



# Managing to Outcomes

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# NRC Strategic Objective

Enable the use and management of radioactive materials and nuclear fuels for beneficial civilian purposes in a manner that protects public health and safety and the environment, promotes the security of our nation, and provides for regulatory actions that are open, effective, efficient, realistic, and timely.



# Reaching the Objective

- Regulations and Standards
- Licensing
- Inspection
- Enforcement
- Setting Goals and Measuring Outcomes



# Safety Outcomes & Measures

Performance monitored and measured through use of graded approach

- Strategic Outcomes
- Performance Measures
- Abnormal Occurrence Criteria
- Reporting requirements/precursor metrics

Significant adverse trends are identified

Individual licensees with performance issues are identified



# Strategic Outcomes

- Very high thresholds
  - No deaths resulting from acute radiation exposures
  - No inadvertent criticality events
  - No releases of radioactive materials that result in significant radiation exposures
  - No releases of radioactive materials that cause significant adverse environmental impacts
- No events that met these thresholds between FY 2001- 2005



# Performance Measures

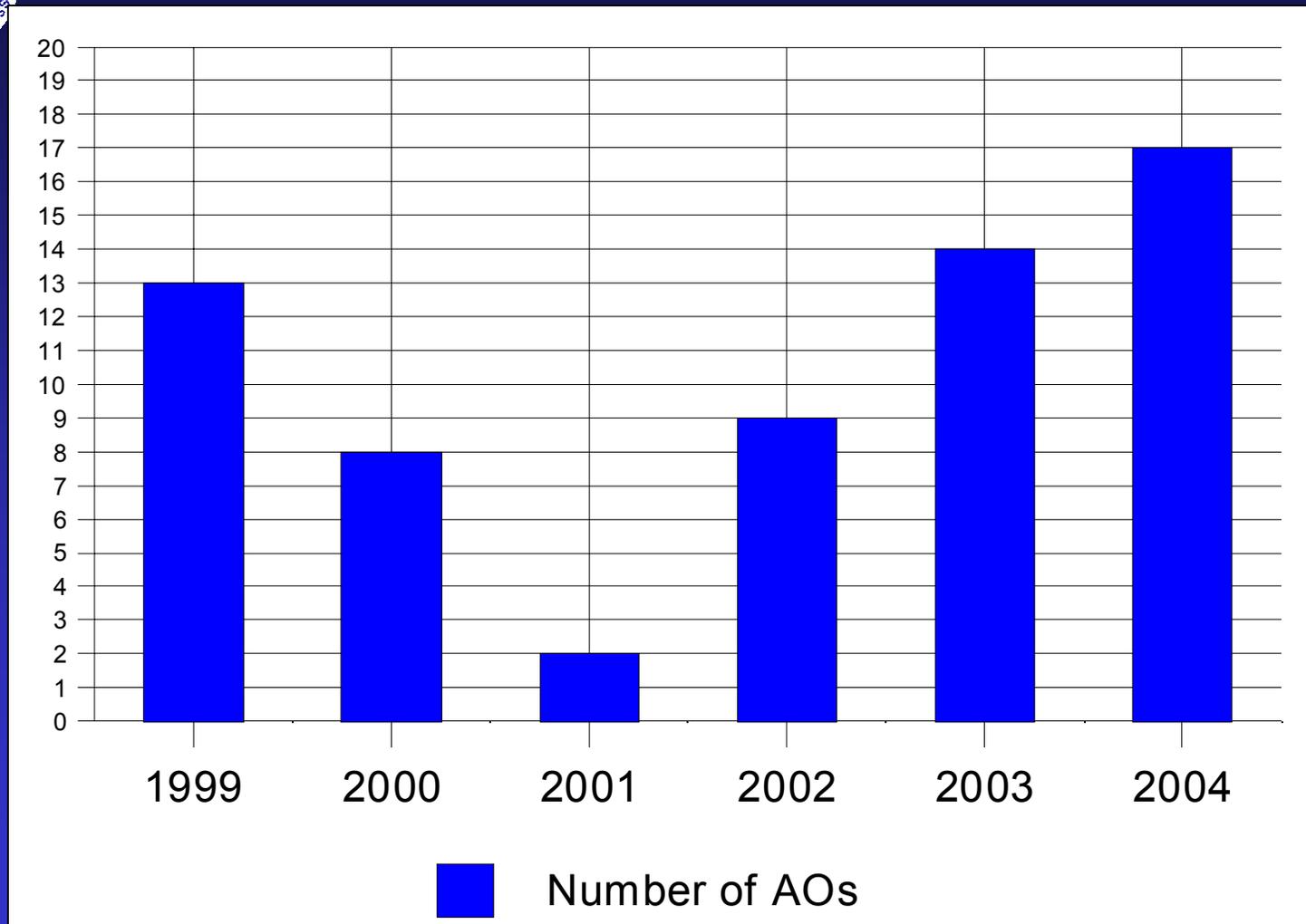
- Zero unrecovered losses or thefts of risk-significant radioactive sources (0 in 2005)
- Not more than five releases to the environment that exceed regulatory limits (0 releases in 2005)
- Less than 6 radiation exposures to the public and occupational workers that exceed the Abnormal Occurrence criteria for human exposure (1 exposure in 2005)



# Abnormal Occurrences

- A higher level threshold to measure more significant events
- Only a few events that meet AO criteria (10 potential events in FY 2005, 6-year average prior to 2005 is 10.5 events per year)
- No significant trends identified

# ABNORMAL OCCURRENCES FISCAL YEARS 1999 - 2004



# Reportable Events/Precursor



- Less than 2.5 total events per 100 licensees per year that meet reporting requirements
  - Average 515 events per year
  - Estimated 21,609 total NRC and Agreement State licensees\*
- Further Perspective: even lower rate of occurrence if equated to the number of actual uses/procedures performed per year by these licensees

\* Based on 21,609 materials licensees (4,500 NRC and 17,109 Agreement State). See 2004 NRC Information Digest (NUREG-1350).



# Examples of Actions Taken

- Radiography source cable failures. Report issued and licensees notified – no further events of this kind.
- Intra-Vascular Brachytherapy misadministrations (medical events). Modifications were made to the licensing requirements for these devices to address the root causes. The result has been a reduced number of these events.
- High frequency of lost or stolen portable gauges. In this case the result was a change in the regulations, requiring additional securing of gauges. Too early to evaluate impact.



# Conclusions

- Safety measures have many uses for a regulator
  - Spotting negative industry trends and individual licensees with performance problems
  - Helping to identify areas where regulatory action such as rulemaking may be needed
  - Helping the regulator identify internal areas for improvement
- Standards alone are not enough, we must ensure they are effective by measuring outcomes and taking action when necessary.
- Safety measures must be continually re-evaluated to ensure they are appropriately sensitive



# Threshold Definitions

## Regulatory Release Limits

This performance measure is defined as any release that exceeds applicable regulations as defined in 10 CFR 20.2203(a)(3) and requires a 30 day written report i.e., any release that results in concentrations of radioactive material that exceeds 10 times any applicable limit in 10 CFR Part 20.



# Threshold Definitions

- Abnormal Occurrence Criteria
  - Exposure Examples: Annual dose (TEDE) greater than 250 mSv or 2,500 mSv to an individual organ other than the lens of the eye bone marrow or gonads.
  - Medical Event Examples:  $> 1$  Gy to major portion of bone marrow, lens of the eye, or gonads or  $> 10$  Gy to any other organ; and either a dose 50% greater than prescribed or is the wrong pharmaceutical.