



NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

## FDA UNIQUE IDENTIFICATION SYSTEM (UDI) FOR MEDICAL DEVICES

FDA PUBLIC MEETING  
OCTOBER 25, 2006



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## WHAT IS NEMA ?

- NEMA is the primary standards-development organization for medical imaging and therapy systems equipment
  
- Diagnostic Imaging and Therapy Systems Division members manufacture over 90% of the market for:
  - X-Ray (incl. mammography) and CT
  - Radiation Therapy
  - MR
  - Nuclear Medicine Imaging
  - Diagnostic Ultrasound
  - Medical Imaging Informatics (PACS)



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## UDI SYSTEM FOR MEDICAL DEVICES

- NEMA supports a practical, cost-effective UDI system which improves patient safety
- NEMA is ready to work with FDA and all key stakeholders to achieve this goal
- NEMA believes all key stakeholders must become involved in this process to ensure success



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## PROBLEMS, ISSUES

- Problem definition - What problem(s) are we trying to solve ? What is the scope of the problem(s) ?
  - Problem must first be specifically defined before manufacturers can begin to develop a "fix"
- Existing tools to address recalls - capital equipment already marked with serial numbers that are used to track product for recalls and adverse events. Tracking begins in manufacturing through installation
- Existing identification systems -Rad. Health Act requires identifiers on X-Ray components - new UDI system would conflict with existing requirements - 21 CFR 1010
- Same regulations need to apply to both users and manufacturers

## PROBLEMS, ISSUES (cont'd.)

- Who will train users
- Cost impacts of increases in user/manufacture infrastructure must be made known
- Electronic medical records - preserving privacy
- What kind(s) of identification technologies should be employed
- How should software revisions to devices be recognized

## ESSENTIAL REQUIREMENTS FOR A UDI SYSTEM

- **MUST Enhance patient safety,**
- FDA must harmonize with existing systems/regulations- goal is global harmonization of requirements - one worldwide system
- **MUST Provide only essential information** related to patient safety to users and regulators - HIPAA
- Satisfy needs of FDA, manufacturers, users
- Require compliance from *both* manufacturers and users
- Provide flexibility - adapt to changes in technology
- Achieve “least burdensome” system which does not impose onerous regulatory or financial burdens

## NEXT STEPS

- Form interdisciplinary Task Force representing hospital users, industry and FDA to define specific problem(s) to be solved
- Develop potential approaches, discuss with stakeholders
- Formally identify the process and next steps through the Task Force and/or Fed. Register
- FDA should publish meeting minutes and a cumulative summary from today's meeting

## CONCLUSION

- NEMA supports a practical, cost-effective UDI system which enhances patient safety
- Phase-in process must be gradual - e.g. 5 years
- Critical details, issues must be resolved
- "Grandfather" existing devices in the field
- Establish mechanism to periodically evaluate UDI system with all key stakeholders involved and revise system if needed - Linkage to performance goals - e.g. recalls, adverse event reporting - How is system working ?



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