application of Human Factors to Consumer Products

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Definitions

For the purpose of this document, we will use the following definitions:

Context of use	The actual conditions in which a product is used, or is proposed to be used, in normal conditions.
Critical task	A task which, if not accomplished according to the manufacturer's directions, could have adverse effects on the product's reliability, efficiency, effectiveness, or safety.
Human-centered design	A system of design and development that aims to make products more efficient, effective, and satisfying, by focusing on the user's needs. This is carried out by applying human factors, and usability knowledge and techniques.
Human factors	The study of relationships between humans and elements of a system. The human factors profession applies theory, principles, data, and methods to equipment, systems, software, procedures, jobs, environments, and training to produce safe, comfortable, and effective human performance. It has two parts – human factors research (acquiring the information) and human factors engineering (applying the information).
Human factors engineering	The application of knowledge about human capabilities and limitations to product design and development to achieve efficient, effective, and safe performance, while considering cost, skill levels, and training demands. It ensures that the product design, required human tasks, and use are compatible with the sensory, perceptual, mental, and physical attributes of the person who will operate and maintain the product.
Human factors testing and evaluation	Testing that evaluates human factors analysis, studies, criteria, decisions, and design characteristics and features. Human factors testing could include engineering design tests, simulations, model tests, mockup evaluations, demonstrations, and subsystem tests. This testing provides objective data about human performance, showing typical users operating and maintaining the product.
Human performance	A measure of human functions and actions in a specified environment, reflecting the experience of actual users compared to the product's performance standards.
Usability	The degree to which a product can be used to achieve specified goals with effectiveness, efficiency, and satisfaction in actual operating conditions.

User experience	A person's opinions and reactions that result from the use, or expected use, of a product. This includes the users' emotions, beliefs, preferences, perceptions, physical and psychological responses, and behaviors that occur before, during, and after use. User experience can be a result of brand image, presentation, purpose, product performance, and interactive behavior.
Vulnerable populations	Groups of people who could be at greater risk of harm from products due to their age, level of literacy, physical or cognitive condition, or other limitations. Examples include children, persons with disabilities, or seniors.

1.0 Purpose and Audience

The U.S. Consumer Product Safety Commission (CPSC) staff[1] and Health Canada's Consumer and Hazardous Products Safety Directorate ("Health Canada") have developed this guidance document to help consumer product manufacturers integrate human factors principles into their product development process.

Many product-related injuries can be prevented by better design. Providing the consumer product industry with suggestions on how to apply human factors principles to their products can help lower the number of product-related adverse incidents and reduce costly compliance and enforcement actions. These suggestions can be tailored to meet the needs of a particular product, while understanding that not all practices apply to all products.

As a first step, Health Canada conducted a literature review. In a manner consistent with copyright limitations, material was extracted from the documents reviewed as input for this document. Further details can be found in the bibliography at the end of this paper.

This document is not a rule or regulation, and is not meant to create legally enforceable responsibilities. *This document must be read in conjunction with the applicable legislation. To the extent that this document might be inconsistent with the legislation, the latter shall prevail.*

Beyond what is outlined in this document, industry is reminded to comply with relevant rules and regulatory requirements in the respective jurisdictions. Rules or regulatory requirements that apply to specific products must be a part of the human factors analysis throughout the life cycle of a product. Beyond this, industry should consider any relevant voluntary standards that may help inform the design of a particular product. Beyond product-specific design considerations, industry must also comply with other requirements, such as record retention and incident reporting.

2.0 Overview

Human Factors is the study of how people use products, and how design can guide this usage. Information on human factors professionals, training, and experience can be found in Appendix A. Consumer product design and development involves four major components: (1) the product use environment, (2) the product users, (3) the product design or user interface, and

[1] This document was prepared under the direction of CPSC staff and has not been reviewed and does not necessarily reflect the views of the Commission.

(4) the tasks to be accomplished by the user. The interactions among the four components and the possible results are depicted graphically in Figure 1.

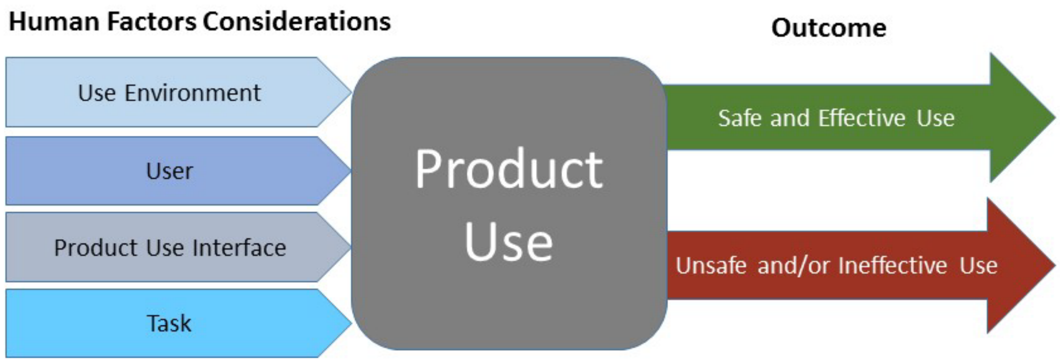


Figure 1: Factors that impact the safe use of the product (adapted from the Food and Drug Administration, Applying human factors and usability engineering to medical devices, 2016)

3.0 Benefits of Applying Human Factors Principles

Designers and developers frequently fail to remember that people with different aptitudes, abilities, and experiences will operate and maintain a product and that this will happen in many different conditions, configurations, and use scenarios. A design method that considers human characteristics, capabilities, and limitations throughout the system design is vital to create safe and effective products. The main benefits of considering human factors are:

- *Improved usability and acceptance.*
- *Increased safety.*
- *Reduced lifecycle cost and risk.*
- *Reduced support and help desk costs*.

There can be great variability in how a product is developed and designed and how it is ultimately used by the consumer. A product can operate perfectly from an engineering sense in a laboratory, or during a demonstration; and then not do well when it is operated by actual people in real-world settings. Enhancing the user's experience with the product can increase satisfaction, acceptance of the product, and safety.

In the following sections, we outline the stages of the product design process and the activities that a human factors specialist can perform in each phase.

4.0 Human Factors Activities in Product Design Process

Product design includes the following six stages:

1. Product planning
2. Idea and concept generation
3. Design and development
4. Testing and validation
5. Production
6. Post-production evaluation

The depth and breadth of each product design stage can vary depending on the particular product, but each will go through a similar process. Frequently the transition point between these stages is not always clear. For example, product planning occurs throughout the process; testing and validation activities begin during design, and might continue through to the post-production evaluation.

4.1 Product Planning

The product planning stage involves taking the necessary steps to bring a product to the marketplace, and the subsequent assessment of its performance. Product planning is a vital function because:

- Every product has a limited life span and will eventually need improvement or replacement.
- The needs, desires, and preferences of consumers change over time, requiring adjustments or improvements to products.
- Competition and the advancement in technology create opportunities and demands for the development of better products.

During product planning, the company identifies:

- the market opportunity,
- the targeted user group(s);
- the non-targeted, but foreseeable user group(s);
- the high-level tasks and activities that need to be accomplished;
- the schedules for those tasks and activities;

- personnel requirements, including the number of people needed and any special skill requirements;
- facility requirements, including any special equipment needed;
- the testing and evaluation of the product as the design and development evolves;
- the estimated costs, including the source(s) of the funding;
- the design, manufacturing, and distribution approaches;
- how the product will be introduced into the marketplace;
- methods for assessing product performance once in the marketplace; and
- how the company will handle consumer complaints and recalls.

Product planning minimizes the "hiccups" that are bound to occur during a product's lifecycle, because potential contingencies would have already been identified and corrective measures could be executed quickly. It helps prepare for surprises that could require costly and time-consuming fixes and delay entry into the marketplace.

Summary of Human Factors Activities in Product Planning Stage
1. **Identify high-level human factors related activities and estimate the resources that need to be allocated to these activities.**

4.2 Idea and Concept Generation

This stage is characterized by identifying a gap between the needs & wants of the consumer, and what is available in the marketplace, then determining possible ways to fill that gap. Human factors specialists can help identify the users of the product and requirements that are essential for a product to be useful and usable. During the concept-generation stage, ideas are translated into design concepts. Devising multiple preliminary designs allows the product development team to compare, select, and build on alternative design concepts.

Consider a "participatory design" approach that involves the likely end users of the product. Make sure that users who are involved in this process have capabilities, characteristics, and experience that reflect the range of users for whom the product is being designed. Actively involve users whether by participating in design, acting as a source of relevant data, or evaluating solutions. The nature and frequency of this involvement can vary throughout the product design process, depending on the nature of the product. The effectiveness of user involvement increases as the interaction with the design team increases.

Summary of Human Factors Activities in Idea and Concept Generation Stage
1. **Identify potential users of the product.**
2. **Determine user needs. Analyze competing products and search for a gap between what consumers want and what is available in the marketplace.**
 ***Surveys, interviews, and focus groups.*** **Such user research techniques can be used to gauge the interest of the consumer, as well as to identify desired features of a new product.**

4.3 Design and Development

This stage is characterized by identifying and analyzing the function(s) of the product including design and development of the product and associated user interfaces. The human factors effort converts the results of the analyses into a detailed design to create a human-system interface that will operate within human performance capabilities and meet the product's functional objectives.

4.3.1 Preliminary Analyses

Conduct preliminary analyses and evaluations to identify user characteristics, user tasks, user interface components, and use issues early in the design process. Determine human performance parameters; the criticality of the task in accomplishing the objective; the system, equipment, software and associated user interfaces; and the environmental conditions. Identify gaps between human performance requirements and foreseeable user capabilities, and approach for mitigation. Consider users' strengths, limitations, preferences, and expectations when specifying which activities are carried out by the users and which functions are carried out by the product itself.

a) Identify User Characteristics

Once foreseeable user populations are identified for the product, gather relevant user characteristics including:

- Physical capabilities and limitations
- Cognitive capabilities and limitations
- Sensory capabilities and limitations
- Knowledge
- Skills

- Experience
- Education
- Training
- Habits and preferences, including cultural norms

In the design and development of a consumer product, consider users' expectations and mental models (*i.e.*, representation of the product, or the interaction that user has in mind). The user should be able to easily identify the product's purpose, and quickly identify any hazards, safety features, controls and displays, while immediately recognizing their relationships. When features function contrary to the user's expectations, errors in use are bound to follow. A common design mistake is to assume that the designer's mental model matches the user's mental model, when, in fact, the user's mental model may be qualitatively different due to different life experiences. New products should build on the user's existing experience and mental models.

User experience depends on the presentation, functionality, product performance, interactive behavior, and assistive capabilities of hardware and software. It is also a function of the user's prior experiences, attitudes, skills, habits, and personality. The concept of usability is broader than simply making products easier to use, and also includes usable product manuals and instructions, online help, and product packaging.

b) Conduct Task analysis

Task analysis is the process of identifying how people think about tasks and how they complete them. This provides a basis for making design conceptual decisions and is an essential, early input to system design. Task-oriented design considers the differences that can be observed between the task as designed, and the way it is actually performed. Design should take full account of the nature of the task and its implications for the user. This includes determining whether specific tasks or functions should be automated, or performed by the user.

Hierarchical Task Analysis. **The aim is to break down the high-level tasks into subtasks and operations to better understand the process and pinpoint potential sources of error.**

c) Identify Context of Use

The extent to which products are usable and accessible depends on the context of use, *i.e.*, the specific users, having specified goals, performing specified tasks, in a specified environment.

The context of use is a major source of information for establishing requirements and an essential input to the design process.

Consider environmental conditions such as temperature, lighting, noise, and spatial layout. In some applications, this might be part of the design, such as adding lights on a snow blower so it can be used at night.

User Observation/Field Studies. **Direct observations that are performed in real-word settings allow human factors specialists to discover more about the context of use and provide essential input to designing usable interfaces.**

Contextual Inquiries. **Specific types of interviews for gathering field data from users in their context, when performing their tasks.**

Think-Aloud Protocol. **Gathering data by asking the users to verbalize their thoughts, feelings, and opinions while performing tasks.**

4.3.2 Evaluating Product Safety Risks

A product safety risk is defined as the level of harm that a consumer product can cause with the likelihood the harm will occur. From a project management perspective, risk identification procedures should be planned and, where risks are identified, risk mitigation measures should be implemented for the entire lifecycle of the consumer product. Risk identification and mitigation should:

- Identify potential cost, schedule, design, safety, and performance risks that result from design aspects of human-system integration;
- Quantify these risks and their impacts on cost, schedule, and performance;
- Define and evaluate sensitivity of potential risks as related to the human interface;
- Identify alternative solutions to human factors problems and define the associated risks of each alternative;
- Document the identified risks, their impact on the product, and the mitigation action(s) taken;
- Take actions to avoid, minimize, control, or accept each human factors risk; and
- Ensure that human performance risks are included in the overall product's risk-management process.

a) Risk reduction process

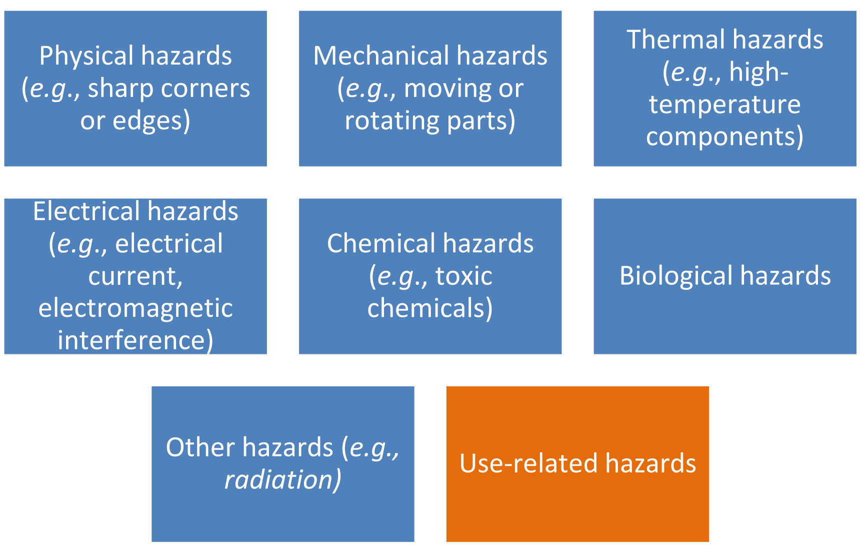
Risks are traditionally addressed in the following order:

1. Provide an inherently safe design.
2. Provide guards and protective devices.
3. Provide information for users to use the product safely.

Inherently safe design features are the most effective step in the risk-reduction process. This is because protective features inherent to the characteristics of the product are likely to remain effective, whereas even well-designed guards and protective devices can fail or be circumvented, and information for use might not be followed. Guards and protective devices should be used whenever design features do not remove hazards or fail to reduce risks sufficiently. The user has to be warned against risks that cannot be eliminated. However, information for use should not be a substitute for the correct application of inherently safe design features or at least safer designs.

b) Hazard identification

Eliminating or reducing design-related problems that contribute to or cause unsafe use is part of the overall risk management process. Hazards considered in risk analysis should include, but are not limited to: physical, mechanical, thermal, electrical, chemical, biological, other hazards such as radiation as well as use-related hazards.



Use-related hazards typically relate to one or more of the following situations:

- The product is used in unintended-but-foreseeable ways that the designer or manufacturer did not consider or dismissed.
- The product use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user.
- The product is not designed to prevent use by consumers who lack the abilities needed to use the product safely.
- The product use is inconsistent with the user's expectations about the product's operation.
- The use environment negatively affects the product's operation.
- The use environment impairs the user's physical, perceptual, or cognitive capabilities when using the product.

c) Process to identify and mitigate use-related hazards

Who are the potential users of the product?

- Identify the potential users of the product, including the intended and unintended users of the product. In particular, consider vulnerable consumers who may use the product without understanding the associated risks, and those who are less capable of avoiding the hazards. For example, a dresser might be purchased and used safely by adults, but children would also likely interact with the dresser, like climbing it, with limited ability to anticipate and avoid the dresser tipping over.

How do people use this product?

Consider all phases of product use from unpacking to assembling, using, maintaining, and disposing.

- Identify known use-related problems: Historical data relating to the product under development, or similar products, can provide invaluable insights. Sources of information include customer complaints, the knowledge of training, sales, or maintenance personnel, and previous human factors or usability engineering studies conducted on earlier versions of the product, or on similar existing products.
- Determine foreseeable uses of the product: 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 product. This includes the use intended by the manufacturer, and uses that were not intended but can reasonably be expected to occur. The foreseeable use analysis should also identify potential uses that the product

may allow because of the clues provided by the product or its context. For example, it is foreseeable that a stool intended for sitting could also become a step stool; and if the product is not designed to be stable under such conditions, it may collapse, potentially harming the user.

- Review and analyze reported incidents in publicly available databases (e.g., SaferProducts.gov) to identify types of incidents and incident scenarios.
- Review past recall announcements involving similar products.

What are the conditions in potential-use environments?

- Consider all aspects of the environment in which the product might be used. Some examples are lighting, temperature, noise, and vibration.

What are the risks to users?

- Estimate and evaluate the risk to the affected user group(s). Pay attention to the differing characteristics of each user group.

What are the potential ways to mitigate the risk?

- Determine ways to eliminate or reduce the risk. Where hazards have been identified, ensure that preventing a risk does not result in creating another one. Consider any relevant voluntary standards that may help inform the design of a particular product.

Failure Modes and Effects Analysis (FMEA) **and** ***Fault Tree Analysis (FTA)*** **are two of the risk-assessment tools that human factors specialists can use to identify, prioritize, and mitigate potential use-related hazards from the system.**

4.3.3 Product Development

a) Product-user interface

The product-user interface consists of all points of interaction between the user and the product during set-up (e.g., unpacking, assembly), use, maintenance, and disposal; including:

- Size, weight, and shape of the product;
- Elements that provide information to the user, such as indicator lights, displays, and auditory and visual alarms;
- Graphic user interfaces of product software components;

- The form in which information, including feedback, is provided to the user;
- Packaging and labeling, including operating instructions, training materials, and other information;
- Components that the user connects, positions, configures, or manipulates; and
- Components the user handles to control the product's operation, such as switches, buttons, and knobs.

To the extent possible, make the "look and feel" of the user interface logical and familiar. This will encourage correct user actions and prevent or discourage actions that could result in harm. Addressing use-related hazards by modifying the product design is more effective than revising the labeling or training.

Users approach a new product expecting the product's components to operate in ways that are consistent with their experiences with similar products or user interface elements. The potential for use-related error increases when this expectation is violated.

Heuristic Evaluation. **Human factors specialists evaluate the usability of the system early on in the design process, based on established human factors guidelines and principles, then record their observations and rank them in order of severity. The method provides recommendations for design improvements.**

b) Models and mockups

Utilize three-dimensional computer models, rapid prototyping, and computer-aided design to support the design of products for which human performance will be a major factor in user acceptance and satisfaction. Computer models can provide relevant information, such as a suitable range of body sizes and postures for evaluating proposed designs and design changes. When used for predictive purposes, such models can produce outputs that are accurate and empirically repeatable. However, computer models should not be used for compliance testing of human performance and human factors design.

c) Evaluating with users

User feedback is a critical source of information. Evaluating designs with users and improving the design based on user feedback helps ensure the product will meet the users' needs. This allows preliminary design solutions to be tested against "real-world" scenarios, with the results being fed back into progressively refined solutions. User-centered evaluation should also take place as part of the final review of the product to confirm that requirements have been met. See section 4.4.3 on how to choose participants and conduct testing.

d) Human-System Interface

You can use a style guide in the development of software user interfaces to define the general principles and specific rules that guide the design and consistency of individual components. To the degree practical, utilize models, simulations, and prototypes to support human-system interface development.

e) Technical documentation and instructions

Technical documentation (electronic and hard-copy) should ensure thoroughness, technical accuracy, suitable format of information presentation, appropriate reading level, appropriate level of technical sophistication, clarity, and quality of illustrations. Include all steps necessary to assemble, use, clean, maintain, dismantle, and dispose of the product in the instructions.

Effective instructions help users to make appropriate decisions concerning the use of the product, and provide directions to avoid misuse. Instructions may also indicate remedial action if an accident occurs, *e.g.*, spilling gasoline while refueling a lawnmower.

Instructions[2] for use are an integral part of the product and should:

- Clearly identify the product;
- Define the intended use of the product, its function and operation, including any considerations for certain populations, *e.g.*, access by children;
- Contain all information required for correct and safe use of the product, *e.g.*, transport, handling, lifting weight, assembly, installation, and storage conditions;
- Contain all information required for cleaning, maintenance, fault diagnosis, signs of deterioration, and repair of the product;
- Identify the potential safety hazards;
- Contain consumer-relevant technical specifications; and
- Include a source of further contact information, such as a phone number, website, and email address of the manufacturer.

[2] For more guidance on developing instructions, you can refer to Manufacturer's Guide to Developing Consumer Product Instructions, CPSC, 2003.

Warnings should be conspicuous, legible, durable, clear, concise, and motivating. Product safety signs and labels should be understandable to end users in all intended countries of use. The content of a warning should vividly describe the hazard and the consequences if the warning is not followed. Effective warnings attract attention by using signal words (*e.g.*, “Danger,” “Warning,” or “Caution”), safety alert symbols, if applicable, and a font in a type size and color that is suitable to the product hazard.

In some cases, there are regulatory requirements that dictate what the labels must contain. Please refer to the appropriate regulatory authority for further guidance.

f) Proper record-keeping

Provide records of design decisions from initial identification of requirements, to verifying requirements during test and evaluation. Proper record-keeping assists in:

- Assessing compliance with applicable laws and regulations;
- Developing and tracking lessons learned;
- Managing change and evolution of the design; and
- Prioritizing and justifying requirements.

All data, such as plans, analyses, drawings, checklists, design and test notes, and other supporting background documents reflecting actions and decision rationale, should be maintained for meetings, reviews, audits, demonstrations, testing and evaluation, and related functions.

Summary of Human Factors Activities in Design and Development Stage
1. Identify all possible users; determine user characteristics
2. Conduct task analysis
3. Identify foreseeable use and misuse scenarios and hazards associated with those scenarios
4. Estimate and evaluate the risk level for each identified hazard
5. Determine ways to eliminate or reduce the hazard
6. Convert the results of task analysis data into a detailed design to create a human-system interface that will operate within human performance capabilities, meet the desired functional requirements, and accomplish the product’s objectives
7. Review layouts and drawings for all designs with potential impact on the human-system interface, and identify for corrective action those designs that may induce use-related error or be unsafe

8.	Apply human factors principles to the engineering drawings and computer-aided design representations to ensure the final product can be used effectively, efficiently, reliably, and safely
9.	Ensure that the human functions and tasks identified through human factors analyses are organized and sequenced for efficiency, safety, and reliability, and provide inputs to the technical documentation
10.	Participate in developing the look, feel, and content of controls and displays, including multifunction displays, to ensure that the user interface supports efficient data input and retrieval, access to required information, and execution of decisions and commands

4.4 Testing and Validation

Human factors testing and validation should occur throughout the design lifecycle so that, as the design evolves, undesirable features can be identified and rectified while the costs of changes are lower. As the last stage before production, final tests are conducted to ensure that the product meets established requirements before it reaches the market. The goals of testing and validation include:

- Verifying that the product can be properly used and maintained by the anticipated user population in the intended operational environment(s);
- Obtaining quantitative measures of performance that are a function of the human interaction with the hardware, software, and associated user interfaces;
- Confirming attainment of overall system performance requirements;
- Ensuring that proposed instructions and illustrations provide adequate training and access to reference information; and
- Confirming that no undesirable design or procedural features have been introduced.

4.4.1 Human Factors Testing

Human factors testing is conducted to demonstrate that the product can be used by the intended or foreseeable users without serious use errors or problems, for the intended or foreseeable purpose, and under the expected and foreseeable use conditions. The testing should be comprehensive in scope, sensitive enough to capture errors afforded by the design of the user interface, and the results must be generalizable to real-world use by consumers. Testing should be designed such that:

- The test participants accurately represent the actual users of the product.

- At a minimum, all critical tasks are performed during the test.
- The product-user interface represents the final design.
- The test conditions are sufficiently realistic to represent actual conditions of use.

Testing can be conducted under conditions of simulated use, but data should also be collected under conditions of actual use when simulations are inadequate to evaluate users' interactions with the product.

4.4.2 Tasks and Use Scenarios

- Include at a minimum all critical tasks identified in the preliminary analyses.
- Ensure that the use scenarios are organized in a logical order to represent a natural workflow.
- Consider more than one human factors test session (*e.g.*, repetition with the same test participants or testing with different participants) for products with many critical tasks.
- Define the level of performance that represents success for each task.
- For products that are used frequently and/or have a learning curve that requires repeated use to establish reasonable proficiency (*e.g.*, the proper setting of a camera based on the subject to be photographed and the lighting conditions), have each test participant use the product multiple times to accurately gauge the typical use of the product. Similarly, in testing a product that requires frequent input, such as a television remote, repeated performance testing could reveal a high frequency of incorrect button selections caused by the button layout being inconsistent with typical user expectations.
- Scenarios involving critical tasks that have a low frequency of occurrence (*e.g.*, changing the oil in a lawnmower) require careful consideration. When tasks are performed infrequently, users may place an increased burden on their memories to determine the proper course of action. This can lead to missed steps and misuse of the product. Intuitive mapping and clear instructions become all the more important when users are expected to depend on recollection for critical tasks.

4.4.3 Selection of Test Participants

Make sure that test participants represent the population(s) of the end users. Conduct screening of potential participants to increase the likelihood of acquiring a representative sample, thereby increasing the generalizability of the testing and the accuracy of the results. Consider demographic variables relevant for testing such as age, gender, and location as well as participant knowledge, skills, abilities, and other characteristics to help ensure that the sample has capabilities representing the target population. An unrepresentative sample can be worse than having no sample, fostering misleading expectations about the target population.

To minimize potential bias introduced into human factors testing, do not use company employees and suppliers as test participants.

If different user groups will perform different tasks or will have different knowledge, experience, or expertise that could affect their interactions with the product, and therefore have different potential for use error, separate these users into distinct groups when selecting and testing participants. For example, a smart phone could have users that are preteens, teenagers, adults, and senior citizens, each with varying needs and capabilities. Also, although they may not be target users, it may be likely for parents to allow toddlers, with their varied needs and capabilities, to play with the phone.

Some products require specific body size dimensions for safe and effective use. Make sure that the test participants represent the relevant dimensions of the intended user. That is, if a clearance-dimension is to be tested, the test participants should, as far as possible, represent the larger people for that dimension. If a reach-dimension is to be tested, the test participants should, as far as possible, represent the smaller people, while also considering the risk that a longer reach from largest users may afford contact with a hazard.

The global region to which a product is marketed may influence its reception by users. User expectations and performance may be affected by culture-based heuristics, regulations, and laws. For example, culture may affect the interpretation and effectiveness of product instructions. Other factors to consider are language barriers and units of measurement. To demonstrate that a product will be used safely and effectively in a particular global region, testers should live in that region.

The number of test participants involved in human factors testing depends on the purpose of the test, the likelihood of use error, the severity of use error, and the complexity of the user interface.

4.4.4 Test Cycle

Any individual test should cover at least one entire use cycle for each element of the product under assessment (*e.g.*, adjustments, displays, controls, visibility). The reliability of some tests can be improved by repeating them several times (at least three times is recommended).

4.4.5 Simulated-Use Human Factors Testing

Simulated-use testing involves systematic collection of data from test participants using a product in realistic-use scenarios under simulated conditions. This can explore user interaction with the overall product, or it can investigate specific human factors considerations identified in the preliminary analyses, such as infrequent or particularly difficult tasks or use scenarios, challenging conditions of use, use by specific user populations, and adequacy of the documentation such as assembly instructions.

Make sure that the conditions for simulated-use testing are sufficiently realistic so that the results are generalizable to actual use. Incorporate the environmental factors into the simulated-use environment (*e.g*., dim lighting and cold weather) to the extent that environmental factors might affect users' interactions with elements of the product.

Provide test participants the opportunity to use the product as independently and naturally as possible, without interference or influence from the test moderator. If users would have access to documentation in actual use, make it available in the test but do not "force" them to use it.

If the users would have access to customer support via telephone or Internet, provide it in the test but make it as realistic as possible; *e.g.,* the help line portrayer should not be in the room and should not guide the test participant through specific test tasks. The objective is to understand how typical end users will use the product. If participants neglect the technical documentation and help line, then typical end users may also do without these, in which case the design features of the product are even more important for inviting proper use and preventing misuse.

Tailor the data collection methods to suit specific needs. For example, data can be obtained by observing test participants interacting with the product. Automated data capture, *e.g*., participants wearing an eye tracking device, can also be used if interactions of interest are subtle, complex, or occur rapidly, making them difficult to observe. Observations can include any instances of hesitation or apparent confusion. You can interview the test participants after using the product to obtain their perspectives on use of the product and any problems that occurred.

4.4.6 Instructions for Use and Labeling

Human factors testing can serve to assess the adequacy of the instructions for use of the consumer product, including the test participants' understanding or knowledge regarding critical aspects of use. The goal is to determine the extent to which the instructions support the users' safe and effective use of the product. If the product instructions are inadequate, it might result in participant's poor performance or subjective feedback. Ambiguities and inconsistencies in both the written and illustrated instructions are common concerns. For example, the user should not have to guess the orientation of the product in an illustration, nor should they have to make assumptions about which parts are being referred to.

The design of the product labeling used in human factors testing should represent the final design. Minor differences between the tested and actual labels can have unexpected effects on user awareness of and adherence to labels, so they should be as close to the final design as possible. This applies to the labels on the product and any accessories, and information presented on the product display, product packaging, instructions, user manuals, package inserts, and quick-start guides.

Summary of Human Factors Activities in Testing and Validation Stage
1. Plan the human factors test to identify the data to be collected, the test procedures, test criteria, and the reporting process.
2. Prepare the test documentation (*e.g.*, checklists, data sheets, test participant descriptors, questionnaires, and operating procedures), and make it available at the test location.
3. Determine the tasks to be performed (to include critical tasks at a minimum), or a simulation thereof, if actual performance is not feasible.
4. Determine criteria for acceptable performance or rejection of the test results.
5. Recruit participants who are representative of the range of the intended or foreseeable user population(s) in terms of aptitudes, skills, capabilities, experience, size, and strength; and who are wearing suitable clothing and equipment appropriate to the task.
6. Conduct human factors tests to demonstrate that the consumer product will be efficient, effective, and safe in the hands of the user. Collect task performance data in actual operational environments or in simulated environments, if collection in the actual operating environment is not feasible.
7. Review the failures that were recorded during testing to differentiate among failures of hardware/software alone, failures resulting from human-system incompatibilities, and use-related failures.
8. Analyze use-related errors to determine the reason for their occurrence. Identify the design characteristics or procedures that may contribute to use-related errors.
9. Determine appropriate corrective action.

4.5 Production

This stage is characterized by manufacturing the product, introducing it to the consumer, and bringing it to the marketplace. The manufacture of safe and reliable consumer products is a function of many factors, including physical working conditions. A satisfactory working and processing environment (*e.g*., good lighting, controlled temperature, and humidity) are important for the manufacture of safe products. Supporting technical or safety documentation, such as drawings, Safety Data Sheets (SDS), replacement parts data, production, inspection, testing and repair instructions, and operating handbooks, must be current with design. Obsolete documents and data should be removed from all places where they might be used inadvertently.

If a manufactured product is potentially hazardous, it may be discarded, redesigned or repaired. If repair is chosen, suitable precautions must be taken to ensure that the repaired product effectively eliminates the identified safety hazard and that changes made to the product do not present new safety hazards. Repair operations performed by distributors or other manufacturers' representatives should be subject to the same controls that would apply to products repaired in the production facility. Any differences in controls should be considered in determining the adequacy of the repair and the instructions and procedures for carrying it out.

4.5.1 Quality Assurance and Inspection

Quality assurance refers to a systematic process taken throughout manufacturing to detect and prevent product deficiencies and safety hazards. Accepted quality management processes and systems can be implemented by manufacturers of all sizes. A quality assurance system is specific to a manufacturer's operations and addresses product safety matters.

It is imperative that consumer products be inspected and tested prior to distribution, to verify their conformance to established requirements and relevant voluntary safety standards. If assembled components or subassemblies are not accessible for inspection and testing, then they should be inspected and tested prior to assembly. Trained personnel should conduct inspections and tests that are meaningful, objective and repeatable. Results should be recorded and maintained for proper record-keeping. Similarly, any inspection that must be performed by the user before operating the product should be clearly indicated and described in the product documentation.

An effective product safety system requires records in sufficient detail to permit timely detection of safety hazards and trends, and for traceability of the assembly operations and components involved. For these purposes, the following records are particularly helpful:

- The results of inspections, tests, and calibrations;
- Consumer complaints, comments, and related actions;
- Actions taken to correct product and system deficiencies; and

- The location of products within the production and distribution systems so that prompt and effective recall can be accomplished, if required.

To help prevent potentially dangerous products from being delivered to consumers, it is crucial that manufacturers have established procedures for taking prompt corrective action. This action includes determining the cause(s) of the hazard, preventing their reoccurrence, and removing affected units from production and distribution channels. By maintaining work instructions, the manufacturer can identify more quickly the affected units and the causes of the hazards. For example, defective units may be limited to a specific batch, and by examining records, the affected batch can be identified quickly and isolated, rather than halting all batches of the product.

4.5.2 Packaging and Advertising

Human factors principles can be applied to the design of the product packaging as well as advertising to improve the appeal of the product to potential users. Consider whether the packaging or advertising may appeal to unintended users (such as children outside of the intended age range). Consider the following examples:

- Color is used to attract attention, group elements, indicate meaning, and enhance aesthetics. Color can make designs more interesting visually and can reinforce the organization and meaning of elements in a design. However, if applied improperly, color can potentially harm the design's form and function.
- Icons are pictorial images to make actions, objects, and concepts easier to find, learn, and remember. Icons can be used for identification, serve as a space-saving alternative to text, and draw attention to an item within a display.
- The old adage-- "a picture is worth a thousand words," is true in most cases. Pictures are generally recognized more readily and recalled easier than text. Instructional and technical material should accompany text with supporting pictures to lessen the ambiguity of tasks and controls.
- Memory aid devices are used to reorganize information so that the information is simpler and more meaningful, and therefore, more easily remembered. These involve the use of imagery or words in specific ways to link unfamiliar information to familiar information that resides in one's memory.
- People are predisposed to perceiving certain forms as humanlike, specifically forms and patterns that resemble faces and body proportions. This tendency, when applied to packaging and design, is an effective way of getting attention, establishing a positive attitude about interactions, and creating a relationship based on emotional appeal.

Summary of Human Factors Activities in Production Stage
1. Participate in the design and development of work stations to ensure that physical working conditions are satisfactory including environment (*e.g.*, good lighting, controlled temperature, and humidity) for the manufacture of safe products.
2. Maintain the instructions for assembly, packaging, and shipping operations affecting safety, *i.e.,* work instructions.
3. Incorporate human factors principles into the design and development of packaging and advertising materials.

4.6 Post-Production

Customer feedback is a critical source of information that can be gained by evaluating the product's performance in the marketplace, and identifying and addressing any issues or concerns with the use of the product. The percentage of returns can be an indication of customer dissatisfaction and potential defects with a product. The percentage of repairs can be an indication of problematic components or deficiencies with the design. Findings from customer satisfaction surveys can identify customer concerns and suggestions for improvements. Incident reports and complaints to customer service can uncover use-related issues of the product, and determine avenues for both remediation and enhancement. This review should pay particular attention to the following:

- The number of calls to the help desk/complaints to customer service;
- Complaints about the product not working properly;
- Complaints where an injury or near-miss occurred;
- Questions about how to perform a particular function or operation; and
- Indications that the product is being used in unintended ways.

4.6.1 Recalls

By incorporating human factors principles during the design and development of the product, a company can improve customer satisfaction with its products and decrease the risk of a product recall.

A product recall involves both direct and indirect costs. Direct costs could include:

- conducting the recall,
- communication costs,

- loss of sales,
- business-interruption costs,
- inventory losses,
- replacement products or components,
- refunds and compensation,
- logistics costs, and
- fines and lawsuits.

Indirect costs could include:

- loss of market share,
- future loss of sales,
- negative impact to brand image,
- cost to rebuild image,
- cost to rebuild company reputation,
- potential collapse of the company, and
- negative impact on morale.

Communication during a recall is the overriding factor tied to the success of the recall and prevention of product-related injuries.[3,4] Companies should ensure that their notices and advertising of recalls are likely to reach the affected consumers and motivate consumers to comply with the recall notice.

The most effective methods of communicating product recalls are communication channels that allow direct contact between the supplier and consumers. Membership programs or registration cards can be extremely effective allowing for identification of the end user. Internet blogs and social networking sites are useful tools to advertise recalls, due to the growing popularity among various consumer demographics.

Ensure that recall notices are easily recognizable understood, and provide all of the information consumers need to know about the recall. Make the wording, tone, and design of the notice vivid to capture attention, motivating consumers to comply. Insufficient information, inappropriate features, and weak language can create barriers to consumer compliance. Returning or fixing a product places a burden on the consumer, and so the consumer may

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[3] Regarding recalls in U.S., for more information see the CPSC Recall Guidance, including guides to planning, social media, at: https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance.

[4] Regarding recalls in Canada, for more information see the Health Canada Recall Guide at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/recalling-consumer-products-guide-industry.html#a5.7

ignore the recall notice. Thus, take an approach that motivates compliance with the recall by reducing the burden on the consumer as much as possible.

Protect your interests by establishing full traceability of your products, both by maintaining a method for tracking where the product will ultimately be used, sold, warehoused, and transported, and by identifying the product in an accessible and unambiguous manner. User-friendly product identification is crucial for consumers and companies to determine quickly whether they possess the products included in a recall. Identifying information should be recognizable by color and shape, it should be readable, and ideally is permanently affixed to the product in a noticeable location.

Summary of Human Factors Activities in Post-Production Stage
1. Analyze the returns to determine if the reason for the return is related to the product-use interface;
2. Examine the repair data to determine the reasons for repairs of the product and the fix applied;
3. Evaluate customer satisfaction surveys, incident reports, and calls to the help desk to determine if any trends emerge relating to the use of the product;
4. Verify that recall communication is clear and motivates compliance; and
5. Improve traceability of products in the event that affected units must be quickly identified and collected.

APPENDIX A

Human Factors Professionals:

1. Education

Many colleges and universities provide courses in human factors, or offer degree and certificate programs in the field. These may be at the undergraduate or graduate level, but degree programs are typically at the graduate level. Depending on the college or university, the relevant courses could be provided via a human factors curriculum, or within industrial engineering or engineering psychology curricula.

2. Practical experience

Proper application of human factors principles results in products that are usable, safe, and well-received. Poor product design can result in bad publicity, monetary costs, and injury, even death. While coursework in human factors can provide a foundation for strategic product design, it is no substitute for practical, real-world experience.

3. Certification

Although not essential to becoming a qualified human factors professional, a professional certification provides the company an added level of comfort that the individual being considered possesses the desired skills and qualifications. The Board of Certification in Professional Ergonomics (BCPE) and the Chartered Institute of Ergonomics & Human Factors (CIEHF), among others, provide professional certification for practitioners of human factors and ergonomics who demonstrate expertise and a comprehensive understanding of the discipline.

Certification is increasingly important in a world where expertise is ever-more valuable to employers, consumers, and individuals. Employers who hire a certified professional may be confident that the individual has a recognized baseline of knowledge and competence. In a crowded field of practitioners, certificate holders distinguish themselves by earning an internationally recognized certification.

4. Finding qualified human factors professionals

Several organizations and their websites may help you find qualified human factors professionals. The most recognizable professional organization dedicated to human factors is the Human Factors and Ergonomics Society (HFES) (www.hfes.org). The HFES promotes the exchange of knowledge concerning the characteristics of human beings that are applicable to the design of systems and products of all kinds.

Other professional organizations that may have human factors professionals among their membership are the American Psychological Association (www.apa.org), the Chartered Institute of Ergonomics and Human Factors (www.ergonomics.org.uk), the International Association of Applied Psychology (www.iaapsy.org), and the International Ergonomics Association (www.iea.cc).

APPENDIX B

Designing Products to Accommodate Users with a Range of Abilities

The needs and abilities of people change as they advance from childhood to old age, and the abilities of individuals in any particular age group can vary substantially. Functional and cognitive limitations vary from comparatively minor impairment, to more extreme forms.

One of the vulnerable populations to consider is children. Children are not merely small adults. Children are much more willing to simply try something and often use trial-and-error interactions. Children do not think in terms of achieving an objective, and often, they can find, and continue to use, inefficient paths to their desired result.

Reductions in sensory, physical, and cognitive abilities are often associated with older users, but such impairments can occur to individuals at any age. Product design should consider and accommodate these differences. Listed below are some of the human abilities that tend to diminish with age. Please refer to the CPSC staff report titled, "*Older Consumer Safety: Phase I,*" for additional details and suggested product-related interventions to compensate for these abilities.[5]

1. Sensory and Perceptual Abilities

a) Vision. Reduced visual acuity and field of vision; reduced color sensitivity, depth perception, and speed of adaptation to changing light levels are some of the deteriorating abilities. People with a visual impairment are at an increased risk of hazards from sharp points and edges on products; unstable items that might fall, uneven surfaces that may result in slip, trip, and fall hazards, and visual warnings that rely solely on color, with poor contrast between text and background.

b) Hearing. Hearing relates to sensing the presence of sounds and distinguishing the location, pitch, loudness, quality, and comprehension of the sound. As people age, they tend to lose the ability to detect higher-frequency sounds. People with hearing loss are at an increased risk if spoken instructions and warnings are not loud or intelligible enough for them, or if frequencies are too high to detect.

c) Touch. As people age, they generally lose sensitivity and can no longer rely on touch and pain to give early feedback on temperature or injury. When operating a product in the dark,

[5] The report can be viewed at: https://www.cpsc.gov/s3fs-public/Older-Consumer-Safety-Phase-I.PDF?0eCv0iDZPLJGTxJQHlEBA9o7Vfy3d1S4

such as in emergency situations, or when the user is otherwise visually impaired, touch may be the only way to detect a control.

d) Smell. Smell relates to the use of receptors in the nose to sense odors. The ability to detect odors decreases somewhat as people age. Impairment of the sense of smell can reduce the body's defense against toxic materials. For example, people with a decreased sense of smell may not be as easily alerted to certain hazards, such as smoke or natural gas leaks.

e) Balance. The ability to maintain balance and avoid falling depends on the interaction of visual stimuli, feedback from the balance mechanism in the ear, and movement of the limbs. The incidence of balance impairments, and thus falls, increases with age.

2. Physical abilities

a) Strength. Strength relates to the force generated by the contraction of a muscle, or muscle group, when carrying out an activity. Limited strength is a common reason for people being unable to operate objects. For example, impairment of grip strength can make it difficult or painful to operate an object against resistance or torque.

b) Fine motor skills. Fine motor skills, or manual dexterity, relates to activities of hand and arm use, particularly coordinated actions of handling objects, picking them up, and manipulating them. Operations that require sustained pressure and twisting of the wrist, such as pushing and turning, may be painful or difficult for people with limited dexterity. The size, shape, and location of controls should be designed to account for these people.

d) Movement. Movement relates to activities of maintaining and changing the body position and transferring oneself from one area to another using legs, feet, arms, and hands. Examples include limited ability to bear mass on the legs, reduced step length and/or height, and restricted range of movement in the joints of arms, legs, and spine. Some people are assisted by equipment, such as wheelchairs or walking aids, which may require extra space around them to allow for approaching and maneuvering.

e) Voice. Voice relates to the sound produced by the vocal organs, usually as speech. The main consequence of speech impairment is the barrier to communication. Alternative forms of communication, such as sign language, or devices, such as speech amplification, speech synthesis, or use of keyboards, may assist.

3. Cognitive abilities

a) Cognition. Cognition is the understanding, integrating, and processing of information. The information includes abstraction and organization of ideas and time management. The design of consumer products should recognize that cognitive processes use accumulated knowledge and prior experience. Individuals can vary in their understanding of consumer products, both in terms of the functionality they offer, and the ways in which they are operated.

b) Intellect. Intellect is the capacity to know, understand and reason. Conditions such as dementia and Alzheimer's disease lead to progressive intellectual decline, confusion, and disorientation. Written text used to label or explain interfaces should use easy-to-understand, common words, and direct wording. Where the intended user group includes users of low literacy, self-explanatory pictograms should be used, whenever possible, in addition to text.
c) Memory. Memory relates to specific mental functions of registering and storing information and retrieving it, as needed. Failing memory affects people’s ability to recall and learn things and may also lead to people being confused. Memory impairment can lead to a hazard if an uncompleted task results in a dangerous situation, such as the gas supply turned on, but not ignited. Design needs to ensure that systems are “fail-safe.”
d) Language. Language and literacy are the specific mental functions of recognizing and using signs, symbols, and other components of a language. Aging may affect a person’s language ability. When people have a stroke, for example, their language ability may be affected. They may be able to think in the same manner but be unable to express their thoughts in words. People of all ages with dyslexia have difficulties in reading and writing. People with language impairment may be at risk if they are unable to comprehend written warnings or significant instructions.

Annotated Bibliography can be viewed at: https://www.cpsc.gov/s3fs-public/Annotated_Bibliography.pdf?FHaLb3lSrsc1QGRThcpH8998uWUyx4kv