Design Considerations for Devices Intended for Home Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on November 24, 2014.

This document supersedes "Design Considerations for Devices Intended for Home Use" issued August 5, 2014.

This document provides clarification about the use of standards applicable to supply mains (section VII-E-1) and electromagnetic compatibility (section VII-E-6).

This document was updated August 8, 2016 to correct the transition date for ANSI/AAMI/IEC 60601-1-2.

For questions about this document regarding CDRH-regulated devices, contact Tosia Hazlett at 301-796-6119 or by e-mail at Tosia.Hazlett@fda.hhs.gov; or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number FDA-2012-D-1161. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1750 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD, 20993, or by calling 1-800-835-4709 or240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

GRZAN

Table of Contents

I. Introduction 1
II. Background 2
III. Scope 3
IV. Definitions 3
V. Environmental Considerations 4
A. Location 4
B. Contaminants 4
C. Water Supply 5
D. Temperature 5
E. Dampness and Humidity 5
F. Atmospheric Pressure Changes 5
G. Air Flow 5
H. Travel and International Use 5
I. Fluid Exposure 6
J. Storage 6
VI. User Considerations 6
A. Physical 7
B. Sensory/Perceptual 7
C. Cognitive 7
D. Emotional 7
VII. Design Considerations 7
A. Lock-out Mechanisms 9
B. Maintenance 9
C. Calibration 9
D. Mechanical 9
E. Electrical Issues 10
1. Supply Mains 10
2. Internal Electrical Power Source 10
3. Permanently Installed Devices 11
4. Outlets and Adapters 11
5. Power Outages 11
6. Electromagnetic Compatibility (EMC) 11
7. Wireless Technology 12
8. Alarm Systems 13
VIII. Human Factors 13
A. User Training and Certification 14
IX. Labeling 15
A. Handling the Device in an Emergency 16
B. Disposal 16
C. Hygienic Maintenance 16
X. Postmarket Considerations 17
A. Customer Service 17
B. Medical Device Reporting 17
XI. Conclusion 18
Appendix 1: List of References 19
Appendix 2: Additional Resources 23

Design Considerations for Devices Intended for Home Use

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA'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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This guidance is intended to assist manufacturers in designing and developing home use devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Devices used in the home or other non-clinical environments are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This guidance identifies several factors that manufacturers of home use devices should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

Throughout this guidance the term "you" refers to manufacturers as defined in 21 CFR 820.3(o). For convenience the definition is restated here: Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

For additional information or questions about the FDA-recognized standards referenced in this guidance document, please contact CDRH's Standards Program.[1]

[1] Web site addresses for all hyperlinked material in this guidance document can be found in Appendix 1: List of References.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

For a variety of reasons, use of devices outside professional healthcare facilities is on the rise. First, the United States population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, they are also associated with unique risks. These risks result from interactions among the user, the use environment, and the device, and can greatly affect user and patient safety.

Due to the increasing prevalence of home use devices, minimizing the risks they posed can greatly improve the public health. With this in mind, FDA developed the following considerations that can help manufacturers reduce or minimize common risks posed by home use devices. These risks are best addressed at the design stage. Failure to adequately consider potentially hazardous situations during the design of home use devices may result in inappropriate use, use error, or incompatibilities between the use environment, the user, and the device. This could cause the device to malfunction, possibly contributing to death or serious injury.

When developing a new home use device, you should take the considerations in this guidance document into account and, to the extent possible, reduce or minimize risk to acceptable levels through device design (sometimes referred to as “designing risk out of the device”). For any premarket submission to FDA, you should ensure that the device is suitable for home use and provide in the submission data that demonstrate how you considered and addressed the relevant hazards and risks, such as the ones mentioned in this guidance document. This can help FDA determine whether applicable safety and effectiveness requirements have been met.

Following the recommendations in this guidance can help you develop a device that is best suited to the home use environment, which should decrease the occurrence of adverse events by minimizing the risks to patient and user safety.

III. Scope

This guidance provides recommendations for minimizing the risks associated with home use devices by considering the user, the use environment, the device or system, human factors, and labeling. This guidance applies to both prescription and over-the-counter (OTC) medical devices, including any class I, II, or III devices intended for home use.[2] The recommendations in this document apply whenever you are designing or developing a home use device, as defined in Section IV of this document. This guidance also provides recommendations regarding postmarket considerations. These recommendations should also be considered when you are designing a device that is likely to be used in the home, even if the device is not intended solely for home use. Review this guidance for the factors that may be applicable to your device type.

IV. Definitions

The following definitions apply for purposes of this guidance document (Please note the definitions below are not intended for use outside this guidance document.):

A **home use device** is a medical device labeled for use in any environment outside a professional healthcare facility. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes. If the device is intended to be used in professional healthcare facilities and also outside those facilities, it meets this definition.

A **user** is a lay person such as a patient (care recipient), caregiver, or family member who directly operates or handles a device or provides assistance to the patient in using the device.

Lay is a nonprofessional or professional person without relevant specialized training (e.g., lay operator, lay responsible organization).

A **qualified healthcare professional** is a licensed or non-licensed healthcare professional with sufficient skills and experience with the use of a device to aid or train someone to use and maintain the device.

A **professional healthcare facility** is either –

(1) any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities; or
(2) a clinical laboratory.

[2] Sponsors of home use in vitro diagnostic tests to diagnose HIV are advised to contact CBER to discuss issues related to those tests.

A **clinical laboratory**[3] is a facility that (1) performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings; and (2) has been certified to perform such testing under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) in accordance with 42 CFR part 493, or has met equivalent requirements as determined by the Center for Medicare and Medicaid Services in accordance with those provisions.

V. Environmental Considerations

When designing a home use device, you should account for the range of environments in which it might be used and the applicable environmental conditions noted below. These conditions should be addressed with all devices that will be used in a home or non-clinical setting. The labeling of the device should include warnings against using the device in environmental conditions that would raise safety or effectiveness concerns; however, managing risk by device design is preferable to managing risk through labeling. FDA recommends that, in your premarket submission for your device design, you include a summary of the efforts you took to account for the following considerations, if they pertain to the intended use environment for your device. If some of the items do not pertain to the type of equipment you are designing, then you will not have to consider them in your device design.

A. Location

Home use device design should permit the device to operate in its intended use location(s) (e.g., urban/suburban/rural, school/office/retail environments, and train/plane/car). Consider where the device will be used and how these locations would affect the user and the device's ability to function and operate safely and effectively. For example, older buildings can have outlets that do not meet current electrical code or a limited number of outlets. See section VII-E-4 for further guidance. Home use device design should take into account the characteristics of the environment in which the device is intended to be used and stored. Your device design should permit the device to move in and out of the environment, as well as move from place to place within the environment (e.g., from room to room). Crowded use environments can interfere with device use and movement, present tripping hazards, or increase the likelihood that device parts will bump into or get tangled with objects in the environment. In addition, the device may not operate in a certain physical location if it relies on a wireless signal that may be unavailable.

B. Contaminants

Home use device design should permit the device to be operated in a non-sterile environment. The risk that the device could be affected by contaminants such as vermin, pets, tobacco smoke, and household chemicals should be mitigated as much as possible by

[3] See also 21 CFR 610.40(f).

designing the device to minimize the ingress of fluids, solids, and airborne particles that would affect device operation.

C. Water Supply

You should specify the type of water that is required to properly operate the home use device, e.g., well water or treated water. For additional information on keeping water safe, see the Centers for Disease Control and Prevention's Web site on emergency preparedness and response.

D. Temperature

Home use devices should be designed for the anticipated temperature range in the intended use environment, especially those that are portable and might be exposed to fluctuations and extremes in temperature.

E. Dampness and Humidity

Home use devices should be designed for the variability in humidity levels that are expected to be present in the intended use environment, especially those that are portable and might be exposed to fluctuations and extremes in humidity.

F. Atmospheric Pressure Changes

Home use devices should be designed to operate properly within a range of atmospheric pressures such as lower pressures that occur in the mountains and during air travel.

G. Air Flow

Home use device design should ensure that air flow will be adequate for proper device operation.

H. Travel and International Use

Design of portable home use devices should anticipate that users will travel—internationally as well as domestically—with their medical devices and may use a variety of transportation modes as they travel. For electrical home use devices, you should provide information in the labeling on the adaptability of the device to the electrical supplies and voltage rates of other countries, and whether an adapter may be used to operate the device. Given that electrical power varies by country, electrical converters and battery back-up may be necessary to operate the device in a country outside the United States. Labeling should also include information on how users can get help if the device malfunctions while they are away from home.

In designing the device, you should also anticipate that users, including users of any body-worn medical devices, may be required to pass through security screening systems while traveling. These systems continue to evolve but currently include backscatter X-ray and millimeter wave technologies. You should consider whether these systems can interfere with the operation of the device. In addition, if users must undergo a security pat-down to avoid the automated screening system, you should consider how the procedure might affect body-worn medical devices, such as a continuous blood glucose sensor. In the instructions for use (IFU), consider referring the user to the Transportation Security Administration (TSA) Web site which includes information about procedures for travel with medical equipment.

I. Fluid Exposure

You should consider what the device can safely tolerate when it is subject to fluid spills or submersion, as well as the amount of fluid that the device can be exposed to without affecting its safe use.

J. Storage

You should provide information to the user about proper storage of the device and its components and accessories. For example, this could include, but is not limited to, keeping the device out of sunlight, keeping it at a proper temperature control, and keeping it dry between uses.

VI. User Considerations

The users of home use devices are different from the health care professionals who typically operate medical devices in a professional health care facility. Home users can have a large range of physical, sensory, and cognitive capabilities and disabilities, and emotional differences that should be considered in your home use device design. If the home use device is not designed for ease of use and understanding, you increase the likelihood of misuse and non-use of the device. Home use devices should be designed to prevent reasonably-foreseeable misuse. You should consider that children or adults might interact with the device in inappropriate ways.

The following personal characteristics can affect device use and should be considered in the design of the device. Note that some home use devices are designed to diagnose or treat medical conditions that can cause functional impairments; therefore, it is important to design those devices to be usable by individuals with impairments. You should account for the following characteristics of your intended users in your device design. If a premarket submission is required, it should identify your intended users and include a summary of the actions you took to account for these characteristics.

A. Physical

You should design for users with a range of physical sizes, mobility, dexterity, coordination, flexibility, strength, and stamina.

B. Sensory/Perceptual

You should design for users with a range of vision and hearing abilities and tactile sensitivities. In your home use device design, you should consider the visibility of the device interface under a variety of ambient lighting conditions, the visibility of any alarm signals and whether they will be differentiated from other sounds in the environment, the types of feedback mechanisms that will operate while the user is interacting with the device, and whether any perceptual issues might affect the user's ability to use the device properly, which could include handling the device and the manner in which it touches the user.

C. Cognitive

You should design for users with a range of abilities to process information and literacy levels, and consider the potential that users might have some type of cognitive impairment that could affect how they interact with the home use device. Consider the amount of experience the users might have with a type of device and with similar devices, and how able and willing they might be to learn and adapt to using a new device.

D. Emotional

You should design for users who may be providing care for a loved one who is unable to use the device unassisted. Whether a person is providing care to others or performing self-care, he or she can be dealing with a new diagnosis or condition along with the need to operate a medical device, which can be overwhelming and cause anxiety for the user.

VII. Design Considerations

The Quality System regulation (QS regulation)[4] describes requirements intended to help ensure that finished medical devices have a reasonable assurance of safety and effectiveness. For example, it requires that you establish and maintain procedures to control the design of the device to ensure that specified design requirements are met. This guidance document provides recommendations on technical issues to consider during the design and development of home use devices. This section outlines certain aspects of design control that are particularly important for home use devices.

Under 21 CFR 820.30 -- Design Controls, a manufacturer must establish procedures to ensure that device design will translate into a device that performs properly according to its

[4] 21 CFR Part 820.

intended use and user needs.[5] Design control requirements of the QS regulation apply to design and development of the device as well as its packaging and labeling (e.g., Instructions for Use), and its cleaning, disinfection, and sterilization procedures. When establishing design controls for home use devices, you should take into account considerations related to device performance and user needs in the home environment, which are discussed in detail below. For more information about creating and implementing design controls, we recommend that you refer to FDA's guidance *Design Control Guidance for Medical Device Manufacturers* (March 11, 1997).

You should consider developing a risk management plan. This risk management plan should describe the process for identifying hazards, estimating and evaluating the known risks, controlling the risks, and monitoring the effectiveness of the controls. In your risk analysis, special attention should be paid to the possible causes of use-related errors and failures, as home use devices are exposed to more hazards than are present in professional health care facilities and present greater potential for harm caused by user error.

Your risk management plan should also include elements to control risk that can enhance the ease of use for the intended user population based on human factors engineering methods (see Section VIII). You should first strive for the highest level of risk control possible by designing risk out of the system to the greatest extent possible. Methods to control risk and to enhance ease of use also include designing the device to reduce or minimize risks, developing protective measures in the device itself (e.g., an automatic shutoff), or providing information for safety. It is important to note that labeling alone generally does not offer sufficient risk control for the home use environment because warning labels, especially lengthy ones, can be ignored by or confusing to the user. Accounting for the considerations described in this document will help mitigate risk and guide device design so that it is appropriate for the intended user and use environment. We recommend that you review ANSI/AAMI/ISO14971:2007/(R) 2010, *Medical devices – Application of risk management to medical devices.*

Software plays a critical role in the operation of some devices. For these devices, you should focus on developing device and software architecture and algorithms for performance, error detection, control, and recovery. When developing a home use device, you should broaden your existing concept development and preliminary testing processes to account for the needs of home users and requirements for straightforward device operation, obvious interface layouts, and appropriate alarm methods. If software upgrades are required, you should consider how this will be performed in the home environment with the lowest risk to the user and least burden on you.

For software in general, we recommend that you review:

- IEC 62304 First edition 2006-05, *Medical device software – Software life cycle processes* and the identical standard ANSI/AAMI/IEC 62304:2006.

[5] See 21 CFR 820.30(g); see also 61 FR 52602 at 52616.

- FDA's guidance *General Principles of Software Validation* (January 11, 2002).
- FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005).

A. Lock-out Mechanisms

FDA recognizes that lockout mechanisms can be used for controlling access to certain device functions, such as preventing the patient from changing settings entered by the health care professional or caregiver. However, the safety of home use devices should not depend solely on such mechanisms. Before using a lock-out mechanism as the only mechanism to reduce or prevent patient harm, you should first rule out other design solutions. However, if a lock-out mechanism is the only mechanism available to reduce or prevent patient harm, it should be used.

B. Maintenance

Home use devices might require routine maintenance for continued optimal performance. We recommend that you minimize the requirements for maintenance to the extent possible. When required, maintenance procedures should be easy to follow, clearly explained, and have a logical flow.

C. Calibration

Home use devices should be designed without the need for calibration, but if that is not possible, the device should be designed to require minimal calibration by the user. Calibration instructions should be step-by-step and preferably provide the user with any feedback necessary to complete the calibration process. This could also include an indication on the device that states that it is calibrated, when it was last calibrated, and when the next calibration is needed.

When the performance of the device depends on the use of calibrators, the traceability of the values assigned to these calibrators should be assured through a quality management system. If the device calibration needs to be done by a trained professional, you should indicate whether the device can remain in the home or has to be calibrated in another location. You should refer to available consensus standards and FDA guidance documents particular to the type of device that you are designing to review specific calibration requirements.

D. Mechanical

Because some home use devices are portable and will be moved around frequently, it is critical to test them to see how they function after impact with the ground or other objects. Devices should have a minimal number of parts that could be detached or fall off and present an inhalation, swallowing, or tripping hazard.

The standard ANSI/AAMI HA60601-1-11:2011 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* includes information on mechanical strength for both transit operable and non-transit operable electrical medical devices. The medical device and its parts, including mounting and other accessories, should have adequate mechanical strength so that they can withstand stress caused by normal use that includes pushing, dropping, rough handling, freefall, vibration, and impact with the ground or another object. If the device will be used while the user is in transit, the device should have adequate mechanical strength and durability to withstand normal transport conditions on trains, road vehicles, cycles, ships, and aircraft. FDA also recommends that you review ASTM D4169-09, *Standard practice for performance testing of shipping containers and systems*, for mechanical strength in the design of medical devices. For portable medical devices that are intended to be used only with a carrying case, the case should be tested along with the device.

E. Electrical Issues

Design of home use devices that use electricity should take into account that some use environments might have unreliable sources of electricity and poor electrical grounding. The General Standard ANSI/AAMI ES60601-1:2012 (edition 3.1), *Medical electrical equipment – Part I: General requirements for basic safety and essential performance* includes information regarding the following electrical issues related to medical devices:

1. Supply Mains

If your device operates from the supply main, you should consider using the applicable specifications of ANSI/AAMI ES60601-1:2012 (Edition 3.1) and ANSI/AAMI HA60601--1--11:2011. The latter specifies voltage ranges over which life-supporting medical devices and medical devices that are not life-supporting should provide their basic safety and essential performance. The following standards have specifications regarding short-term voltage interruptions and specifications regarding long-term interruptions of the supply mains:

ANSI/AAMI/IEC 60601-1-2 Fourth edition 2014-02, *Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*.[6]

2. Internal Electrical Power Source

[6] FDA's recognition of the 2014 version of the IEC 60601-1-2 is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=34000. Please note that the 2014 version of the IEC 60601-1-2 standard includes a transition period through December 31, 2018 as noted in FDA's recognition. You may consider using IEC 60601-1-2:2007 during this transition period. FDA's recognition of the 2007 version of the IEC 60601-1-2 is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=33996.

If device operation depends on an internal electrical power source (e.g., batteries), the instructions for use (IFU) should describe the typical operation time or number of procedures and the typical service life of the power source. If the device uses a rechargeable power source, the IFU should explain whether the device can be used while it is charging. If the internal power source is replaceable, the IFU should explain the replacement process procedure. If a device operates on battery power, you should inform the user how long he or she can expect the device to work on a fully charged battery. To the extent possible, the device should notify the user in advance that the battery will need to be recharged or replaced soon. The design should consider that the user might not routinely recharge the device or might select inexpensive batteries that could otherwise result in suboptimal performance.

3. Permanently Installed Devices

If a device is to be permanently installed in a home, the labeling should include clear information and specifications about proper protective grounding and recommend that the installation should be performed by a qualified professional.

4. Outlets and Adapters

You should inform the user if the device should not share an outlet with another electrical device or be connected to an outlet controlled by a wall switch. You should also consider whether surge protectors, extension cords, or ground fault interrupters are appropriate for use with your device and inform the user accordingly. As some plugs are not compatible with some outlets in the home, your IFU should inform the user about the type of adapter, if any, that can be used and how to use it safely with the device.[7]

5. Power Outages

If a device requires AC power to operate, you should consider providing or identifying back-up power options, such as a battery or generator. You should also provide instructions in the device labeling for emergency contact information in the event of a power outage (e.g., manufacturer, power supply company, or clinical care provider, as appropriate). If the device cannot operate without a backup power supply, this should be noted either on the device or in the warnings section of the IFU. The manufacturer could also identify alternative means of providing the same or similar treatment that does not require using an electrical device. The IFU should disclose the continued device use time or number of procedures available following a loss or failure of the electrical power supply. If you provide a backup power source with your device, your IFU should specify how long the user should expect the device to work on backup power.

6. Electromagnetic Compatibility (EMC)

[7] NOTE: ANSI/AAMI HA 60601-1-11:2011 specifies that equipment intended for home healthcare use a two-pronged plug or be battery powered.

Electromagnetic compatibility (EMC) is the ability of a device to operate properly in the presence of electromagnetic disturbances that are expected to occur in the environments of intended use without introducing excessive electromagnetic disturbances into that environment. FDA recommends that you consider using the FDA-recognized ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02 standard, which describes EMC testing and includes tests for immunity of the device to outside electromagnetic disturbances in the use environment and also for emissions from the device into that environment. If you use ANSI/AAMI/IEC 60601-1-2 Edition 3:2007 during the transition period to Edition 4 that ends December 31, 2018, you should be aware that electromagnetic disturbance in the home healthcare environment can exceed the default test levels for the hospital environment that are specified in Edition 3. You should design your device intended for home use to be immune to disturbance levels that can be expected in the home healthcare environment.[8]

You should provide summary information in your premarket submissions to FDA describing the testing that was performed and how it was conducted, the device functions and modes that were tested, the pass/fail criteria used, reference standards and any deviations or allowances that were taken, any device modification needed to pass the testing, and appropriate labeling. Device manufacturers should consider appropriate levels of testing in accordance with the risks presented by the environments of intended use in addition to the general immunity testing specified in the standards.

You should also note possible sources of disturbance for electrically powered medical devices in the use location(s) that could be near or in contact with other objects that would interfere with their performance, such as large electric motors or amateur radio transmitters, radio and television transmitters, radar, anti-theft systems (including demagnetizers), stereo speakers, cell phone, and radio frequency identification (RFID).

7. Wireless Technology

If a device incorporates radio frequency (RF) wireless technologies, the device description in the premarket submission should contain a complete description of the exact wireless technology used, frequency and frequency band, output power, functions, including any alarm conditions communicated wirelessly, performance, and risk management. Compliance of RF wireless technologies with applicable technology standards and Federal Communications Commission (FCC) rules does not necessarily alleviate home use device safety and effectiveness concerns. Any submission for a device that includes RF wireless technology should address the areas of concern listed in FDA's guidance *Radio Frequency Wireless Technology in Medical Devices* (August 13, 2013). Particular points to address

[8] Although not a requirement, the Agency generally finds testing to the following immunity tests levels acceptable for the home environment based on FDA's experience with home use devices: Electrostatic Discharge (ESD): ± 8 kV contact discharge, ± 15 kV air discharge; Power frequency magnetic fields: 30 A/m at 50 Hz or 60 Hz; Conducted RF: 3 V r.m.s outside industrial, scientific, and medical (ISM) and amateur radio bands between 0.15 MHz and 80 MHz, 6 V r.m.s. in ISM and amateur radio bands between 0.15 MHz and 80 MHz; Radiated RF: 10 V/m, 80 MHz to 2.6 GHz. You may provide justification for testing to alternative levels.

include quality of service needed, data integrity, coexistence, security, and EMC of the wireless signals based on the use of the data intended by the manufacturer.

Due to the increased use of RF wireless technology that operates in shared frequency bands, if applicable, you should carefully address RF wireless coexistence through testing the device with other common applications of RF wireless technology that can be expected to be present in the environment of use. If it can be expected that two or more similar devices will be operating wirelessly in close proximity (e.g., mobile or body worn devices located in a waiting room or the same room of a home), the ability to operate properly under these conditions should also be tested.

8. Alarm Systems

Alarm systems are of particular concern for home use devices because noise and other distractions inside and outside the home can interfere with the users' ability to be made aware of an alarm signal. For example, users can have hearing impairments, including the inability to hear specific frequencies. Device alarm systems with high or medium-priority alarm signals should be designed to be perceived in environments typically found in the home. If the alarm system incorporates wired or wireless connections to other locations, the entire device system should be designed and tested to mitigate risks from loss or degradation of these connections.

Alarm signals may not apply to all devices. If the need for an alarm applies to your device, FDA recommends that you provide alarm signals in at least two of the three following modes: visual, auditory, tactile. This alarm signal could be localized to the area where the device is being operated or in another location, which is known as a distributed alarm system. For example, the alarm could sound in another room or in a remote location where it is being monitored. FDA recommends that you consider using the following standard:

- IEC 60601-1-8 Edition 2.1 2012-11, *Medical electrical equipment; Part 1-8; General requirements for basic safety and essential performance; Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.

VIII. Human Factors

To understand the hazards associated with the use of a medical device in the home, 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.

Human factors engineering offers well-established methods to identify design issues that could affect medical device safety and efficacy. One particularly effective human factors method is to conduct "usability" testing. In a typical usability test session, representative device users perform selected tasks under conditions of simulated (not actual) use in an appropriately realistic environment. Depending on the nature of the device and the goals of

the test, the test environment could range from a conference room to a sophisticated, high-fidelity simulation of the expected use environment or an actual home. Testing early in the design process and then several more times as the design evolves is an effective way to prevent user interaction problems from persisting into the later stages of the design process, at which point effective solutions to problems may be more limited and more expensive to implement.[9] Following the formative stage of design development, FDA recommends that you conduct a human factors validation study.[10]

We recommend that you consult FDA's guidance on this topic, Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016), that represents FDA's approach on this topic.

Additionally, you may refer to relevant U.S. and international standards, such as:

- ANSI/AAMI HE 75:2009, *Human factors engineering—Design of medical devices*.
- ANSI/AAMI/IEC 62366:2007/(R) 2013, *Medical devices—Application of usability engineering to medical devices*.

A. User Training and Certification

When designing devices, you should take into account that users may not understand multiple steps, may receive minimal training or teaching on how to operate these devices, and may not be able to understand multiple warnings and precautions. In addition, users may not understand the need to calibrate, clean, and maintain the device. User training may be critical for safe operation of home use devices.

We recommend that you consider the need for training as you determine the complexity of your home use device. The content and time needed for successful training depends on factors specific to the device. We suggest you validate the effectiveness of your training program.

For many devices, the user may also need a care partner to help operate the device safely and to provide monitoring of the patient while the device is being used. We recommend that you outline the responsibilities of the care partner, the caregiver, and the care recipient during the training sessions and provide instructions to users on emergency procedures, such as the procedures necessary if a serious adverse event occurs. We recommend that you provide guidance to the user on any retraining or recertification that is needed for safe operation of the device and indicate how frequently this needs to be done.

FDA recommends that you review AAMI TIR49:2013, *Design of training and instructional material for medical devices used in non-clinical environments*.

[9] Such testing may be subject to IDE requirements in section 520(g) of the FD&C Act and 21 CFR Part 812 and the human subject protection requirements in 21 CFR Parts 50 and 56 depending on the nature of the testing.
[10] Such a study may also be subject to the IDE and human subject protection requirements referenced above.

IX. Labeling

Labeling for home use devices must address all applicable requirements in 21 CFR Part 801 and 809.10. Labeling considerations should be for both prescription and OTC devices. In general, the IFU for the user should be simple, concise, and easily understood. Instructions written for the user should be written in a narrative format, and pictures may be helpful to explain instructional steps. Although instructions, labeling, and training can influence users to use devices safely and effectively, use of such material assumes that the user will remember or refer back to the information. These approaches are less effective than designing the system so that it is inherently apparent to users. The device's labeling should include contraindications that clearly explain why any individual should not use the device, and clear warnings of all hazards that cannot be designed out. Using the same terms throughout the labeling to identify the device avoids confusion for the user. Labeling on devices should be simple, visible, and clear and readily understood by the user; it should also be able to withstand defacement or wear. In addition to developing clear and effective labeling for the device, you should consider situations when the device may be separated from the labeling and what end users need to do to access the labeling, such as finding it on a Web site or calling someone who may be able to help them with safe device operation.

In addition to the labeling requirements found in 21 CFR Part 801 and 809.10, you may obtain information for developing labeling for home use devices from the following documents:

- *Labeling of Home-Use In Vitro Testing Products*: Approved Guideline, Clinical and Laboratory Standards Institute, GP-14 (June, 1996).

- FDA's guidance *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* (December 11, 2014).
  FDA recommends that implanted devices include labeling that encourages patients to register the conditions under which the implant can be scanned safely with the MedicAlert Foundation or equivalent organization.

- FDA's *Guidance on Medical Device Patient Labeling* (April 19, 2001).

- FDA's guidance *Investigational Device Exemptions (IDE) for Devices Indicated for Nocturnal Home Hemodialysis* (April 15, 2008).

- Clause 5 of ISO 15197:2003, *In vitro diagnostic test systems – Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus*.

A. Handling the Device in an Emergency

FDA recommends that manufacturers of life-supporting and life-sustaining care devices for the home have plans for providing emergency service and supplies during natural disasters and public health emergencies. You may refer to FDA's booklet Home Use Devices: How to Prepare for and Handle Power Outages for Medical Devices that Require Electricity (2011). The booklet provides information that a user should have in the event of a power outage, including a contact telephone number for the manufacturer. The booklet advises the user that he or she keep all of his or her device information in one place that is readily accessible, such as on the refrigerator or on a device identification card that the user carries. The booklet recommends that users contact their local power companies and their local social services departments to be put on lists for special attention when public health or safety emergencies happen. The booklet also advises users to look for signs of damage to the device and how to identify the circumstances under which the device or its accessories should not be used.

Refer to the following sources for additional information about handling the device in an emergency:

- Department of Homeland Security's Web site: Prepare for Emergencies Now: Information for People with Disabilities.
- FDA's Web site about medical device safety in emergencies: FDA Offer Tips about Medical Devices and Hurricane Disasters.

B. Disposal

The IFU should include information concerning the proper disposal of the device and its accessories. You should provide proper warnings and precautions regarding safe disposal of waste products when using the device in the home environment and help the user understand the difference between biological waste and regular waste. If the device or accessories require professional assistance to dispose of biological or biohazardous waste, the IFU should state that the user should make proper arrangements for safe waste disposal.

C. Hygienic Maintenance

Home users do not have easy access to the cleaning, disinfecting, and sterilization supplies that are readily available in professional health care facilities. Ideally, home use devices should be designed to be cleaned, disinfected, or sterilized with readily available supplies and use simple techniques. If a home use device or its accessories require cleaning, disinfection, or sterilization prior to use, FDA recommends that you describe in the labeling for your device or system the complete cycles and methods for cleaning, sterilizing, or disinfecting the system. FDA's guidance on this topic *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (March 17, 2015) represents FDA's approach on this topic.

If a medical device or its accessories require professional hygienic maintenance prior to re-use, contact information for those services should be provided in the labeling and IFU. A technical description for hygienic maintenance requirements in the labeling and IFU should include methods to clean, disinfect, sterilize, rinse, dry, handle, and store the device before and after any type of service procedure, as well as indicate what steps are required if a device is transferred to another user. The IFU should also cover how to obtain consumable or disposable supplies.

For medical device reuse information written for the user, see FDA Offers Tips About Medical Devices and Hurricane Disasters: Reuse of Medical Devices.

For more information on hygienic maintenance information on reprocessed single-use devices, see FDA's guidance *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices* (September 25, 2006).

FDA also recommends that you refer to ANSI/AAMI HA60601-1-11:2011 section 7.5.2, Additional requirements for professional hygienic maintenance, in the design of medical devices.

X. Postmarket Considerations

A. Customer Service

If you already have in place a toll-free technical assistance telephone number, email address, or Web site address for users regarding questions about use and maintenance of the device, or if the device is life-supporting or life-sustaining and you have a person available 24 hours a day to talk with users, it is important to keep these systems in place. Information obtained through technical assistance is valuable data to be captured for analysis within your quality system.

B. Medical Device Reporting

The Medical Device Reporting (MDR) regulation[11] requires you to submit reports to the FDA whenever you become aware of information that reasonably suggests that a device you market may have caused or contributed to a reportable death or serious injury, or has malfunctioned and the malfunction would be likely to cause or contribute to a reportable death or serious injury should it recur.

For the FDA Form 3500A, instructions for completing specific items on the form, and the coding manual see MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

[11] 21 CFR Part 803

For additional guidance on the MDR regulation and the reporting requirements refer to FDA's guidance *Medical Device Reporting for Manufacturers* (March, 1997). You should also see FDA's draft guidance *Medical Device Reporting for Manufacturers* (July 9, 2013). FDA's draft guidance represents FDA's proposed approach on this topic.

XI. Conclusion

By taking into consideration the physical environment, the user, the user interface, including device design, labeling and instructions for use, and by utilizing human factors, you can produce devices that suit the home use environment and are thereby more likely to provide reasonable assurance of safety and effectiveness for their intended use. By including descriptions of your efforts to take into account the various factors outlined in this guidance document in your premarket submissions, you can better assure that your devices meet applicable safety and effectiveness requirements. Designing your home use device in this manner should result in a safer and easier-to-use device, minimize use error, and reduce the likelihood that adverse events will occur—the preferred outcome of a well-designed medical device.

Appendix 1: List of References

For the most recent version of a CDRH guidance, check the CDRH guidance web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.

1. U.S. Food and Drug Administration. Center for Devices and Radiological Health. Standards Management Program. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm or by calling 301-796-6574.

Standards Developing Organizations referred to in this guidance:

- Association for the Advancement of Medical Instrumentation (AAMI)
- ASTM (formerly known as American Society for Testing and Materials)
- Clinical and Laboratory Standards Institute
- International Electrotechnical Commission (IEC)
- International Organization for Standardization (ISO)

- The American National Standards Institute (ANSI) accredits the procedures of Standards Developing Organizations.

Standards referenced in this guidance:

- ANSI/AAMI/ISO14971:2007/(R)2010, *Medical devices—Application of risk management to medical devices.*
- IEC 62304 First edition 2006-05, *Medical device software – Software life cycle processes* and the identical standard ANSI/AAMI/IEC 62304:2006.
- ASTM D4169-09, *Standard practice for performance testing of shipping containers and systems*.
- ANSI/AAMI ES60601-1:2012 (Edition 3.1), *Medical electrical equipment – Part I: General requirements for basic safety and essential performance*
- ANSI/AAMI HA 60601-1-11:2011, *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*.
- ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02, *Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*.

- IEC 60601-1-8 Edition 2.1 2012-11, *Medical electrical equipment; Part 1-8; General requirements for basic safety and essential performance; Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.
- ANSI/AAMI HE75:2009, *Human factors engineering--Design of medical devices*.
- ANSI/AAMI/IEC 62366:2007/(R)2013, *Medical devices—Application of usability engineering to medical devices*.
- AAMI TIR49:2013, *Design of training and instructional material for medical devices used in non-clinical environments.* (TIR=Technical Information Report)
- *Labeling of Home-Use In Vitro Testing Products: Approved Guideline*, Clinical and Laboratory Standards Institute, GP-14 (June, 1996).
- Clause 5 of ISO 15197:2003, *In vitro diagnostic test systems – Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus*.

2. Centers for Disease Control and Prevention. Emergency Preparedness and Response. Keep Food and Water Safe After a Disaster or Emergency. Available at: http://emergency.cdc.gov/disasters/foodwater/facts.asp

3. U.S. Department of Homeland Security. Transportation Security Administration. Travelers with Disabilities and Medical Conditions. Available at: http://www.tsa.gov/traveler-information/travelers-disabilities-and-medical-conditions

4. *Design Control Guidance for Medical Device Manufacturers* (March 11, 1997) Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

5. *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (January 11, 2002). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

6. *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry and FDA Staff* (May 11, 2005). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

7. *Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff* (August 13, 2013). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm

8. *Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff* (February 3, 2016). Available at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm259760.pdf

9. *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment; Guidance for Industry and FDA Staff* (December 11, 2014). Available at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm107708.pdf

10. *Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers* (April 19, 2001). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm

11. MedicAlert Foundation at http://www.medicalert.org

12. *Investigational Device Exemptions (IDE) for Devices Indicated for Nocturnal Home Hemodialysis; Guidance for Industry and FDA Staff* (April 15, 2008). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071138.htm

13. U.S. Food and Drug Administration. Center for Devices and Radiological Health. "Home Use Devices: How to Prepare for and Handle Power Outages for Medical Devices that Require Electricity", 2011. Available at: www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/UCM252812.pdf

14. U.S. Department of Homeland Security. Federal Emergency Management Agency (FEMA). "Prepare for Emergencies Now: Information for People with Disabilities," FEMA R-6 Catalog No. 09774. Available at: http://www.ready.gov/sites/default/files/FEMA_Disabilities_R-6_web_june2012.pdf

15. U.S. Food and Drug Administration. Center for Devices and Radiological Health. FDA Offers Tips about Medical Devices and Hurricane Disasters at http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm055987.htm

16. U.S. Food and Drug Administration. Center for Devices and Radiological Health. FDA Offers Tips about Medical Devices and Hurricane Disasters: Reuse of Medical Devices. Available at: http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm055987.htm

17. *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Guidance for Industry and FDA Staff* (March 17, 2015) at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm253010.pdf

18. *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices; Guidance for Industry and FDA Staff* (September 25, 2006) at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434

19. U.S. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program: Reporting Serious Problems to FDA. Available at http://www.fda.gov/safety/medwatch/howtoreport/downloadforms/default.htm

20. *Medical Device Reporting for Manufacturers; Guidance for Industry and FDA Staff* (March, 1997) at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm

21. *Medical Device Reporting for Manufacturers; Draft Guidance for Industry and FDA Staff* (July 9, 2013) at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm

Appendix 2: Additional Resources

1. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association, "Health Literacy: Report of the Council on Scientific Affairs," JAMA, February 10, 1999 — Vol 281, No 6.

2. California Department of Toxic Substances Control. UW for Residents-*Batteries*. Available at: http://dtsc.ca.gov/HazardousWaste/UniversalWaste/Res_Batteries.cfm

3. Consumer Product Safety Commission, 16 CFR Part 1501, Method for identifying toys and other articles intended for use by children under 3 years of age which present choking, aspiration, ingestion hazards because of small parts.

4. Mahadevan, R. Center for Health Care Strategies (CHCS), Health Care Literacy Fact Sheets, October 2013. Available at: http://www.chcs.org/resource/health-literacy-fact-sheets/

5. Global Harmonization Task Force document SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*.

6. Institute of Medicine of the National Academies, "Health Literacy: A Prescription to End Confusion" (2004). Available at: http://www.nationalacademies.org/hmd/Reports/2004/Health-Literacy-A-Prescription-to-End-Confusion.aspx

7. Keay, S. et al. The safe use of infusion devices. Continuing Education in Anaesthesia, Critical Care & Pain (2004) 4 (3) 81-85.

8. National Research Council. Health Care Comes Home: The Human Factors. Committee on the Role of Human Factors in Home Health Care, Board on Human-Systems Integration, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press, 2011.

9. RTCA DO-160G:2010, *Environmental conditions and test procedures for airborne equipment*. (NOTE: RTCA, Inc. was originally founded in 1935 as the Radio Technical Commission for Aeronautics.)

10. U.S. Environmental Protection Agency. Wastes-Non-Hazardous Waste-Industrial Waste: *Where You Live – State Medical Waste Programs and Regulations*. Available at: http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm

11. U.S. Environmental Protection Agency. Wastes-Resource Conservation-Common Wastes and Materials: *Batteries*. Available at: http://epa.gov/osw/conserve/materials/battery.htm

12. U.S. Food and Drug Administration. Medical Devices. *Device Advice: Comprehensive Regulatory Assistance*. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

13. U.S. Food and Drug Administration. Center for Devices and Radiological Health. *Home Use Devices*. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm

14. U.S. Food and Drug Administration. Center for Devices and Radiological Health. *Human Factors and Medical Devices*. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm

15. U.S. Food and Drug Administration. *Medical Device Reporting*. Available at: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm