Overall Pilot Project Activities

Shawn R. Smith

NRC/Office of State and Tribal Program

Major Pilot Project Milestones

- Chairs Selected
- Implementation Plan Developed
- Working Groups Established
- Charters and Work Product Plans Developed

Project Management

NRC/Office of State and Tribal Programs

- Planning, Coordination, and Logistics
- Tracking Assignments
- Maintaining Information Infrastructure
- Funding for travel and per diem of State member on the working groups

Pilot Project One

- Lead Organization: NRC/Office of State and Tribal Programs (STP)
- Goal: To have Agreement States involved in establishing materials priorities for the development.

Pilot Project Two

- Lead Organization: The Conference of Radiation Control Program Directors, (CRCPD)
- Goal: To have Agreement State/CRCPD take lead responsibility for administration of a national radiographer safety certification program.

Pilot Project Three

- Lead Organization: NRC/Office of Nuclear Material Safety and Safeguards (NMSS)
- Goal: To develop and test a structured process for evaluating cumulative licensee data and performance.

Pilot Project Four

- Lead Organization: The Organization of Agreement States (OAS)
- Goal: To have an Agreement State assume the responsibility for development of licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved.

Pilot Project Five

- Lead Organization: NRC/Office of Nuclear Material Safety and Safeguards (NMSS)
- Goal: To revise IMC 2800 and its associated non-medical Inspection Procedures and Temporary Instruction.

National Materials Program Pilot Project One

The Establishment of Priorities

Co-Chairs: Shawn R. Smith
Ruth McBurney

Pilot One Working Group Members

Co-Chairs:

- Shawn R. Smith — NRC STP
- Ruth E. McBurney — TX Dept. of Health

Members:

- Kimberly Farrell — NRC OCFO
- Jayne Halvorsen — NRC NMSS
- James Lynch — NRC Region III
- Anita Turner — NRC NMSS
- Robert Walker — MA Dept. of Public Health

Alliance

A cooperative process between the Agreement States and NRC that identifies radiation safety regulatory priorities and the means to address those priorities

Purpose

- Develop a process to identify and prioritize regulatory items
- Ensure that both Agreement State and NRC regulatory needs are considered in the establishment of national priorities
- Demonstrate shared decision-making between NRC and Agreement States

Work Products

- A national priority list agreed upon by both NRC and Agreement States
- A framework and process that NRC and the Agreement States could use to prioritize regulatory needs in a National Materials Program under the Alliance Option

Development of National Priority List

- Obtained and analyzed input on a list of regulatory needs
- Developed prioritization package
- Developed evaluation strategy
- Analyzed the results
- Produced prioritized list of needs

Pilot Process

- Collected regulatory needs from NRC headquarters and regional offices and from Agreement States
- Developed list of needs for prioritization
- Developed prioritization worksheet
  - Based on performance goals
  - Levels of priority: high, medium, low and not applicable

Pilot Process (continued)

- NRC offices and Agreement State Program Directors completed prioritization worksheets
- Results converted to numerical values for statistical analysis
- Generated the following based on analysis:
  - Prioritized list based on overall level of priority
  - Priority matrix with respect to performance goals
  - Prioritized list based on performance goals

Pilot Process
(continued)

- Compared list based on overall need to list based on performance goals
- Compared top ten needs from NRC and Agreement States separately to combined list

Development of Prioritization Framework and Process

- Alliance Groups identified and roles defined
- Process developed for
  - Prioritization of regulatory needs
  - Establishment of regulatory agenda
  - Definition of specific work products

Groups within the Alliance

- Priorities Committee
- Steering Committee
- Administrative Core

Priorities Committee

- Composed of NRC and Agreement States
- Develops and provides recommendations
- Members will serve for identified staggered terms
- Convenes twice annually for a prioritization process meeting

Steering Committee

- Composed of NRC Management and the Chairs of OAS and CRCPD
- Provides management oversight of the Alliance process
- Makes decisions on regulatory efforts

Administrative Core

- Supported by STP
- Provides administrative and logistical support
- Tracks assignments and products
- Maintains Information Infrastructure

Prioritization Process

- STEP 1:

  Regulatory needs are identified by the Agreement States and NRC and communicated to the Priorities Committee.

Prioritization Process

- STEP 2:

  Priorities Committee analyzes the identified regulatory needs and develops and maintains a database of regulatory needs.

Prioritization Process

- STEP 3:

  Priorities Committee seeks input annually from Agreement States and NRC.

Prioritization Process

- STEP 4:

  Priorities Committee evaluates the input on priorities for regulatory needs and makes recommendations to the Steering Committee.

Prioritization Process

- STEP 5:

  Steering Committee establishes the regulatory agenda, defines specific work products, and commits appropriate NRC and/or Agreement State resources.

Next Steps

- Constitute Steering Committee and Administrative Core
- Research 2 regulatory needs identified in prioritized list
- Complete Test of Proposed Prioritization Process
- Issue final report in September 2004

National Materials Program Pilot Project Two

National Industrial Radiographer Safety Certification Program

Chair: Jan Endahl

What was our charge?

- CRCPD serves as the lead organization for oversight of a national industrial radiographer safety certification program
  - Review requests for recognition as certifying entities
  - Review program changes
  - Make recommendations for program evaluations

Why is a national IR safety certification program important?

To Ensure…

- Efficient use of resources and expertise
- Comparable programs
- Uniform acceptance of certification cards
- Integrity of the certification programs

What we did and how we did it…

- Created process flow charts
- Formalized review criteria
- Tested the criteria
- Solicited comments

We learned…

- Early communication is important
- Present criteria and process are adequate for:
  - identifying key program elements
  - outlining necessary procedures
  - assessing minimum requirements
  - reviewing programs for uniformity

We recommend…

- Making rulemaking, administrative and procedural improvements
- Establishing protocols for uniform sharing of information
- Evaluating certification programs

What’s next?

National Materials Program Pilot Project 3

Operating Experience Evaluation

Co-Chairs: Marcia Howard

Michael Markley

PILOT FOCUS

- Initial focus on event evaluation for possible generic implications and additional regulatory action
- Focus on operating experience evaluation for integrated NRC and Agreement State (AS) review, assessment, and decision-making processes
- Increase partnering and integrated decision making

USE OF OPERATING EXPERIENCE INFORMATION

- Domestic and foreign event data
- Inspections, special studies, and generic reviews
- Industry-wide analyses
- Risk insights and metrics
- Performance indicators
- Feedback for regulatory action

SCOPE OF WORK

- How operating experience information can be better communicated between NRC and Agreement States?
- How can operating experience information and trending optimize resource utilization?
- How can risk insights be better integrated into regulatory decision making?

PILOT ACTIVITIES

- Examined incident and working group reports
- Conducted interviews/questionnaires of managers, inspectors, and reviewers
- Test cases:
  - Intravascular brachytherapy
  - Portable gauges

ISSUES AND OPTIONS

ISSUE 1: COMMUNICATION

- Many things done well
- Common use of terminology
- Timely dissemination

- OPTIONS:
  - Use of electronic media
  - Central clearinghouse
  - Communication plans
  - Ready-to-use products

ISSUES AND OPTIONS

ISSUE 2: PARTICIPATION

- Conducted with existing resources
- Increase decision-oriented activities

- OPTIONS:
  - NRC/AS Roundtable
  - Counterpart Meetings
  - Agency Action Review Meeting (AARM)
  - Meeting participation via teleconference
  - Outreach activities

ISSUES AND OPTIONS

ISSUE 3 : DATA EVALUATION AND TRENDING

- Nuclear Materials Events Database (NMED)
- Sealed Source and Devise Registry (SSDR)

- OPTIONS:
  - Enhance NMED usefulness as tool for communicating studies and trending
  - Update on failures and malfunctions
  - Incorporate use of risk guidelines

ISSUES AND OPTIONS

ISSUE 4: GENERIC COMMUNICATIONS

- NRC Bulletins and Generic Letters are rare
- Issue mostly Information Notices and Regulatory Issue Summaries
- NMSS Newsletter

- OPTIONS:
  - Reexamine thresholds and follow-up
  - Update guidance and communications
  - Conduct self-assessment

ISSUES AND OPTIONS

ISSUE 5: USE OF RISK INFORMATION

- Guidance and training: work-in-progress
- Resource utilization

- OPTIONS:
  - Procedural rather than tutorial
  - User-friendly products concisely identify risks
  - Communication plans
  - Licensees address vulnerabilities

ISSUES AND OPTIONS

ISSUE 6: CONSISTENCY

- 4 NRC Regions
- 33 Agreement States

- OPTIONS:
  - Clearinghouse
  - Quality assessments
  - Timely and effective closure of deficiencies
  - Budgeting for relationship-building participation

WORKING GROUP MEMBERS

- Marcia Howard, Ohio (Co-chair)
  mhoward@gw.odh.state.oh.us
- Michael Markley, NRC/IMNS (Co-chair)
  mtm@nrc.gov
- Debbie Gilley, Florida
- Duncan White, NRC/RI

National Materials Program
Pilot Project Four

State Guidance Development

Chair: Robert Gallaghar

What is our charge?

- Develop licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved by the NRC and Agreement States

Why is this important?

- Provide Efficiency Gains For All Programs…
- Development by a single program will eliminate need for each program to “go it alone” in the creation of such guidance
- Resulting product consists of a set of licensing guidance which all programs could use in the review of applications to authorize the new use or modality

Pilot Four Working Group Members

Chair:

- Robert Gallaghar — Massachusetts Dept. of Public Health

Members:

- Debbie Gilley — Florida Dept. of Health
- Eric Jameson — Georgia Dept. of Natural Resources
- Gibb Vinson — Illinois Emergency Management Agency
- Cassandra Frazier — NRC Region III

How we chose the new medical use of material?

We…

- Reviewed regulatory needs analyzed by Pilot Project One
- Surveyed Agreement States, and NRC Headquarter and Regional Offices
- Surveyed major medical institutions in the United States

What medical use have we chosen and why?

I-125 seed localization of non-palpable breast lesions

- Iodine-125 is an AEA material
- Use fits into 10 CFR 35.1000 or equivalent state regulations
- NRC and Agreement State review has not been performed

Path Forward

- Draft Work Product available for comment
  - May 14, 2004
- Draft Pilot Project Report
  - September 2004

National Materials Program Pilot Project 5

Revised Inspection Manual Chapter 2800, Materials Inspection Program, and the associated routine inspection procedures

Chair: Thomas Young

Basis for Revised Inspection Manual Chapter (IMC) 2800

- Mallinckrodt Lessons Learned Task Group Report—Phase I (November 2000)
- Phase II Byproduct Material Review (August 2001)

Phase II Recommendations for IMC 2800

The following were selected as “quick hits”:

- Revise inspection priorities
- Empower inspectors
- Streamline inspection preparation
- Revise initial inspections
- Revise field office inspections
- Expand the use of NRC Form 591

Seven Risk-Informed Focus Elements

1) Security and control of licensed material
2) Shielding of licensed material
3) Comprehensive safety measures
4) Radiation dosimetry program
5) Radiation instrumentation and surveys
6) Radiation safety training and practices
7) Management oversight

Impact to the Inspection Process

- Inspection remains a performance-based evaluation of licensee activities
- Changes in preparation and documentation of inspections
- 14 percent FTE reduction overall for the materials inspection program

Revised Materials Inspection Program--Completion Steps

- 2002-03, NRC field testing
  - Revised IMC 2800
  - 12 Inspection Procedures (IPs)
  - Preliminary Analyses
- 2003
  - Summer, Final Analysis
  - Fall, Final Versions of IMC 2800 and 12 IPs
- 2004
  - NMP-Pilot Project Final Report