Using and Referencing ISO and IEC Standards for Technical Regulation

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Overview

- U.S. government use of standards
- Brief overview of the U.S. Food and Drug Administration
- FDA use of standards
- FDA's new Staff Manual Guide and Standards Committee
- Benefits of using voluntary consensus standards
- FDA policy issues regarding voluntary consensus standards

U.S. Government Use of Standards

- National Technology Transfer and Advancement Act (NTTAA; PL 104-113)
- OMB directive (OMB A-119)
- Interagency Committee on Standards Policy (ICSP) – more info at http://standards.gov/icsp/query/index.cfm.
- Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment produced by National Institute of Standards and Technology (NIST)

Brief Overview of FDA

FDA's mission, simply stated, is to:

- promote and protect the public health by helping safe and effective products reach the market in a timely way;
- monitor products for continued safety after they are in use; and
- help the public get the accurate, science-based information needed to improve health.

Brief Overview of FDA

- **Wide array of products -** From common food ingredients to complex medical devices, lifesaving drugs, and radiation-emitting consumer and medical products.
- **$1 trillion a year -** FDA-regulated products account for about 25 cents of every consumer dollar spent.
- **Variety of approaches –**
  - New drugs and complex medical devices must be proven safe and effective before companies can market them.
  - Other products, such as x-ray machines and microwave ovens, must measure up to performance standards.
  - And some products, such as cosmetics and dietary supplements, can be marketed with no prior approval.

Brief Overview of FDA

- Science-based, efficient risk management allows FDA to provide the most health promotion and protection at the least cost to the public.
- No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great -- especially for products used to treat serious, life-threatening conditions.

Brief Overview of FDA

- FDA uses regulations and product standards as the "yardsticks" that define specific requirements manufacturers must follow to assure product safety and to provide accurate information to health professionals and consumers.

FDA Use of Standards

- 21 CFR 10.95, Participation in outside standard-setting activities
- FDA Policy on Standards ("Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines", 60 FR 53078 (Oct. 11, 1995).

FDA Use of Standards

- FDA Centers use voluntary consensus standards to varying degrees, depending on the product and regulatory approach
- FDA Center experts actively participate in dozens of standards organizations
- Each Center may have a preferred standards forum depending on history, statutory requirements and experience

FDA Use of Standards – Medical Devices

- The Center for Devices and Radiological Health (CDRH) has recognized nearly 800 standards – over 200 from ISO and 70 from IEC – arguably more than any other medical device regulatory authority
- CDRH standards database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm, last updated on May 21, 2007
- CDRH has also issued "Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff, June 20, 2001"

FDA Use of Standards – Foods and Cosmetics

- The Center for Food Safety and Nutrition (CFSAN) actively participates in Codex Alimentarius Commission (CODEX) committees
- Code of Federal Regulations Title 21, Part 130, Subpart A, Sec. 130.6 requires that all food standards adopted by CODEX are to be reviewed by FDA
- CFSAN also participates in dozens of standards organizations

FDA Use of Standards – Human Drugs

- The Center for Drug Evaluation and Research (CDER) participates more than a dozen standards organizations
- The Federal Food, Drug, And Cosmetic Act, Chapter V - Drugs And Devices, subchapter A, sec. 501 recognizes use of United States Pharmacopeia standards

FDA Use of Standards – Biologics and Veterinary Products

- The Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM) also participate in a variety of standards organizations

FDA's New Staff Manual Guide and Standards Committee

- Staff Manual Guide adopted in March 2007
- Purpose is to establish Agency-wide policies and procedures related to standards management to assure a unified approach to standards within FDA
- FDA formed a Standards Committee with representatives from all Centers to communicate about standards issues and carry out standards policy

Benefits of Using Voluntary Consensus Standards

- Greater potential to save time and money over FDA development of technical standards
- Open participation by affected parties
- Often represents leading-edge thinking on an issue
- Can lead to international harmonization on issues

FDA Policy Issues Regarding Voluntary Consensus Standards

- Forum–shopping and protection by standards-development organizations (SDOs) of their “territory”
- Normative references in standards
- World Trade Organization definition of a voluntary consensus standards body
- Government agencies retain the authority to set requirements
- Government agencies reserve the right to select standards

Conclusions

- FDA experts participate in dozens of standards committees
- This is a significant investment of resources in voluntary consensus standards development
- FDA receives much benefit from participating in voluntary consensus standards
- The SMG and Standards Committee will help FDA coordinate standards participation and usage across the Agency

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