



United States Nuclear Regulatory Commission

Medical Issues

**Organization of Agreement States
October 3, 2000**

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Topics

- **Part 35 Rulemaking**
 - Revision of 1979 Medical Policy Statement
 - Revision of Rule
 - Revision of NUREG 1556 Vol. 9
- **Part 35 Implementation**
 - Medical Inspection Pilot Program
 - Implementation Plans
- **45 CFR Part 61**



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Key Issues

- **Radiation Safety Committee**
- **Procedures for administrations requiring written directives**
- **Training and experience requirements**
- **Notification following a medical event**
- **Reporting and notification threshold for unintended radiation exposure to embryo/fetus and nursing child**



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Status

- **Medical Policy Statement**
 - SRM issued 6/23/00
 - Published in FR on 8/3/00 (65 FR 47654)
- **10 CFR Part 35**
 - SECY-00-118 sent to Commission 5/31/00
 - Awaiting Affirmation and SRM



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Medical Inspection Pilot Program

- **Intended to Focus on Safety**
 - **Compliance**
 - **Risk-Informed**
 - **Performance Based**
 - **Efficiency & Effectiveness**
 - **Minimize Regulatory Impact**
 - **Enhance Public Confidence**



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Medical Inspection Pilot Program

- **TI issued 4/24/00**
 - **Training conducted for Regions on 4/24/00 and 6/5/00**
 - **In effect for 1 year, then evaluate results**
- **Findings from pilot will be factored into overall revision of Medical Inspection and revision of Materials Inspection Program**



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Part 35 Implementation

- **Training for Regional Inspectors and Reviewers**
- **Agreement State Coordination**
- **Recognition of Specialty Boards**
- **Public Outreach**
- **Technical Assistance Request Processing**
- **Inspection Manual Chapter and Inspection Procedures Revision**



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Part 35 Implementation

- **Sealed Source and Device Certificate Updates**
- **10 CFR 32.74 (Manufacture and distribution of sources)**
- **Technical training center**
- **Nuclear Materials Event Database**



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45 CFR Part 61

- **Healthcare Integrity and Protection Data Bank effective October 26, 1999**
- **Reporting required of Federal and State agencies responsible for licensing and/or certification**
- **NRC examining its role and what will be reported**



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45 CFR Part 61

- **Reportable Actions**
 - Civil Judgments
 - Criminal convictions
 - Actions taken by agency
- **NRC staff considering:**
 - Confirmatory Action Letters
 - Orders
 - Enforcement Actions
 - License application/amendment denials