Medical Issues

Organization of Agreement States
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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
United States Nuclear Regulatory Commission

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
United States Nuclear Regulatory Commission

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
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
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
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
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
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