「医療事故対策適合品」マークについてお伺いします

業界では、医療事故防止対策が講じられた医療用具について、医療機関が容易に確認でき、使用上の混乱を防止することを目的として、自主的な適合マーク（医療事故対策適合マーク）を設定しています

【参考資料（８頁）を参照下さい】

質問３-７　「医療事故対策適合品」マークをご存知でしたか？

① □知っている
② □マークを見たことはあるが、医療事故対策適合品マークであることは知らなかった
③ □知らなかった

質問３-８　質問３-７で、①もしくは②とお答えの方にお伺いします。
何で知りましたか？（何でマークを見たことがありますか）
（複数回答可）

① □企業担当者からの情報提供
② □製品カタログ
③ □製品の箱・包装
④ □その他（　　）

質問３-９　「医療事故対策適合品」マークは製品を選定する上で役立つと思われますか？

① □役立つ
② □どちらとも言えない
③ □役立たない

②、③とお答えの方は、理由をお聞かせ願います。

質問３-１０　医療用具（機器）に関しては、企業によって規格が統一されていないものがあったり、企業ごとに取扱い方法が違ったり、同じ用途であっても企業ごとに名称が異なっているもの等があります。また、各企業が個別に医療機関の要望に応じて製品開発・改良をしているケースもあり、それらがヒヤリ・ハットの原因となっているとの指摘もございます。

そこで、実際にそのような経験があるかお伺いします。

① □経験がある　⇒　質問３-１１をお答え願います
② □経験はない

質問３-１１　質問３-１０で経験があるとお答えの方にお伺いします。
具体的どんな事例があり、どのように対処していますか？
（可能な限り製品名、製造業者がわかりましたらご記入願います）

【例】○○社製の製品名△△は、包装に表示してある名称が、他の製品と紛らわしく間違えそうになるので、院内で自作ラベルを貼付している

その他、ご意見・ご要望がございましたら、ご自由に記入願います。

ご協力ありがとうございました。

参考資料

「医療事故対策適合品」マーク

医療事故防止対策推進のため策定された基準(厚生労働省)への適合が容易に確認できるよう、業界として自主的な基準適合マークを設定しました

対象製品　　：医療事故防止対策のために制定された厚生労働省基準に適合する医療用具

表示場所　　：包装袋・箱及びパンフレット

表示製品の維持・管理：日本医療器材工業会(医器工)

医療機器企業における情報の収集と提供に関するアンケート様式（対象：医療機器企業）

医療機器企業における情報の収集と提供に関するアンケート

昨年 10 月よりクラスⅢ・Ⅳの医療用具について医療用具ＧＰＭＳＰが施行されており、また、今回の薬事法改正においては市販後安全管理が許可要件及び遵守事項となります。 今後、企業における情報提供と収集について体制を整備することが益々重要になってまいります。 今回、厚生科学研究の一環として医療機器企業（日本画像医療システム工業会、日本医用機器工業会、日本医療器材工業会傘下企業）の実態調査をおこなうことになりました。

つきましては、御社の市販後調査責任者または市販後調査部門等へご回送の上、１２月　２０　日迄にご回答いただきたくお願い申し上げます。複数の団体に所属する企業は、データ整理の都合上、同一の回答を各事務局までご回答ください。

なお、本アンケートの結果、企業の個別データを公表したり、行政などへ報告するものではございません。

回答送り先：　⇒　ＦＡＸ：各工業会宛

御社名：　　担当者：

連絡先ＴＥＬ：

以下の質問について、該当する番号に○を付けてください。

○会社概要について

１）御社の従業員数はどのくらいですか（医療用具部門及び医薬品部門）
　① 1000 人以上　② 500～999 人　③ 100～499 人　④ 50～99 人　⑤ 50 人未満

２）御社の取扱い製品は
　① 医療用具のみ　② 医療用具と医薬品の両方　③ その他（賛助会員等）

３）御社の取扱い医療用具のクラスは？（該当するクラスは全て記載してください）
　①　クラスⅣ　② クラスⅢ　③ クラスⅡ　④ クラスⅠ　⑤ 生物由来製品

○医療用具ＧＰＭＳＰへの社内体制整備について

４）医療用具ＧＰＭＳＰが平成 13 年 10 月 1 日から施行されたことを知っていますか
　① 知っている　② 知らなかった

５）御社内で市販後調査責任者は決めましたか
　① 決めた（日付：　　）　② 未だ、決めていない

６）市販後調査責任者の所属部署は？
　①市販後調査　②薬事　③品質保証　④学術　⑤事業本部　⑥営業　⑤その他（具体的に　　）

７）市販後調査責任者の役職は？
　①取締役クラス　②執行役員・事業部長クラス　③部長クラス　④課長クラス　⑤係長クラス　⑥その他

８）市販後調査責任者は、責任者の業務について十分に認知していますか？
　① 当然、認知している　② 部下に任せてある　③ まだ、責任者を決めていない

９）　御社の医療用具を担当する市販後調査担当者の人員数は？
　① 専任者数（　　人）　② 兼務者数（　　人）

１０）市販後の情報収集や分析、報告などの体制の整備状況は？
　① 整備した　② 整備したが不十分（理由：　　）　③ まだ不十分

１１）市販後調査業務に関する文書は作成しましたか
　① 手順書を作成した（日付：　　）
　② 手順書は作成していないが、何らかの文書を作成した（日付：　　）
　③ まだ、作成していない

１２）市販後調査業務について経営者、役員などへの報告は行いましたか
　①　体制及び内容等について議論した　② 簡単な報告をした　③ 全くない

○不具合報告等について

１３）（過去５年間）御社では不具合報告、研究報告または外国における措置報告を行ったことがありますか？

① 不具合報告あり ② 研究報告あり ③ 外国における措置報告あり ④ ない

１４） 報告することを最終的に決定する方はどなたですか？

① 社長 ② 取締役・執行役員 ③ 市販後調査部門長（市販後調査責任者含む）

④ 薬事・品質保証部長 ⑤ 製造部門長 ⑥ 営業部門長 ⑦ その他（ ）

１５）御社では回収報告はどの部署が担当していますか

①市販後調査 ②薬事 ③品質保証 ④学術 ⑤事業本部 ⑥営業 ⑤その他（具体的に ）

１６） 回収を最終的に決定する方はどなたですか？

① 社長 ② 取締役・執行役員 ③ 市販後調査部門長（市販後調査責任者含む）

④ 薬事・品質保証部長 ⑤ 製造部門長 ⑥ 営業部門長 ⑦ その他（ ）

○医療機関からの苦情の社内体制について

１７） 苦情（医療機関等からの品質情報）は営業所等からまず社内のどの部門に報告されますか？

① 市販後調査部門 ② 品質保証部門 ③ 薬事部門 ④ 製造部門 ⑤ 事業本部 ⑥ 営業部門

⑦ その他（ ）

１８） 市販後調査部門及び品質保証部門の苦情の把握について？

① 市販後調査部門及び品質保証部門は全ての苦情を把握している

② 市販後調査部門は全ての苦情を把握しているが、品質保証部門は全ての情報は把握していない

③ 品質保証部門は全ての苦情を把握しているが、市販後調査部門は全ての情報は把握していない

④ 市販後調査部門及び品質保証部門は一部情報のみ

⑤ 市販後調査部門及び品質保証部門は全く苦情を把握していない

１９） 苦情情報の中にある不具合報告等の検討が必要な事象についての社内情報は市販後調査部門にどのように報 告されていますか？

① 市販後調査部門に全て報告される

② 市販後調査部門には不具合報告等を行う事象のみ報告される

③ 市販後調査部門へは報告していない

２０） 医療機関等への苦情報告の回答（対応）はどの部門が最終決定していますか？

① 市販後調査部門 ② 品質保証部門 ③ 薬事部門 ④ 製造部門 ⑤ 事業本部 ⑥ 営業部門

⑦ その他（ ）

２１）医療機関からの製品改良の要望や苦情は月平均いくつぐらいありますか

① ほとんどない ②１０件以内 ③ １０－５０件 ④５０－１００件 ⑤１００件以上

２２）製品改良や苦情等に個別に対応したために他の医療機関で新しい事故に繋がるという指摘もあります。
また、自社単独では対応できないので、業界全体で対応したいという意見もあります。

① そういうケースはない。 ②業界全体で対応すべきケースもある。

具体的なケースがあったら、下記に記入してください。

○教育訓練、記録の保存、自己点検について

２３）営業担当者にＧＰＭＳＰについての研修を実施していますか

①実施している（年　　回）　②計画している実施がしていない　③計画していない

２４）ＧＰＭＳＰ関連業務の記録を作成し保存していますか

①業務全部の記録をとり保存している　②一部について保存している　③全くしていない

２５）ＧＰＭＳＰに関する自己点検を実施しましたか

①実施した（　　回）　②実施の計画をしている（予定時期：　　年　　月）　③ 計画していない

○薬事法改正について（詳細は現在決定しておりませんが、参考資料としたくご回答願います。）

２６）今回の薬事法改正により市販後の安全管理が強化されることを知っていますか？

①　知っている　②　知らなかった

２７）製造販売業者において、総括製造販売責任者、安全管理責任者及び品質保証責任者の三役が設けられることを知っていますか？

①　知っている　②　知らなかった

２８）総括製造販売責任者を担当される方の担当・所属は？（回答可能な場合のみで結構です。）

①　薬事・品質保証　②　製造部門　③　営業部門　④　総務部門　⑤　学術部門　⑥　その他（　　）

２９）総括製造販売責任者を担当される方の役職は？（回答可能な場合のみで結構です。）

①取締役クラス以上　②執行役員・事業部長クラス　③部長クラス　④課長クラス　⑤その他（　　）

３０）安全管理責任者を担当される方は？

①　市販後調査責任者　②　市販後調査責任者の上位者　③　市販後調査責任者の下位者

３１）生物由来製品及び特定生物由来製品の指定が告示される事をご存じですか？

①　知っている　②　知らなかった

３２）該当品目を製造する場合、生物由来製品製造管理者を設置しなければならないことをご存じですか？

①　知っている　②　知らなかった

３３）上記設問以外でご意見等がございましたら、お願いいたします。

以上、ご協力ありがとうございました。

このアンケート内容等で質問等がありましたら、以下の３名にお尋ね下さい。

山本章博：医療器材工業会（電話：０３－５２１２－３７２１）
浦富敬輔：J.M.S　（０８２－２４３－５８０６）
泉孝吉：シンコアジャパン（０３－５８１７－０３３９）

Guidance for Industry and FDA Premarket and Design Control Reviewers

Medical Device Use-Safety:

Incorporating Human Factors Engineering into Risk Management

Guidance for Industry and FDA Premarket and Design Control Reviewers

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

Document issued on July 18, 2000

This document replaces the draft guidance document of August 3, 1999, entitled *Device Use Safety: Incorporating Human Factors in Risk Management*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to: Ron Kaye or Jay Crowley at 1350 Piccard Dr. (HFZ 230), Rockville, MD 20850. Comments may not be acted on by the Agency until the document is revised or updated. For questions regarding the use or interpretation of this guidance contact Ron Kaye or Jay Crowley at (301) 443-2436 or by electronic mail at: HFSO@cdrh.fda.gov.

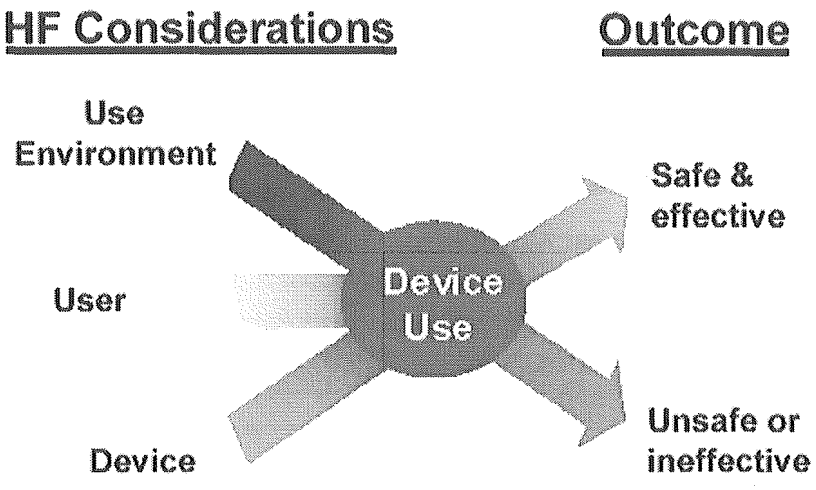
Additional Copies:

Additional copies can be obtained from the Center for Devices and Radiological Health's (CDRH) World Wide Web site at http://www.fda.gov/cdrh/HumanFactors.html or CDRH's Facts-on-Demand at 1-800-899-0381 or 301-827-0111 (specify number 1497 when prompted for the document shelf number).

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

Identifying, Understanding, and Addressing Use-Related Hazards

Authors: Ron Kaye
Jay Crowley



Center for Devices and Radiological Health
Office of Health and Industry Programs
Division of Device User Programs and Systems Analysis

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Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

1.0 Introduction

This guidance[1] describes how hazards related to medical device use should be addressed during device development as part of the risk management process. Potential use-related hazards are best identified and addressed using *human factors engineering* (HFE)[2]. The process of incorporating these approaches in the risk management processes is explained. Documenting these efforts can demonstrate that the device manufacturer has undertaken efforts to control use-related hazards. The goal is to minimize use-related hazards, assure that intended users are able to use medical devices safely and effectively throughout the product life cycle, and to facilitate review of new device submissions and design control documentation.

Addressing use-related hazards should be undertaken within the context of a thorough understanding of how a device will be used. Essential components of this understanding include:

- Device users, (e.g., patient, family member, physician, nurse, professional caregiver)
- Typical and atypical device use,
- Device characteristics,
- Characteristics of the environments in which the device will be used, and
- The interaction between users, devices, and use environments.

Following a thorough understanding of device use, specific ways that devices could be used that are likely to result in hazards should be identified and investigated through analysis and testing. In addition to investigating known or suspected problems with device use, testing prototype devices with users can identify ways of using devices that could be hazard-related that were not anticipated. This is important because it is extremely difficult to identify all significant device use problems in advance.

After use-related hazards are understood, the hazards are mitigated or controlled by modifying the device user interface (e.g., control or display characteristics, logic of operation, labeling) or the abilities of users to use the device (e.g., training, limiting use to qualified users). The field of

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[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] The term Human Factors Engineering and its acronym (HFE) are used extensively in this document. On occasion the term Human Factors (HF) is also used. The two terms distinguish between application (HFE), and the scientific principles and academic research that provides the basis for it (HF).

human factors provides a variety of useful approaches to help identify, understand, and address use-related problems.

This guidance does not focus on any specific kind of medical device, but applies to all medical devices and accessories that involve interaction with users (e.g., thought, perception, decision-making, and manipulation with hands). It is intended for medical device manufacturers, the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) reviewers of pre-market submissions and design controls, and as a general reference for post-market surveillance activities associated with use-related hazards. It is assumed that readers have some understanding of design controls, risk management and HFE. Some readers might find it helpful to review references 10, 16, 19, 28 and 33 listed in Section 7.0.

1.1 Use-Related Hazards

A *hazard* is a potential source of harm. Hazards arise in the use of medical devices due to the inherent risk of medical treatment, from device failures (or malfunctions), and from device use. Hazards resulting from medical devices impact patients, family members, and professional healthcare providers. This document addresses hazards resulting from interactions between users and devices. It does not focus on hazards inherent to medical treatment or caused by device failure.

Hazards associated with device use are a common and serious problem[3]. Evidence from researchers (Cooper, Leape, and others) suggests that the frequency and consequence of hazards resulting from medical device use might far exceed those arising from device failures. Therefore, it is essential to ensure safe and effective *device use* if all hazards are to be controlled effectively. An Institute of Medicine report (reference 19, section 7.0) released in November 1999 estimates that as many as 98,000 people die in any given year from medical errors that occur in hospitals, which is more than the number who die from motor vehicle accidents, breast cancer, or AIDS. Though many of these errors are not related directly to the use of medical devices, some are, and the importance of incorporating HFE principles into device design to reduce device related medical errors was highlighted.

Medical device designers are interested in developing highly reliable devices. To do this, they consider the possibilities of hazards arising from failures of the device and its components. These kinds of failures can be identified through conventional reliability analyses. Designers need a more complete and accurate understanding of device use and approaches to include consideration of unique limitations and failure modes of device users as critical components of the device-user system. Relatively few user actions that can cause the device to fail other than the most apparent (e.g., fire or explosion), or well-known instances of use problems are considered by designers. This limitation during device design increases the likelihood of unexpected use scenarios (see Section 1.2) and use-related hazards for users and patients.

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3 Incidents of death or serious injury resulting from how a device is used, "user error" are reportable events under FDA's Medical Device Reporting (MDR) program.

Hazards typically considered in risk analysis include:

- Chemical hazards (e.g., toxic chemicals),
- Mechanical hazards (e.g., kinetic or potential energy from a moving object),
- Thermal hazards (e.g., high temperature components),
- Electrical hazards (e.g., electrical shock, electromagnetic interference (EMI)),
- Radiation hazards (e.g., ionizing and non-ionizing), and
- Biological hazards (e.g., allergic reactions, bio-incompatibility, and infection).

These hazards most often result from instances of device or component failure that are not dependent on *how* the user interacts with the device, unless the way a device is used causes it to fail. In addition to the hazards mentioned above, there are certain kinds of hazards for medical devices that often result from device use. Hazards caused specifically by how a device is used are referred to in this document as *use-related hazards* (Figure 1). These include misdiagnoses (e.g., failure to identify disease or measure physiological parameters accurately), failure to recognize and act on information from monitoring devices, and improper treatment (e.g., ineffective or dangerous therapy).

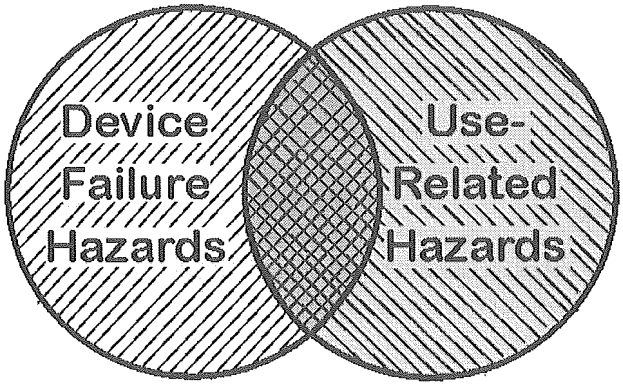

Figure 1. Device Failure Hazards and Use-Related Hazards

Use-related hazards occur for one or more of the following reasons:

- Devices are used in ways that were not anticipated,
- Devices are used in ways that were anticipated, but inadequately controlled for,
- Device use requires physical, perceptual, or cognitive abilities that exceed those of the user,
- Device use is inconsistent with user's expectations or intuition about device operation,
- The use environment (see Section 3.2.1) effects device operation and this effect is not understood by the user, or
- The user's physical, perceptual, or cognitive capacities are exceeded when using the device *in a particular environment.*

1.2 Use Scenarios Resulting in Hazards

Use-related hazards often occur as a result of a sequence or chain of events involving device use. For instance, a user might not understand the calibration procedure required for a home-testing device. The user could calibrate it incorrectly, use the device and then act on the results it provides. Although the user's technique following the calibration might be appropriate, inaccurate results are obtained because the device was not calibrated accurately. Decisions involving a patient's health could be made on these inaccurate results. This use scenario involves the failure to understand the procedure, the incorrect calibration and the subsequent use of the device and the inaccurate results. In this example, a hazard occurred due to how the device was used. In this document, the concept of "use *scenarios* that result in hazards" refers to problematic use of the device in its entirety. An alternate terminology could be "failures" or "faults" in which scenarios resulting in hazards can be viewed essentially as failures or faults that occur during the interaction between the user and the device.

2.0 Risk Management

The guidance presented in this document describes how HFE approaches can be integrated into Risk Management to help identify, understand, control, and prevent failures that can result in hazards when people use medical devices. Risk management is a systematic application of policies, procedures, and practices to the analysis, evaluation, and control of risks. It is a key component of quality management systems, and is a central requirement of the implementation of Design Controls in the Quality Systems Regulation. Risk management involves the identification and description of hazards and how they could occur, their expected consequences, and estimations or assessments of their relative likelihood. The estimation of risk for a given hazard is a function of the relative likelihood of its occurrence and the severity of harm resulting from its consequences. Following the estimations of risk, risk management focuses on controlling or mitigating the risks.

Estimates of the risk of use-related hazards can be difficult to make. They can also be misleading. Problems with device use that could result in hazards are often difficult to anticipate due to the many ways and conditions under which users interact with devices. This causes some use-related hazards to not be included in risk management. Also, when they are anticipated, their true likelihood is difficult to estimate analytically. Even use-studies can be misleading measures of likelihood because the rate of use-related hazards observed is likely to be less than in actual use (Section 5.3.1). From a perspective of human factors engineering (HFE) in medical device use, the risk associated with low-likelihood use-related hazards could be misleading because users are often less able to react appropriately to situations that occur infrequently. Therefore, it is important to carefully consider the severity of harm in the management of device use risks.

Thorough consideration of use-related hazards in risk management processes should include the following tasks:

1. Identify and describe use-related hazards through analysis of existing information (see Section 5.3),
2. Apply empirical approaches (see Section 5.5), using representative device users, to identify and describe hazards that do not lend themselves to identification or understanding through analytic approaches,
3. Estimate the *risk* of each use-related hazard scenario,
4. Develop strategies and controls to reduce the likelihood or mitigate the consequences of use-related hazard scenarios,
5. Select and implement control strategies,
6. Ensure controls are appropriate and effective in reducing risk,
7. Determine if new hazards have been introduced as a result of implementing control strategies,
8. Verify that functional and operational requirements are met, and
9. Validate safe and effective device use.

This process will be discussed in Section 5 in conjunction with HFE approaches.

3.0 Human Factors

To understand use-related hazards, it is necessary to have an accurate and complete understanding of *how* a device will be used. Understanding and optimizing how people use and interact with technology is the subject of human factors engineering (HFE). HFE considerations important to the development of medical devices include device technology, the users, environment in which the technology will be used, how dangerous device use is, and how critical the device is for patient care. An introduction to human factors (HF) considerations for medical devices can be found in the FDA document, *Do It By Design.*

3.1 HF in the Use of Medical Devices: Overall Considerations

Several general HFE concepts should be considered before proceeding with a discussion of HFE approaches in the context of risk management.

3.1.1 User Preference does not Necessarily Indicate Safety and Effectiveness

A focus solely on user preference in the development of a design does not assure that safety and effectiveness have been adequately considered. Users generally prefer devices that are easy and satisfying to use and are aesthetically pleasing. Too often, device manufacturers and users emphasize these device characteristics at the expense of safety and effectiveness.

Although design features that assure safety and effectiveness could decrease user preference in some instances, they are necessary nevertheless. For instance, safety-related user interface

design features such as shields over critical controls, mechanical or software-based interlocks, or verification requirements could slow down the use of a device or effect its aesthetics.

3.1.2 Use Scenarios with a Low Frequency of Occurrence that Result in Hazards Require Careful Consideration

Rare or unusual use scenarios resulting in hazards with serious consequences often prove to be the greatest threat to safe and effective medical device use after a device becomes available for general use. Users are often not prepared for infrequent, unexpected use scenarios because they are often not dealt with adequately in device design, training, or operating instructions. Infrequent but dangerous use scenarios are often difficult to identify, which underscores the necessity for careful application of the analytic and empirical approaches (Section 5.5.) early in, and throughout the design process.

3.1.3 Direct Inspection or Paper-based Analyses of a Device Might not Identify all Hazards

Use-related hazards involve interactions among aspects of the use environment, user, and the device (see Figure 2). Many hazards involving unsafe or ineffective device use can be identified through careful inspection and analyses of existing information pertaining to the use of similar devices. Some use scenarios are rare. Some involve unusual or unexpected ways of interacting with a device, or involve use in unusual circumstances. Use scenarios of this kind are difficult to identify by using *only* analytic approaches (see Section 5.4). Therefore, it is important to obtain information from the intended user population and test devices under actual or simulated use conditions (see Section 5.5).

3.2 Human Factors Considerations for the Device-User System

Safe, effective, or unsafe, ineffective use of medical devices is determined by the following major components of the device-user system: (1) Use Environments, (2) User Characteristics, and (3) Device User Interface Characteristics. This interaction and its possible results is depicted graphically in Figure 2.

3.2.1 Medical Device Use Environments

Use environments for medical devices can vary widely and can have major impacts on device use and use-related hazards. The amount of thinking and concentration a person exerts while using a device is called *mental workload.* The mental workload imposed on users by the environment in which they use devices can exceed their abilities to use devices properly. For instance, in an operating room, there could be too many alarms on different devices for an anesthetist to be able to identify the source of any single alarm. Mental workload is often used synonymously with mental "stress". There can be a physical component to workload associated with medical device use (*physical workload*) that also adds to the stress experienced by the user. Under high stress levels, the user is distracted and will have less time to make decisions, consider multiple device outputs, follow complex operating logic, or physically manipulate device components. Devices that can be used safely under conditions of low stress (i.e., low workload) could be difficult or dangerous to use under conditions of high stress.

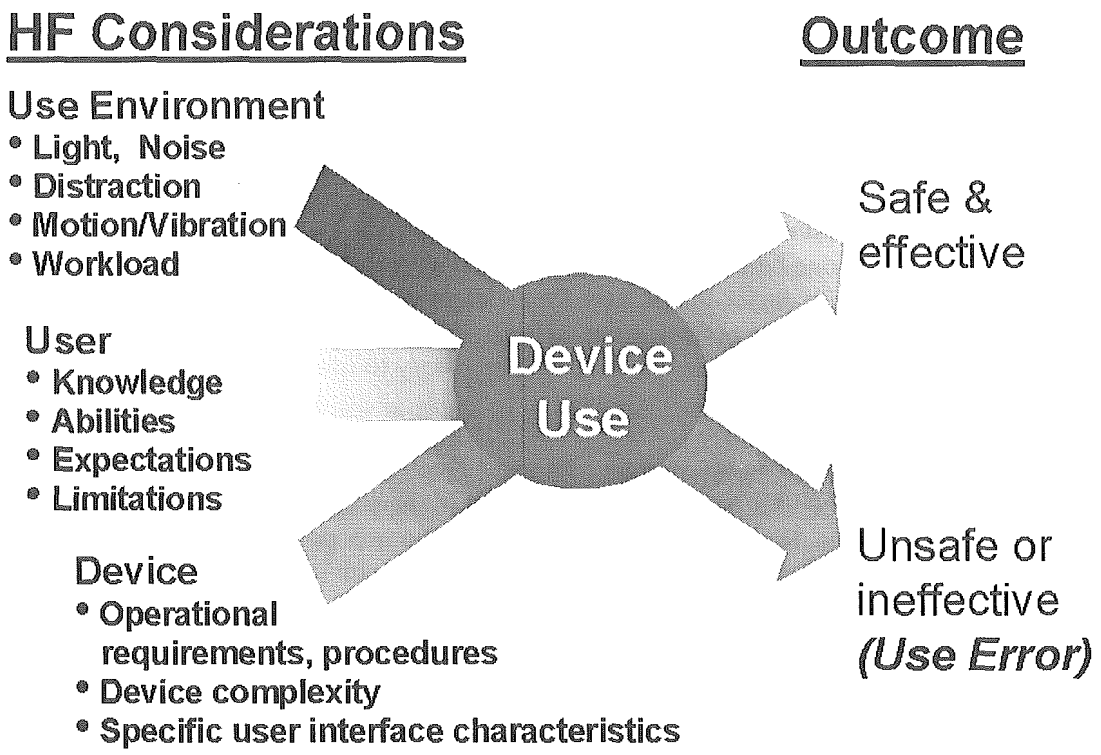

Figure 2. Interaction of HF Considerations Results in: (1) Safe and Effective Use, or (2) Unsafe or Ineffective Use

Use environments can also limit the effectiveness of visual and auditory displays (lighted indicators, auditory alarms and other signals) if they are not designed appropriately. If the users cannot understand critically important information, errors are likely. For devices used in noisy environments, the user might not be able to notice alarms if they are not sufficiently loud or distinctive. When multiple alarms occur for different devices or on the same device, the user could fail to notice them or to make important distinctions among them. Similarly, motion and vibration can affect the degree to which people are able to perform fine physical manipulations such as typing on the keyboard portion of a medical device. Motion and vibration can also affect the ability of users to read displayed information.

Important considerations for displays (including visual alarm indicators) and device labeling include ambient light levels, viewing angles, and the presence of other devices in the use environment. If the device will be used in low light conditions, display scales or device status indicators might not be clear to the user. Some scales will be read inaccurately when viewed from an angle due to parallax or because part of the display is blocked. Other display information can be lost under brightly-lit conditions due to insufficient contrast. When certain types of equipment are used in close proximity with other devices, it could be difficult for users to associate visual displays and auditory signals with the corresponding equipment. With too much distraction, important information could be missed.

3.2.2 Medical Device Users

A device that is easy for one person to use safely and effectively might present problems for another person. Similarly, a device that is easy for a certain group of users to use safely and effectively could be difficult for another group. Users need devices that they can use safely and effectively. To assure that these needs are met, it is necessary to understand abilities and limitations of the intended users.

It is convenient to refer to the group of users who use a given device as its *user population.* It is then helpful to describe the user population with respect to the abilities and limitations of its members. For any device, the abilities and limitations of the user population might be relatively uniform. On the other hand, the user population might contain sub-components that have significantly different abilities. Examples are young and old users, or home users and professional healthcare providers. Fatigue, stress, medication, or other temporary mental or physical conditions can temporarily effect ability levels of device users.

Important characteristics of user populations include:

- General health and mental state (stressed, relaxed, rested, tired, affected by medication or disease) when using the device,
- Physical size and strength,
- Sensory capabilities (vision, hearing, touch),
- Coordination (manual dexterity),
- Cognitive ability and memory,
- Knowledge about device operation and the associated medical condition,
- Previous experience with devices (particularly similar devices or user interfaces),
- Expectations about how a device will operate,
- Motivation, and
- Ability to adapt to adverse circumstances.

For example, older users might have difficulty remembering specific sequences for operation, using their hands to do tasks that require fine manipulation, or sensing device outputs such as auditory alarm sounds or information displayed visually. Highly trained and motivated users (i.e., developers, sales personnel, participants in previous use-studies, expert users) are often much more capable of operating complex devices than typical users. They are also likely to adapt better to unexpected or variable circumstances. *Motivated and adaptable users are more likely to take actions to compensate for problems with the design of a device.* But, if the same