

# FDA Standard Recognition Process

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## How does FDA use Standards?

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FDA officially **RECOGNIZES** standards and communicates that recognition to the public.

Medical Device Applicant shows **COMPLIANCE** with standards in medical device submissions to justify safety & effectiveness .

FDA uses standards in a similar manner as FDA **GUIDANCE DOCUMENTS**.

## How does FDA use Standards?

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FDA uses standards to:

- Provide clearer regulatory expectations & streamline review
- Increase consistency, credibility, and predictability
- Promote international harmonization
- Facilitate market entry for safe & effective medical devices
- Adopt unambiguous nomenclature used in technical community

## FDA Recognized Standards

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### **FDA doesn't recognize every standard.**

*A FDA Committee reviews standards for recognition.*

*Currently, we recognize  $\approx$  1190 standards.*

### **Recognition is announced in FR (Federal Register) Notice**

*These notices are published at least twice a year.*

*They take effect immediately. (No notice/comment period)*

### **Recognized Consensus Standards Search Database**

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

## Recognized Consensus Standards Search Database

**Search Database** ? Help

Standards Organization

Standard Designation Number  
*Note: numbers only, e.g., 14971, 60601-1*

Standards Title or Keywords  
*Note: do not include standard designation number*  (30 chars. max)

Specialty Task Group Area

Product Classification Product Code  Regulation Number (e.g., 888.1111)

Type of Standard  
*(use ctrl button with mouse click to select up to 3 types, e.g., Horizontal, National, Materials Specification)*

All Standard Types  
 Vertical  
 Test Methods  
 National  
 Material Specification  
 International  
 Horizontal

FR List Publication Date  to

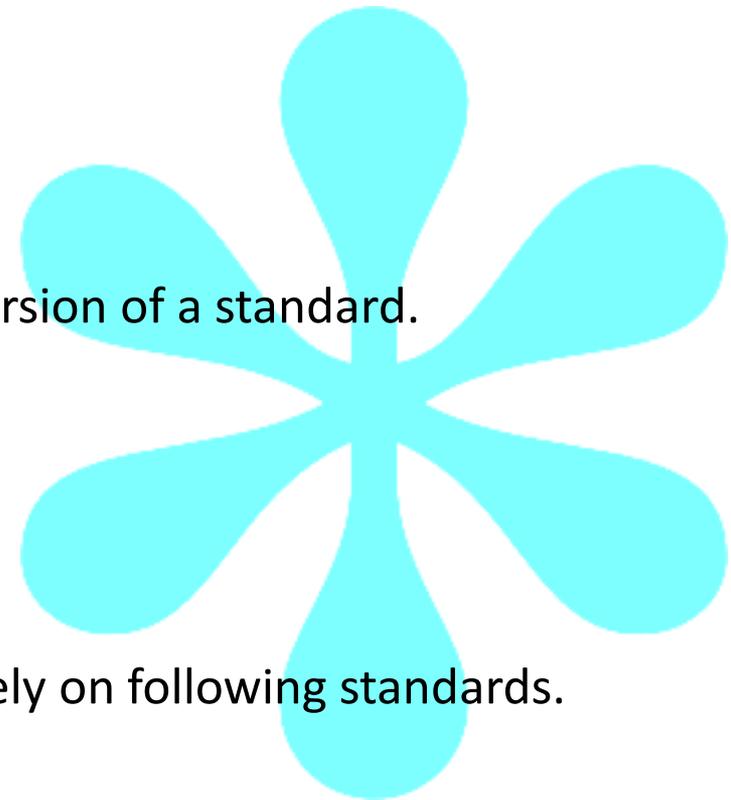
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## FDA Caveats to Standards

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- Recognition of part of a standard
- FDA may not recognize the most current version of a standard.
- Additional guidance for use of a standard
- Medical device clearance seldom relies solely on following standards.



## Reporting Standard Conformance in your Submission

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- Submit FDA form 3654
- Provide more detail in the appropriate submission section  
(*e.g., IEC60601-1 in Electrical Safety*)
  - Identify the standard & amendments cited, and if it is recognized by FDA.
  - How you used the standard.  
(*e.g., use of optional pathways within the standard*)
  - Justify any deviations from the standard. (including not using standard)
  - Justify any differences between the tested and marketed devices.
  - If conformance included performance testing, provide test reports.

## FDA's involvement in standards development

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