

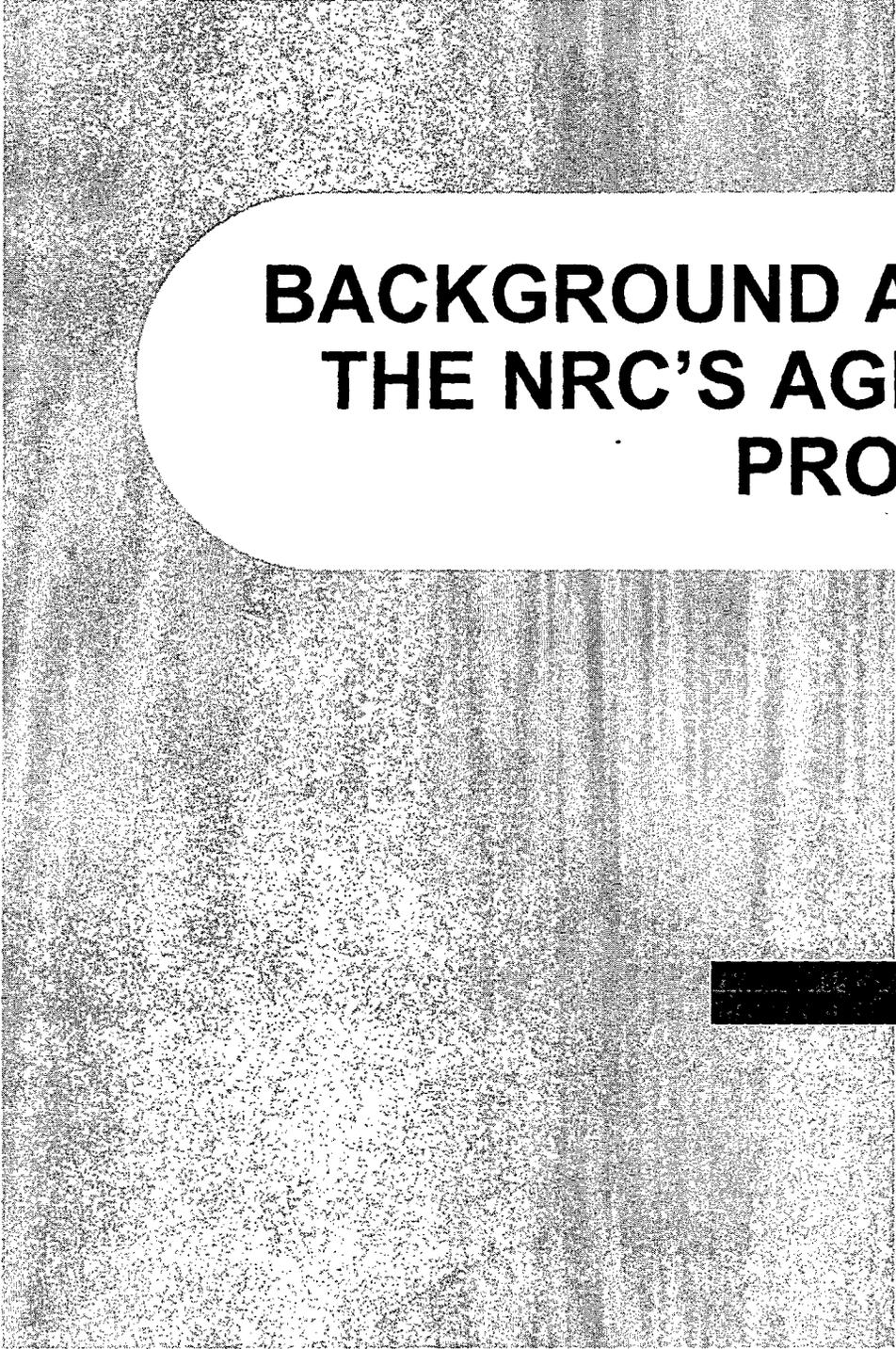
Sollenberger, Dennis

From: Aaron McCraw - FSME
Sent: Monday, September 22, 2008 11:06 AM
To: Donna Janda
Cc: Dennis Sollenberger
Subject: Agreement State Presentations
Attachments: 1 - Background and Overview of the Agreement State Program.ppt; 2 - Overview of Process to Become AS.ppt; 3 - Once the Agreement is Effective.ppt; 4 - Successful Strategies.ppt

Donna,

Here's a copy of the slides Jim Lynch and I are going to be using in Missouri on Wednesday. Feel free to use them for your New Jersey public meeting. These are based on the slides that Duncan, Dennis S., and I used to brief New Jersey initially. There are a couple Missouri specific slides in the first presentation. Be sure to remove those. Also, the 4th presentation probably won't do you much good for the public meeting, but I thought I'd include them in case you need them in the future.

-Aaron
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**BACKGROUND AND OVERVIEW OF
THE NRC'S AGREEMENT STATE
PROGRAM**

What is an Agreement State?

- A State that has assumed regulatory authority over certain categories of radioactive materials through a cooperative Agreement with the NRC.

What is an Agreement State?

- The State becomes responsible for licensing, inspection, and enforcement of medical, academic, and industrial uses of certain radioactive materials.
- The State also becomes responsible for responding to certain types of incidents and allegations within their borders.

Categories of Agreements

- Standard Agreement
 - Authority to regulate
 - Byproduct material as defined in Sections 11e(1), 11e(3), and 11e(4) of the Atomic Energy Act (material yielded in or made radioactive through the process of producing or utilizing special nuclear material);
 - Source material; and,
 - Special nuclear material in quantities not sufficient to form a critical mass.
 - At State's request, sealed source and device evaluation authority may be retained by NRC.

Categories of Agreements

- **Uranium Mill Agreement**
 - Authority to regulate byproduct materials as defined in Section 11e(2) of the Atomic Energy Act (tailings or wastes produced by the extraction or concentrations of uranium or thorium from ore).
- **Low-Level Waste Agreement**
 - Authority to regulate land disposal of radioactive waste.
- **Full Agreement**
 - Authority to regulate all categories of material previously mentioned.

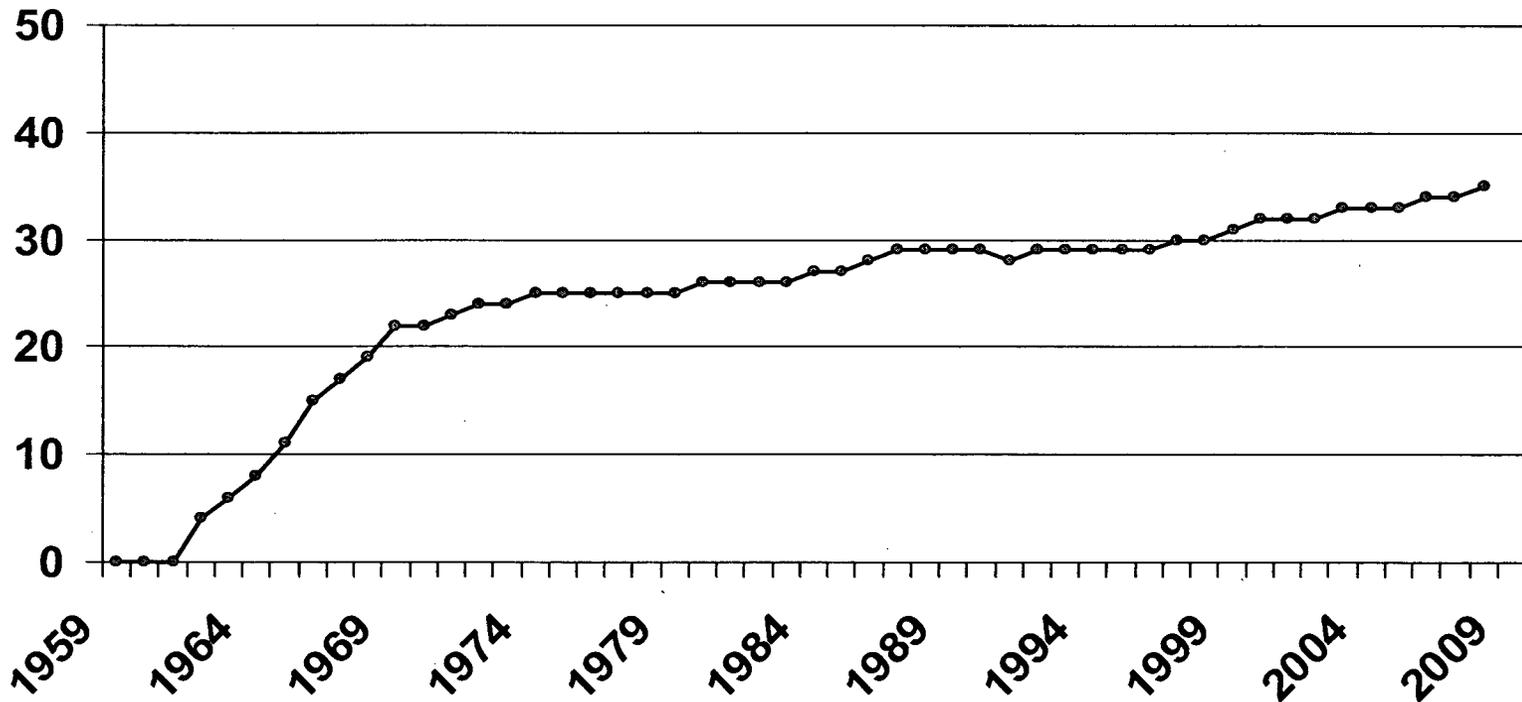
Areas of Authority Reserved to NRC

- NRC retains authority over:
 - Protection of common defense and security
 - Federal agencies
 - Production and utilization facilities
 - Exports and imports
 - Disposal in the ocean
 - High-level waste handling and disposal
 - Transfer of materials to persons exempt from licensing (consumer products)
 - Large quantities of special nuclear material
 - Off-shore waters
 - Certain aspects of mill tailings management

The Origin of the Agreement State Program

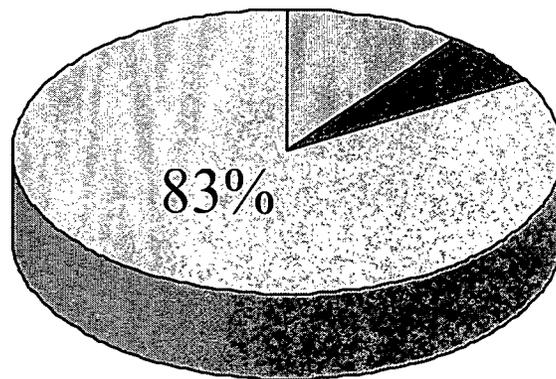
- Authority to enter into Agreements with States was granted by Section 274 of the Atomic Energy Act, enacted in 1959
 - Initiative from the States to regulate atomic energy
 - Established a cooperative program
- First Agreement was signed in 1962.

Number of Agreements States Since the Program Began



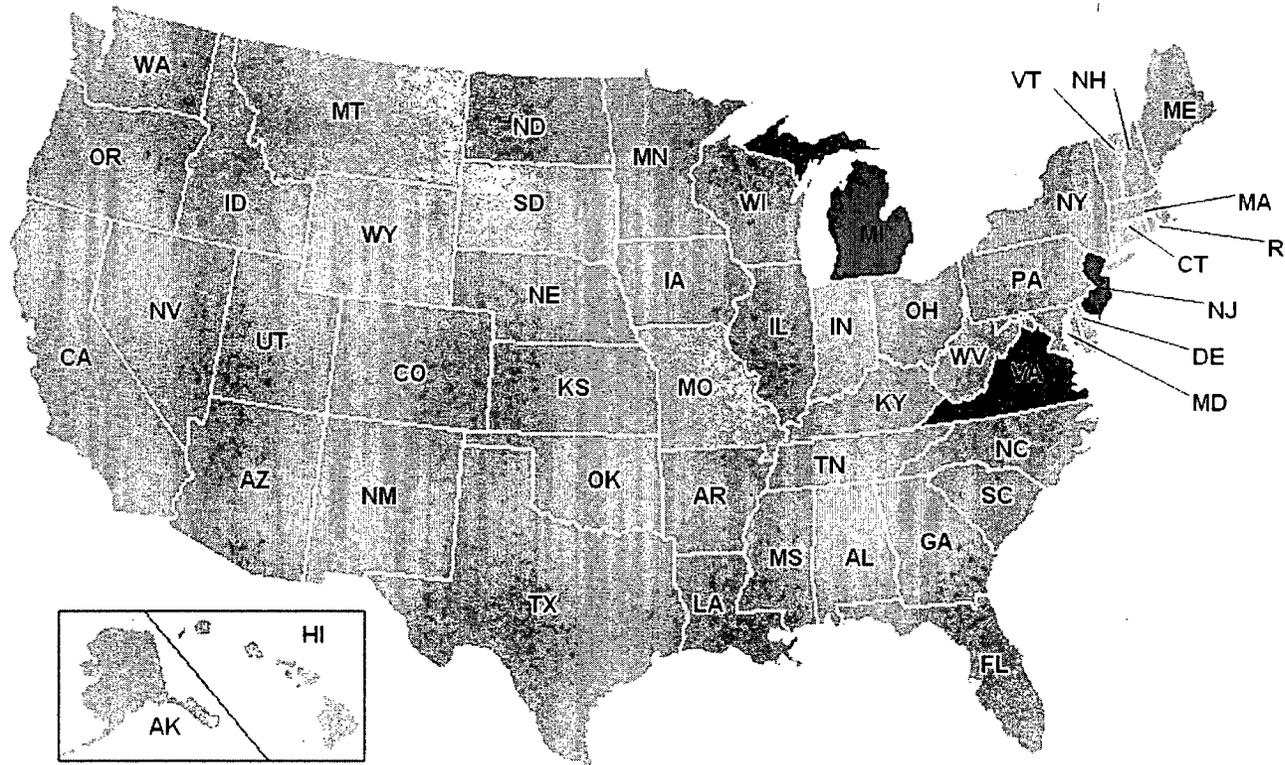
Agreement State Program Overview

- 35 Agreement States regulate 18,500 radioactive material licenses
- NRC regulates 3,700 licenses

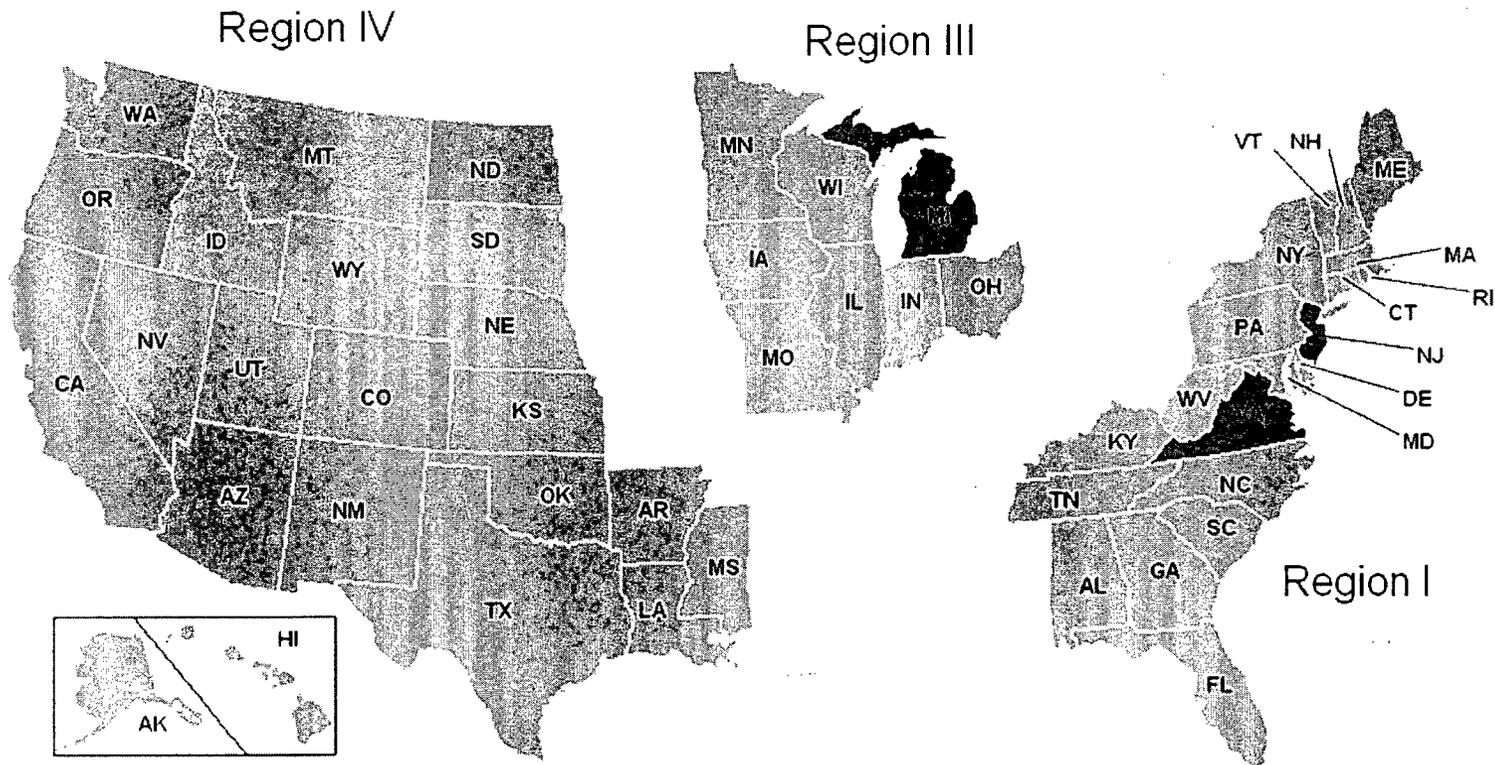


- NRC
- Interested States
- Agreement States

The Agreement State Map

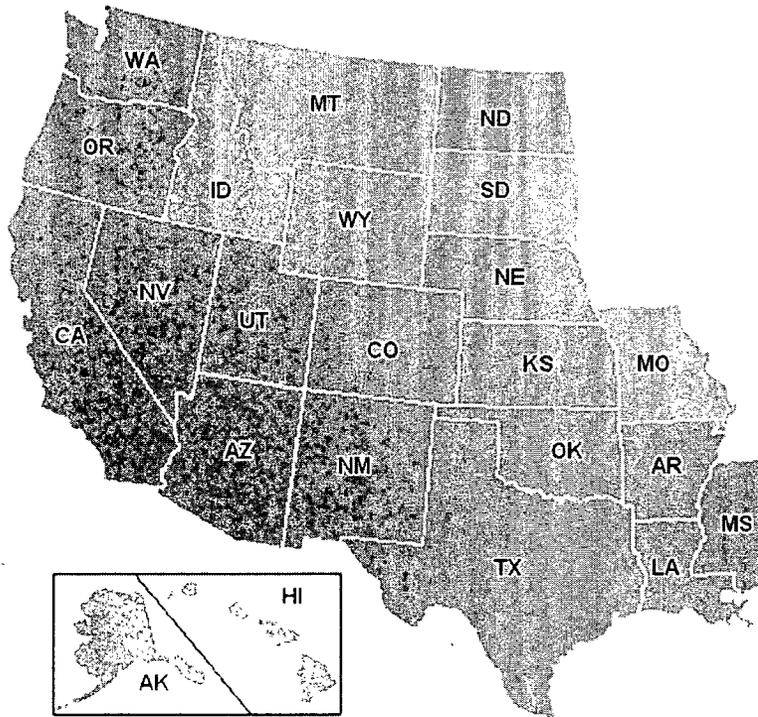


The Agreement States by Region

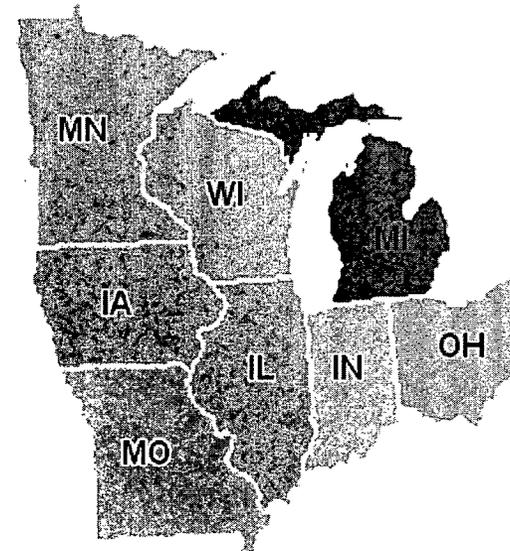


Regional Responsibilities for Missouri

Reactors – Region IV



Materials – Region III



Materials in Missouri

- Approximately 300 licenses
- Major licensees include:
 - Mallinckrodt
 - Major manufacturer and distributor of medical isotopes
 - University of Missouri
 - Several large medical centers

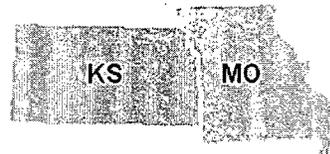
Similar-sized Agreement States

Kansas

Size: 315 licenses

Director: Tom Conley

Phone: (785) 296-1565



Wisconsin

Size: 335 licenses

Director: Paul Schmidt

Phone: (608) 267-4792

Mississippi

Size: 333 licenses

Director: B.J. Smith

Phone: (601) 987-6893

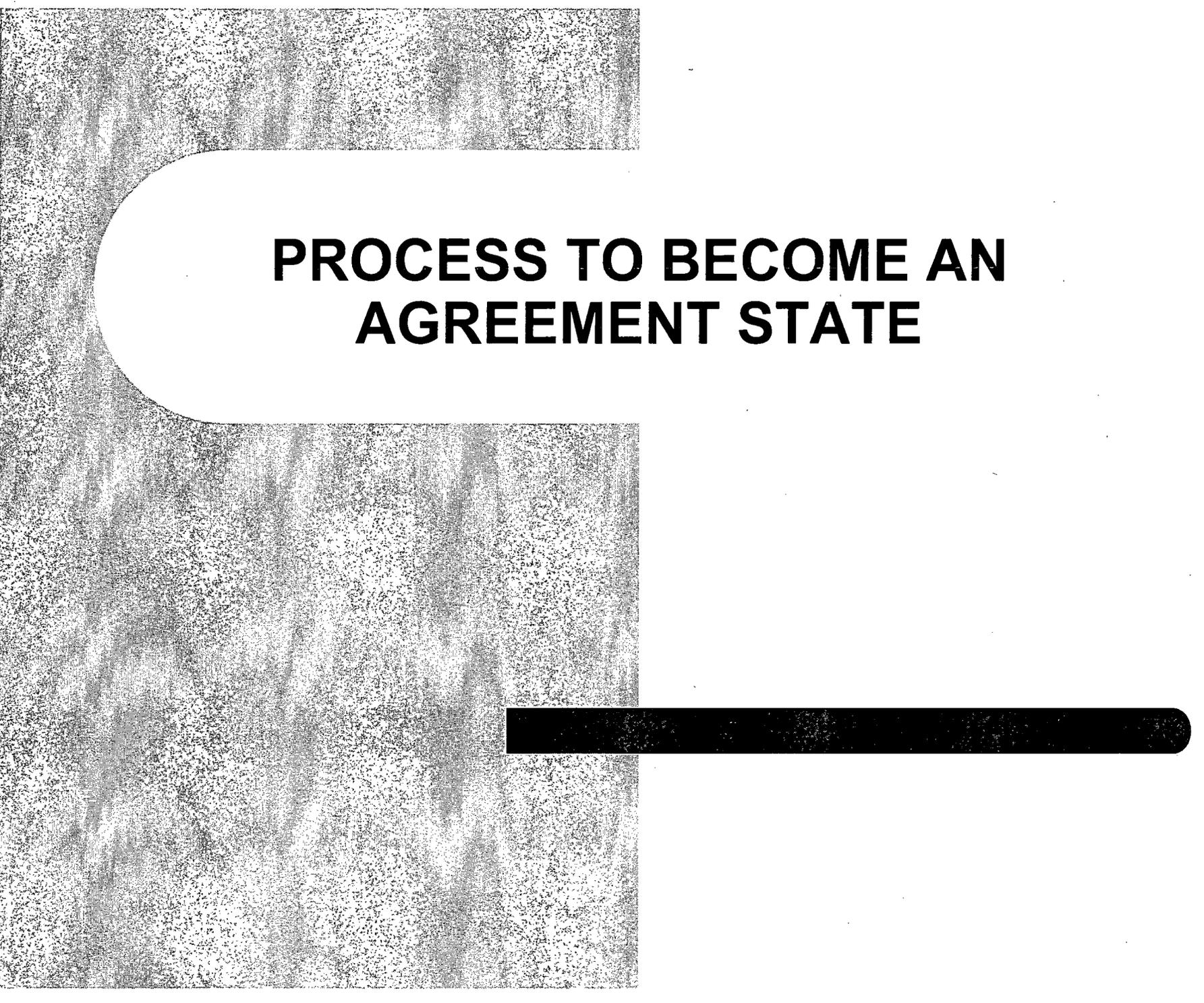


Materials in Missouri

- Annual fee revenues from licensees in Missouri was \$1.6M in 2007.
- As a result of Energy Policy Act of 2005, NRC will assume authority for naturally occurring and accelerator-produced radioactive materials (NARM) on October 1, 2008.

Funding Agreement State Programs

- NRC, as matter of policy, does not provide seed money to establish Agreement Programs.
- NRC is not authorized to provide operating funds.
- NRC does provide funding for Agreement State staff training and travel.
- Direct technical assistance is provided on a fee reimbursable basis.



**PROCESS TO BECOME AN
AGREEMENT STATE**

Policies and Procedures

- “Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement”
– January 23, 1981

[Federal Register, January 23, 1981 (Volume 46, Number 15)]
[Notice]
[Page 7540-7542]

FEDERAL REGULATORY COMMISSION

Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Statement of Policy.

SUMMARY: The Nuclear Regulatory Commission has revised its statement of policy regarding criteria for guidance of States and NRC in discontinuance of NRC regulatory authority and assumption of regulatory authority by States through agreement. This action is necessary to make certain changes to update the policy statement, to allow States to enter into agreements for low-level waste only, and to incorporate the provisions and requirements of the Uranium Mill Tailings Radiation Control Act of 1978. Adoption of this policy will allow revised States to enter into agreements with the NRC and regulate low-level waste only. Additionally, those States that meet the criteria for the regulation of uranium tails and millings may exercise regulatory authority over those activities provided by the Uranium Mill Tailings Radiation Control Act of 1978 as amended.

The revised statement of policy reflects the following principal changes:

1. Modification of Criterion 27 to allow a State to enter an agreement for the regulation of low-level waste as a separate category.
2. Inclusion of additional criteria for States wishing to continue regulating uranium and thorium processing activities after November 3, 1981.
3. Editorial and clarifying changes to make the statement current.

DATES: This policy statement is effective January 23, 1981.

FOR FURTHER INFORMATION CONTACT:

John F. Keady, Chief of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: 301-412-1767.

SUPPLEMENTARY NOTES:

1. These criteria were developed to implement a program authorized by Pub. L. 96-273 which was enacted in the form of a new section to the Atomic Energy Act (Section 214) and approved by

Policies and Procedures

- FSME Procedure SA-700, "Processing an Agreement"
 - July 19, 2007



Office of Federal and State Materials and Environmental
Management Programs (FSME) Procedure Approval

Processing an Agreement - SA-700

Date: July 19, 2007

Review Date: July 19, 2010

James H. Hoffbauer
Director, FSME

Original signed by
Jacob A. Hoffman

Date: 7/18/2007

A. Douglas Wine
Deputy Chief, FSME

Original signed by
A. Douglas Wine

Date: 7/17/2007

William B. Barnhart
Deputy Director, DMS&A

Original signed by
William B. Barnhart

Date: 7/17/2007

ML0216060

NOTE

These Procedures were jointly drafted by the Office of State and Tribal Programs (STP).
Any changes to the procedures will be the responsibility of the FSME Procedure Committee as of
October 1, 2008. Copies of FSME procedures will be available through the SBC website.

Policies and Procedures

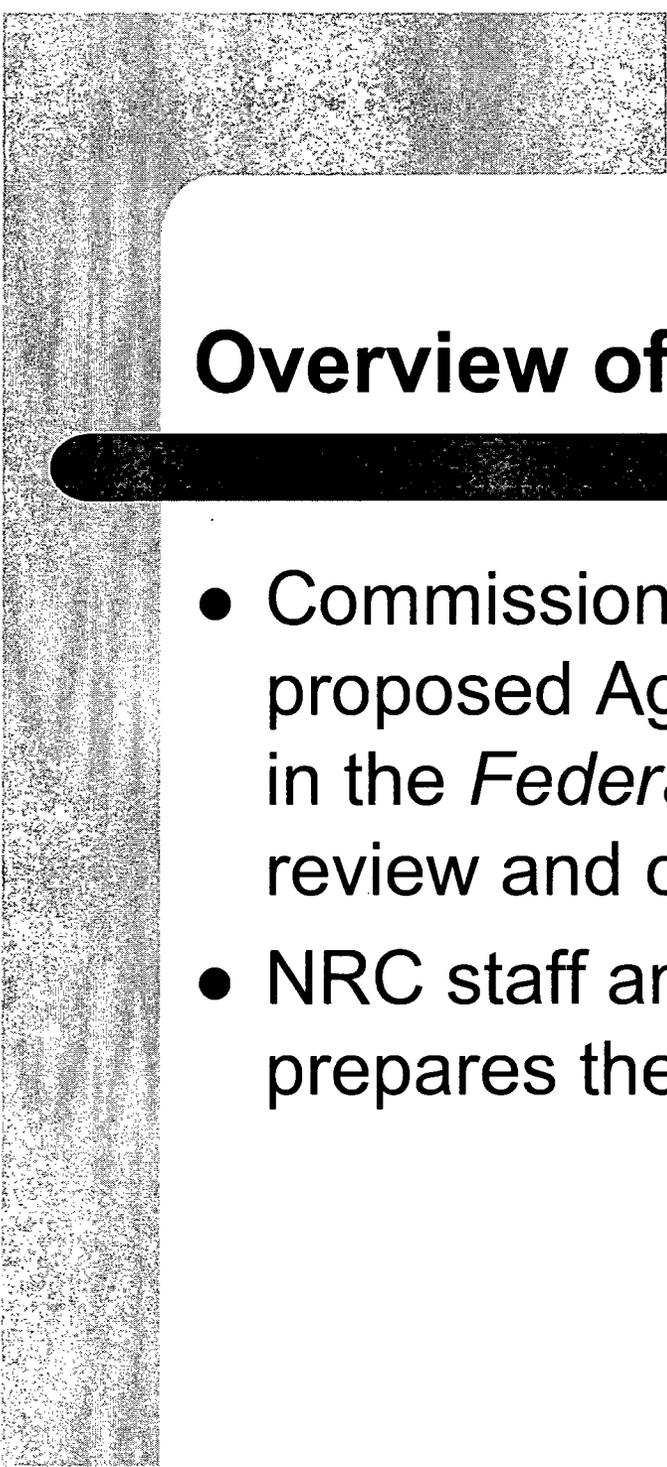
- Policy Statement – “Statement of Principles and Policy for the Agreement State Program”
- Policy Statement – “Adequacy and Compatibility of Agreement State Programs”
- Management Directive 5.8, “Proposed Section 274b Agreements With States”

Overview of Process

- Governor signs Letter of Intent.
- NRC assigns Project Manager.
- State develops/submits draft request (“application”).
- NRC reviews draft application for completeness only.
- NRC provides letter to State detailing review team’s comments.

Overview of Process

- State develops a final application.
- Governor submits application and certifies that the State has an adequate program.
- NRC staff prepares draft assessment following guidance in SA-700.

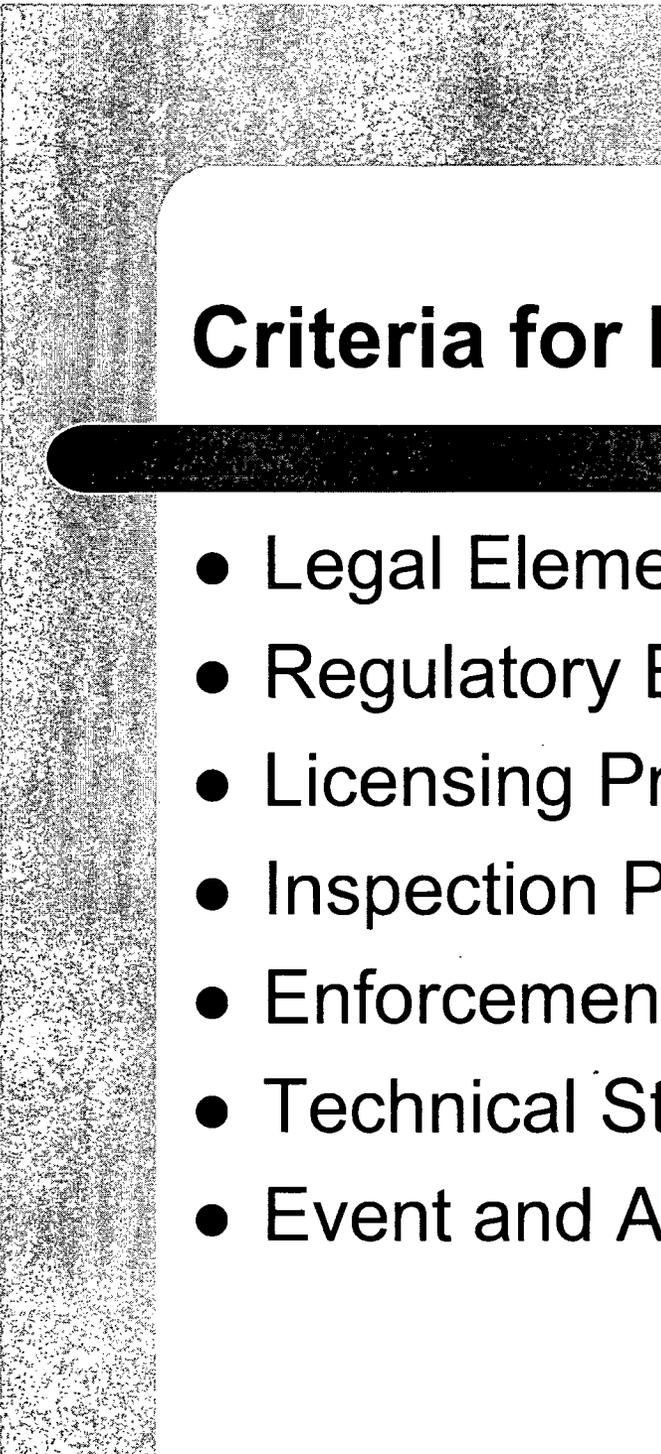


Overview of Process

- Commission approves publication of the proposed Agreement and draft assessment in the *Federal Register* for 30-day public review and comment.
- NRC staff analyzes public comments and prepares the final assessment.

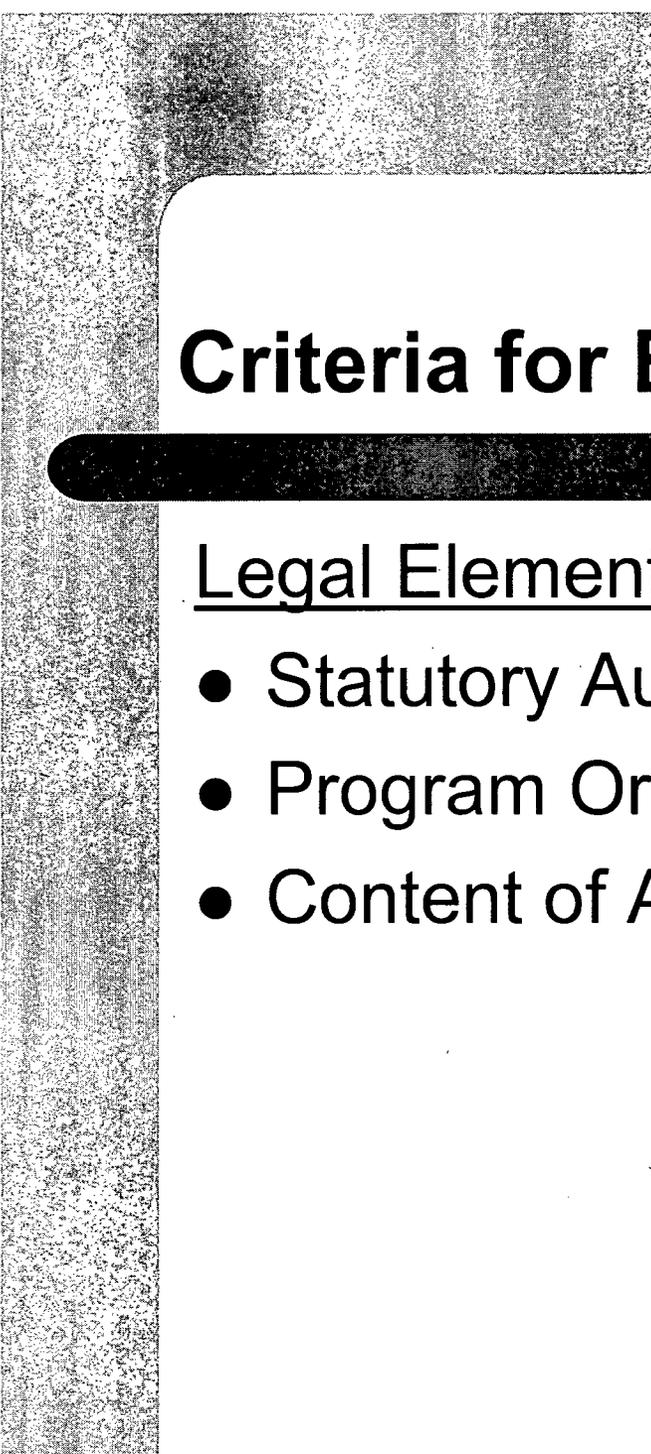
Overview of Process

- Commission approval of final Agreement.
- Chairman and Governor sign.
 - 30-day effective date
- Final Agreement published in *Federal Register*.
- Orderly transfer and assumption of authority.
- Continued post-Agreement program of exchange-of-information and assessment of program performance through the Integrated Materials Performance Evaluation Program



Criteria for Entering into an Agreement

- Legal Elements
- Regulatory Elements
- Licensing Program
- Inspection Program
- Enforcement Program
- Technical Staff
- Event and Allegation Response



Criteria for Entering into an Agreement

Legal Elements

- Statutory Authority
- Program Organization
- Content of Agreement

Criteria for Entering into an Agreement

Regulatory Elements

- Radiation Protection Standards
- Transboundary Requirements
- Orderly Pattern of Regulation or Health and Safety Significance

Criteria for Entering into an Agreement

Licensing Program

- Materials Licensing
- Licensing Quality
- Licensing Administrative Procedures
- Sealed Source and Device (SS&D) Safety Evaluations, if applicable

Criteria for Entering into an Agreement

Inspection Program

- Inspection Procedures
- Inspections Quality Assurance
- Inspection Administrative Procedures

Criteria for Entering into an Agreement

Enforcement Program

- Routine Enforcement Procedures
- Escalated Enforcement Procedures

Criteria for Entering into an Agreement

Technical Staff

- Technical Staff Organization
- Formal Qualification Plan
- Current Technical Staff Qualifications

Criteria for Entering into an Agreement

Event and Allegation Response

- Event and Allegation Response Procedures
- Event Reporting Procedures

Timeline for Processing an Agreement

- NRC completeness review of draft request for Agreement – 6 weeks
- State prepares and submits formal request – 8 weeks
- Draft staff assessment of formal request and proposed Agreement completed – 10 weeks

Timeline for Processing an Agreement

- Commission and public review of draft assessment and proposed Agreement – 12 weeks
- Final staff assessment completed – 4 weeks
- Final processing and Commission approval – 13 weeks
 - Effective date – 1 month after signature.
- Total time to process an Agreement – 53 weeks

**ONCE THE AGREEMENT BECOMES
EFFECTIVE**

Exchanges of Information

- Agreement States submit event reports to NRC
 - 24-hour significant reportable events report to NRC Operations Center and follow up to the Nuclear Material Events Database (NMED)
 - 30- and 60-day reportable events submitted to NMED
- Abnormal Occurrence Report
 - Sent to Congress; coordinated by NRC

Exchanges of Information

- Allegation referrals
- States provide copies of completed Sealed Source and Device Evaluation to NRC
 - Maintained on secure NRC website
- NRC provides copies of exempt or "E" licenses to State for processing of possession license
- Review of Draft and Final Regulations through NRC

Exchanges of Information

- Annual OAS and CRCPCD Meetings
- Monthly teleconferences with OAS/CRCPCD
- Other workshops/meetings
- All Agreement State Letters
- Requests for information

Technical Assistance

- Routine interactions with Regional and FSME staff on specific issues
- Management Directive 5.7, "Technical Assistance to Agreement States"
 - <http://www.hsrdo.org/nrc/special/md05-007.pdf>

Confirmatory Licensing or Inspection Assistance

- Handled by correspondence or telephone at no cost
- Casework (minor)
- Licensing policy
- Inspection practice
- Interpretations

Direct Licensing or Inspection Assistance

- Handled on fee reimbursable basis
- Inspections
- License application evaluations
- Special evaluations and studies

Integrated Materials Performance Evaluation Program (IMPEP)

- NRC given authority to periodically review Agreement State Programs under Section 274j. of the Atomic Energy Act
 - Management Directive 5.6 “Integrated Materials Performance Evaluation Program”
 - Various FSME Procedures

IMPEP

- Jointly developed by NRC and States
- Common process for review of Agreement State and NRC Regional material programs
- Focuses on performance outcome, not how performance is achieved
- Performance Findings and Root Causes
- Ratings for each indicator and overall performance

IMPEP

- Recommendations & Good Practices
- Routine on-site reviews normally conducted every 4 years
 - May be decreased based on program performance
- Independent review teams
- Reviews scaled to the size of the program
- Agreement State participation

Common Performance Indicators

- Technical Staffing and Training
- Status of Materials Inspection Program
- Technical Quality of Inspections
- Technical Quality of Licensing Actions
- Technical Quality of Incident and Allegation Activities

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented
- Qualification criteria for hiring new technical staff are established and are being followed
- Vacancies are filled in a timely manner
- There is a balance in staffing between the licensing and inspection programs
- Management is committed to staff training and qualification
- License reviewers and inspectors are adequately trained and qualified to perform their duties

Status of Materials Inspection Program

- Routine inspections for highest hazard licensees, scheduled at 1-, 2-, or 3-year intervals, completed within 25% window
 - One year for inspections of new licensees.
- Inspection frequencies are at least as strict as those set in NRC guidance
- Inspection correspondence is dispatched to licensees in a timely manner
- 20% of “candidate” reciprocity licensees are inspected annually
- Timely security inspections of affected licensees

Technical Quality of Inspections

- Inspections of licensed activities are focused on health, safety, and security issues; address previously identified open items and/or past violations
- Procedures are in place and used to help identify root causes and licensee performance weaknesses
- Inspection findings lead to appropriate and prompt regulatory action
- Supervisors conduct annual accompaniments of each inspector
- Inspector accompaniments by review team

Technical Quality of Licensing Actions

- License reviews are thorough, complete, consistent, and of acceptable technical quality
- Verify that essential elements of license applications have been submitted and meet current regulatory guidance
- Health, safety, and security issues are properly addressed
- Appropriateness of tie-down conditions
- Financial assurance
- Pre-licensing checks

Technical Quality of Incident and Allegation Activities

- Actions taken are appropriate, well-coordinated, timely, and health and safety issues are addressed
- Corrective actions and followup measures are appropriate, include root cause analysis, and receive an independent review
- Proper notification and reporting of incidents

Non-Common Performance Indicators

- Compatibility Requirements
- Sealed Source and Device (SS&D) Evaluation Program
- Low-Level Radioactive Waste (LLRW) Disposal Program
- Uranium Recovery Program

Compatibility Requirements

- Applies only to Agreement States
- Ensure that collective national effort to regulate materials under the Atomic Energy Act is coherent and without:
 - Conflicts, gaps or duplication
- Ensure certain areas (standards, definitions, and “transboundary” elements) are identical

SS&D Evaluation Program

- Applies to NRC and Agreement States
- Adequate technical evaluations of SS&Ds
- Three subelements:
 - Technical Staffing and Training
 - Technical Quality of the Product Evaluation Program
 - Evaluation of Defects and Incidents Regarding SS&Ds

LLRW Disposal Program

- Agreement States only
- Five subelements
 - Same as Common Performance Indicators but focusing on LLRW activities

Uranium Recovery Program

- NRC Region IV or Agreement State
- Five subelements
 - Same as Common Performance Indicators but focusing on uranium recovery activities

Management Review Board (MRB)

- Independent board that makes final determination of adequacy and compatibility based on IMPEP team's report and information presented by Region or State.
- MRB Members:
 - Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs
 - General Counsel
 - Director, FSME
 - NRC Regional Representative
 - Agreement State Liaison

MRB Meeting

- Open to the Public
- Team presents findings based on objective assessment against IMPEP criteria
- Team recommends rating for each performance indicator reviewed
 - Satisfactory
 - Satisfactory, but needs improvement
 - Unsatisfactory

MRB Meeting

- Overall program findings
 - Adequate; Adequate, but needs improvement; or Inadequate
 - Compatible or Not compatible
- Recommendations and Good Practices
- Timing of next review/interaction
- Lessons learned, precedents, IMPEP experience

Periodic Meetings Between IMPEP Reviews

- Sharing of information between NRC and the States
- Early discussion and identification of Program strengths and weaknesses
- Results presented to MRB
- MRB may direct corrective measures to address weaknesses affecting performance (e.g., staffing shortage, inspection backlogs)

Assessing State Program Improvement

- Mechanisms to address State program areas needing improvement:
 - Monitoring
 - Heightened Oversight
 - Probation
 - Emergency Suspension
 - Suspension
 - Termination

Monitoring

- An informal process to maintain increased communications with a State
- Can be considered based on IMPEP review, followup review, or periodic meeting
- Requires an action plan and quarterly conference calls

Heightened Oversight

- A formal process to maintain increased communications and to assess State performance improvements
- Can be considered based on IMPEP review, followup review, or periodic meeting
- Requires a Program Improvement Plan, bimonthly calls, and a followup review approx. 1 year later.

Other Methods

- Probation
- Emergency Suspension
- Suspension
- Termination



SUCCESSFUL AGREEMENT STATE STRATEGIES



Organization

- Centralized radiation control program
 - “Functional” distribution of responsibilities can be successful, but it requires a lot of coordination.
- “Visible” to senior management to ensure adequate oversight and support

Funding

- Dedicated fund
 - Licensing fees go directly into special account and bypass general treasury
 - Provides more flexibility for short- and-long term planning
- States' fees are typically less than NRC fees
 - Creates licensee support for Agreement
- Some States have “tied” their fees to NRC fees
 - Usually at a certain percentage (e.g., 75%)

Funding

- Some States will charge for individual inspections and licensing actions (previous NRC method)
 - Generally flat fee for routine activities with charges for special or followup activities
- Monetary civil penalties
- Special or specific funding of program prior to the Agreement to fund additional staff and training
- DHS and CDC bio-terrorism funds for radiation positions

Staffing

- Guidance in FSME Procedure SA-700
- General recommendation for licensing and inspecting: 1-1.5 FTE/100 Licenses
 - Must also take into consideration event response, rulemaking, special programs, and administration
- Similar-sized programs typically have 5-6 technical FTE plus management and administrative support

Retention/Succession Planning

- Salaries must be comparable to competing private industries and government agencies.
- “Career Ladder”
- Many retirements in the radiation protection field; best to be prepared to address attrition
- When developing staffing plan, have 1-2 “training” positions to always have people in the qualification process to counteract attrition



Information Management

- Computer databases to maintain licensing and inspection information
- Electronic licensing/inspection correspondence templates
- Event tracking software, such as the Nuclear Material Events Database (NMED)

Information Management

- License file system; protection of sensitive license info (ex. Financial Assurance and Increased Controls)
- FUTURE: National Source Tracking System and Web-Based Licensing
- Helps to have expertise on staff or available to satisfy information management needs

Quality Assurance

- Peer/management review of regulatory actions
- Periodic self-audits
 - Use IMPEP criteria in Management Directive 5.6
- Cooperative peer review agreement with neighboring program

Regulations

- 6- or 12-month regulatory process helps in timely adoption
- Best to stay ahead of the game
 - Track status using State Regulation Status sheet available on FSME website
- Adoption by reference