

PDR

MEDICAL REGULATORY REVISIONS PART 35

010014

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*Division of Industrial and Medical
Nuclear Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555*

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L-4-: PT35 medical use...

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PROCESS

- Public Participation in Process
- NRC / State Working Group
- Proposed Rulemaking
- Final Rulemaking

COMMISSION DIRECTION

- Continue ongoing program with improvements
- Capture not only Relevant Safety - Significant Events, but also Precursor Events
- Consult with ACMUI and Medical Community
- Use of Professional Standards and Guidance

COMMISSION DIRECTION

(Continued)

- Utilize Risk-Informed Performance-Based Approach
- Higher Risk Activities Should be Primary Focus of Efforts and Resources
- Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities

SRM ITEMS

- Focus Part 35 on Procedures that Pose Highest Risk
- Oversight Alternatives for Diagnostic Procedures Consistent with Risk
- Capturing of Relevant Safety Issues and Precursors
- Change “Misadministration” to “Medical Event”

SRM ITEMS

(Continued)

- Redesign Part 35 to Allow for Timely Incorporation of New Modalities
- Revise to Focus on Patient Safety
- Use of Available Industry Guidance and Standards

ACMUI VIEWS AND RECOMMENDATIONS

- Concurred with Commissions' Position to:
 - Continue the Ongoing Medical Program, with Improvements
 - Decrease Oversight of Low Risk Activities; and
 - Continue Emphasis in High Risk Areas
- Supported use of Professional Medical Organizations and Societies

ACMUI VIEWS AND RECOMMENDATIONS

(Continued)

- Recommended “Quality Improvement Approach” vs “Quality Management Approach”
- Believed that the NRC Should not Intrude Into Medical Judgments

ACMUI MEDICAL POLICY STATEMENT #2 PROPOSAL

- The NRC will regulate the radiation safety of patients **only** where justified by the risk to the patients, and **only** where voluntary standards or compliance with these standards are inadequate.
- **Assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.**

ACMUI MEDICAL POLICY STATEMENT #3 PROPOSAL

- The NRC will {minimize intrusion} **not intrude** into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

ISSUES

- QM Requirements
- Misadministration vs Medical Event
- Training and Experience
- Capturing Emerging Technologies
- Accreditation Process

ISSUES

- Medical Judgment
- Sophistication of Practice
- “Bad Apple” Factor
- Authorized User

MODALITY APPROACH

- Who Licensed?
- Technical Issues: (e.g., surveys, access controls)
- Training and Experience
- Licensee Event Reports: (Misadministrations, etc.)
- Quality Management
- Records
- Organization / Internal QA