FDA Standard Recognition Process

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How does FDA use Standards?

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?

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

FDA doesn't recognize every standard.

A FDA Committee reviews standards for recognition.

Currently, we recognize ≈ 1190 standards.

Recognition is announced in FR (Federal Register) Notice

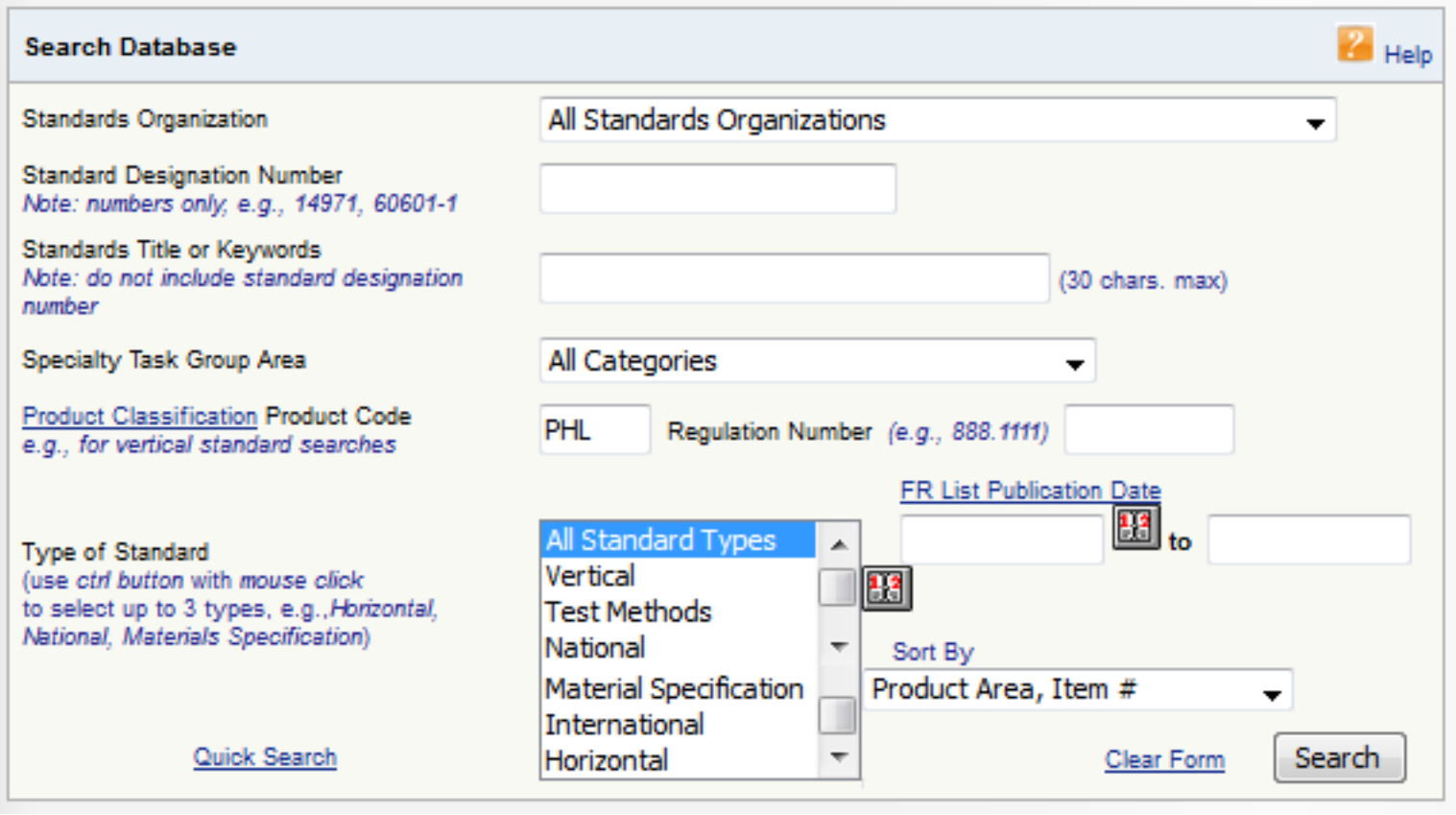
These notices are published at least twice a year.

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

Recognized Consensus Standards Search Database

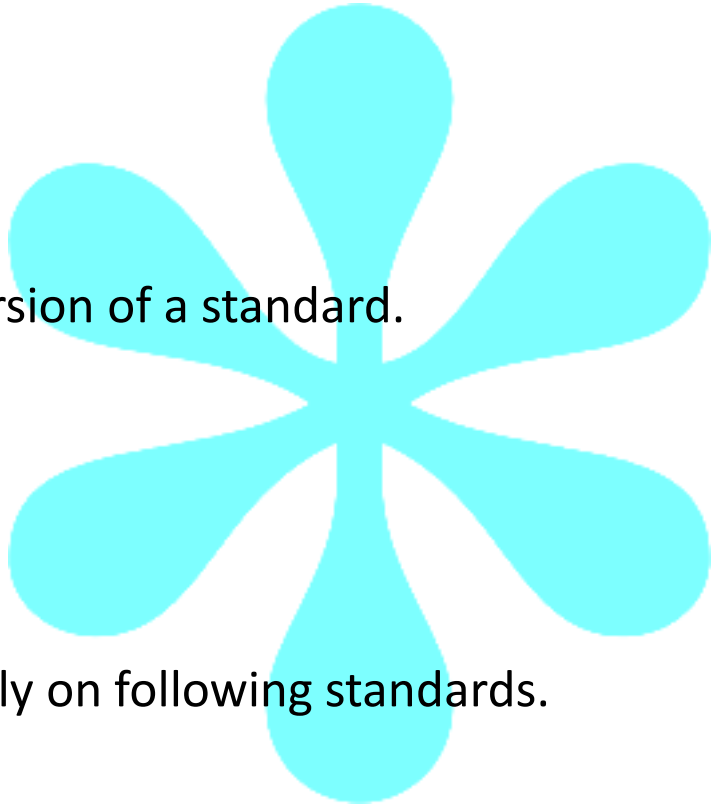
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Recognized Consensus Standards Search Database



FDA Caveats to Standards

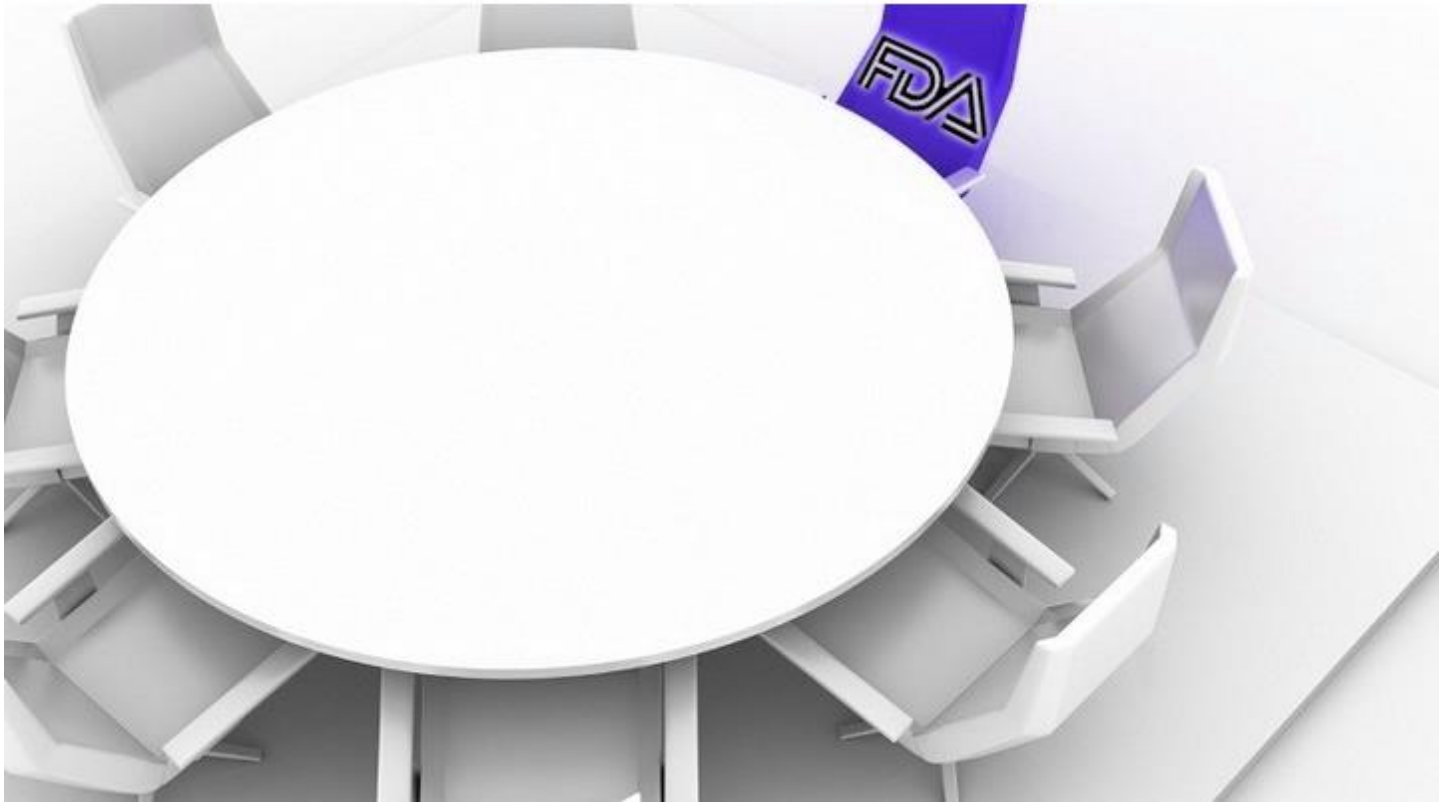
- Recognition of part of a standard
- FDA may not recognize the most current version of a standard.
- Additional guidance for use of a standard
- Medical device clearance seldom relies solely on following standards.



Reporting Standard Conformance in your Submission

- 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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