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Drug, Biologic and Medical Device Development, Quality Assurance and Regulatory Affairs Consulting  
Specializing in Combination Products

## **Guidance: Design Considerations for Devices Intended for Home Use**

The Home Use Guidance is intended to assist manufacturers in designing and developing safe and effective prescription and over-the-counter Class I, II and III medical devices that comply with regulatory requirements. It identifies factors that manufacturers should consider during device design and development to minimize risks. It should be considered for devices likely to be used in the home, even if not intended solely for home use. The guidance does not explicitly say that it applies to combination products containing a device constituent part, although it seems likely that it will be applied in such cases.

- **Design considerations**

- Consider all environments and conditions of possible device use
- Minimize need for maintenance and user calibration; indicate if the device must be calibrated in a non-home location; home use devices should be designed to be cleaned, disinfected, or sterilized with readily available supplies and use simple techniques
- Test devices to see how they function after impact
- Consider reliability of electricity and electrical grounding and electromagnetic compatibility of use environments
- High or medium-priority alarms perceivable in home environments

- **User considerations**

- Capabilities, impairments and disabilities
  - Physical (size, mobility, dexterity, coordination, flexibility, strength)
  - Sensory (vision, hearing tactile)
  - Cognitive (ability to process information, literacy)



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- Emotional differences (user anxiety)
- Previous experience
- Misuse by children or adults
  
- **Design Controls**
  - Develop risk management plan to identify hazards, evaluate risks, control risks, and monitor risk-mitigation effectiveness
  - Design risk out of the system to the greatest extent possible, then develop internal device protective measures and where all else fails provide safety information (labeling); do not depend solely on lock-out mechanisms
  
- **Human Factors**
  - Consider the need for training; validate the effectiveness of training programs; define caregiver and care recipient responsibilities of the during the training; provide instructions to users on emergency procedures
  - User IFU should be simple, concise, and easily understood; include contraindications and warnings of hazards for use, disposal and use environmental conditions that raise safety or effectiveness concerns
  
- **Submissions**
  - Include a summary of design efforts to account for
    - Intended use location, temperature, humidity, atmospheric pressure and air flow levels
    - Use in non-sterile environment



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- Water quality required for proper operation
  - Travel and International use
  - Tolerance to fluid spills or submersion
  - Storage Instructions
  - Wireless technology, performance, frequency/band, power output, functions, wireless alarms
- **Analysis**
    - The final guidance contains few surprises. It is somewhat simpler than the draft guidance. It contains similar recommendations with no new recommendations. The final guidance applies to the development of Class I, II and III medical devices. It invokes Design Controls. This is the first time that FDA has implied that Class I medical devices are subject to Design Controls. The final guidance does not explicitly indicate that it applies to combination products. But by implication, this is the first formal signal that FDA intends to require the application of Design Controls to combination products containing a Class I medical device constituent part.

- **Revision update**

On November 24, 2014, FDA issued a revision to the recently issued CDRH/CBER Guidance entitled, Design Considerations for Devices Intended for Home Use. The revision seems to have been prompted by the issuance of the 2014 version of the IEC 60601-1-2 standard.

The changes should have no impact on combination products or medical devices used in the home unless they are electrically powered (e.g. infusion pumps). The main differences between the version published on August 5, 2014 and the revised version is clarification of the use of standards applicable to electrical supply mains (section VII-E-1) and electromagnetic compatibility (section VII-E-6). A footnote is added in the revision of section VII-E-1, Supply Mains, recognizing the 2014 version of the IEC 60601-1-2. It



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notes that the standard provides a transition period through April 2, 2017. Certain language in section VII-E-6 Electromagnetic Compatibility, in the original version, is now deleted which stated that if a premarket submission for home use device describes electrical components, the submission should include a complete description of its EMC characteristics and information to verify those characteristics should be included in the submission. Also deleted is the recommendation that, since levels of electromagnetic disturbance in the home healthcare environment can exceed default test levels for the hospitals specified in earlier editions of ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02, devices should be designed to be immune to the higher test levels specified by Edition 4. A related footnote states that FDA generally finds the following immunity tests levels to be acceptable for the home environment: Electrostatic Discharge (ESD):  $\pm 8$  kV contact discharge,  $\pm 15$  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. Alternative levels may be justified.