

FDA Meeting On Unique Identifiers for Medical Devices

Panel discussion on Use of Automatic Identification Technologies

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Introduction

- Background
- ECRI white paper on automatic identification of medical devices
- Some issues to consider
 - Including ECRI perspectives
- Panel discussion

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ECRI Overview

- World's most comprehensive source of information on healthcare technology (i.e., medical devices and systems)
- Serves healthcare community with a variety of advisory services, publications, and databases
- Non-profit organization chartered in 1955
- A Collaborating Center of the World Health Organization
- *Consumer Reports*-like evaluator of Healthcare Technology

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Background

- Obvious potential value in using unique identifiers for medical devices
 - Patient safety
 - Assisting with recalls
 - Tracking medical device incidents
 - Identifying incompatible or counterfeit devices
 - Inventory management
 - Cost containment

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Background ...

- Key challenges include
 - Diversity among device types to be identified
 - Diversity among types of identification technologies
 - Nonstandard approach to device identification and inventory management
 - Implementation costs

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ECRI's White Paper

- Extensive overview on automatic identification of medical devices
- Commissioned by FDA
- www.fda.gov/cdrh/ocd/ecritask4.html
- Review of identification technologies
- Analysis of available literature
- ECRI commentary

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ECRI's White Paper ...

- Technology overview
 - Bar code identification systems
 - Radio frequency identification systems
- Detailed discussion of automatic identification technologies for medical devices
 - Who is using it
 - How it is being used
 - Potential benefits of the different technologies
- Stakeholders, position statements, standards, existing unique identifiers, nomenclature, etc.

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Sample White Paper Content

- Bar code identification
 - Line of sight (i.e., limited range) with handheld readers
 - Widely adopted
 - Relatively inexpensive
- Radio frequency identification
 - New and emerging technology
 - Can be used over a wide range within a healthcare facility
 - Costs for tags, readers, and associated software relatively high

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Issues to Consider

- Varying sizes of medical devices
- Sterilization and disinfection of reusable medical devices
- Growing number of devices with built-in software and interconnections
- Human readable vs. “machine” readable identifiers
- Rapid evolution of “reader” technologies

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ECRI Perspectives

- Automatic identification of medical devices has tremendous potential
- Diversity – on a variety of levels – will make universal implementation very difficult and costly
- Consider addressing high-value technologies first
- Rapid evolution of identification technologies will limit our ability to standardize on one method

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Panel Discussion



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Thank You!

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