Getting to the Root Causes of Non-Compliance: A Prescription for Prevention

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Objectives

➢ To emphasize how stakeholders *really* evaluate radiation safety programs and the important role compliance plays in this assessment

➢ To *objectively* identify the common violations issued to permit holders in Texas

➢ Show how this data can be put to use for *prevention* by identifying the root causes of non-compliance

➢ Make you an offer you *can’t* refuse!
Health and Safety Outcome Measures

- **Systemic:** ultimate program outcomes
  - ✔ number of injuries, illnesses, fatalities
  - ✔ OSHA 200 log or equivalent

- **Organic:** indicators of program design and implementation
  - ✔ numbers of unsafe conditions, practices, behaviors, attitudes
  - ✔ regulatory compliance
A Word About Inspections
(to the regulated community)

- The public and the radiation safety profession benefit from the compliance inspection process.
- These works are intended to make permit holders aware of the common deficiencies, so they can be avoided.
- This should not be done to the exclusion of other important safety tasks!
Licensees: Top Ten Violations 1988-1997

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Total†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Absent surveys</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Leak testing</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Personnel monitoring</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>Instrument calibration</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>Inventories</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Transfer records</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Disposal records</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Main program</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td><strong>Total†</strong></td>
<td><strong>65%</strong></td>
<td></td>
</tr>
</tbody>
</table>

†Annual Top Ten Varied from 55% to 75% of all NOVs
Licensee: Top Ten Violations By Year 1988-1997

Percent of All Violations Issued

- Procedures
- Surveys Not Done
- Leak Tests Not Done
- Monitoring Records
- Calibration Exceeded
- Inventory/Use Log
- Transfer Records
- Surveys/Disposal Records
- Inspec./Main. Not Done
- Training

Percentages:
- 25.0%
- 20.0%
- 15.0%
- 10.0%
- 5.0%
- 0.0%
Licensee NOV’s by Regulatory Citation: 25 TAC 289

<table>
<thead>
<tr>
<th>Act</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>202(e)</td>
<td>Radiation protection program</td>
<td>17%</td>
</tr>
<tr>
<td>201(g)</td>
<td>Sealed source leak test</td>
<td>16%</td>
</tr>
<tr>
<td>202(p)</td>
<td>Surveys and monitoring</td>
<td>11%</td>
</tr>
<tr>
<td>201(o)</td>
<td>General public dose limits</td>
<td>8%</td>
</tr>
<tr>
<td>201(d)</td>
<td>Receipt, transfer, disposal records</td>
<td>8%</td>
</tr>
</tbody>
</table>

» Top five account for 60% of total, based on 1999 data.
Licensee Violations
Severity Level Distribution
1988-1997

Severity Level I: 1%
Severity Level II: 2%
Severity Level III: 21%
Severity Level IV: 72%
Severity Level V: 4%
Figure 2: Summary of overexposure and total incidents reported to the Texas Department of Health, Bureau of Radiation Control from 1988 to 1997.

- Overexposure
- Total Incidents

1994 - Revision of regulations
Educational Value

Figure 1: Dose irregularities, misadministrations, and total misapplication events reported in Texas from 1988 to 1997 (n=355).
Educational Value

Summary of reported misadministrations and dose irregularities from 1988 to 1997 in Texas by radionuclide (n=365).

Other includes: I-125, Co-57, Au-198, P-32, Sr-89.
Summary of reported misadministrations and dose irregularities from 1988 to 1997 by application process variable (n=355).

- Compound: 44%
- Patient: 14%
- Activity: 11%
- Radionuclide: 10%
- Study: 9%
- Quality: 9%
- Other: 3%
What Does All This Cost?

- Estimating the administrative cost to the BRC associated with the issuance of violations:
  - baseline cost of inspection process
  - some added cost to issue and resolve NOV’s
  - if this added cost could be estimated, then reductions through education could be quantified

- Cost to the permit holders not included, but equally important
Estimating the Cost

- $100,000.00
- $90,000.00
- $80,000.00
- $70,000.00
- $60,000.00
- $50,000.00
- $40,000.00
- $30,000.00
- $20,000.00
- $10,000.00
- $0.00

Diagram:
- Derived Administrative Costs
- Number of Violations
- R² = 0.8014
- Registrants
- Licensees
The EU (Emery Unit)!
Administrative dollars per NOV saved, at STP
The Next Step: Root Cause Analysis

**Ex: Sealed Source Leak Test NOV**

- **Problem**
  - Done or not done
  - Ever? Or not at proscribed frequency?
  - Time frame based on permit condition or regulation?
  - Documentation incomplete?
  - Found leaking, but not reported?

- **Root Cause**
  - Failure to execute
  - Frequency
  - Violation of regulation or permit condition
  - Completeness
  - Inappropriate actions
Fault Tree Analysis: Sealed Source Leak Test NOV
Fault Tree Analysis:
Sealed Source Leak Test NOV

VIOLATION OF REGULATION

OR

FAILURE TO EXECUTE

DOCUMENTATION

FREQUENCY

ACTIONS

OR

TASK NOT PERFORMED

PERFORMED BUT NOT DOCUMENTED

PERFORMED DOCUMENTED/ INCORRECTLY DOCUMENTED

PERFORMED REQUIRED FREQUENCY

FOUND LEAKING: NOT POSTED OR TAKEN OUT OF SERVICE

FOUND LEAKING: AUTHORITIES NOT NOTIFIED
Results of Analysis

- Failure to execute 34%
- Failure to execute and frequency 43%
- Failure to execute and completeness 7%
- Failure to execute and inappropriate actions 7%
- Inappropriate actions only 5%
- Other only 2%
- Other 7%

Total 93%
Implications

➢ Consider the findings within the context of the regulator’s common plea: read your permit!
   ✓ Do the permit holders really know what they are supposed to do?

➢ What can be done to improve compliance?
   ✓ create summaries of requirements inherent to permits and their identified regulations?
   ✓ modify the way RSO’s are trained?
   ✓ re-structure permit inspection process?
What About Other States?

- Are the trends shown here consistent?
- Are the root causes consistent?
- Could there be some basic, simple interventions?
To facilitate comparisons, *here’s the deal*: 

- Identify number of licensees and average number of NOV’s per permit inspection.
- We’ll calculate an appropriate sample size and sampling strategy.
- You get the coding forms completed.
- “We” (grad student) will summarize and analyze as their research project.
- Findings provided to you and OAS.
We Need to Stress That We’re All in the Same Pool!

- By any measure, the radiation safety record is excellent!
- This success is due in part to the inspection process: hate it or love it, it benefits all.
- NOV outcome data can be valuable for prevention
- Emphasize the common goal and work together to achieve it!
References


