

Use of Risk Information in the Nuclear Materials Regulatory Process

Case Studies in Gas Chromatographs, Static Eliminators and Fixed Gauges



Stakeholder Meeting

February 9, 2001
U. S. Nuclear Regulatory Commission
Rockville, Maryland

Opening Remarks



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Agenda

- Opening Remarks
- Overview
- Gas Chromatographs
- Static Eliminators
- Fixed Gauges
- General Comments
- Closing Remarks

Background and Overview



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SECY 99-100

- Framework for risk-informed regulation
- 5-step process
 - ▶ Identify
 - ▶ Decide how to modify regulatory approaches
 - ▶ Change regulatory approaches
 - ▶ Implement risk-informed approaches
 - ▶ Develop or adapt risk-informed tools

SRM on SECY 99-100

- Commission approved staff's proposal
- Directed staff to:
 - ▶ Develop appropriate material and waste safety goals
 - ▶ Use an enhanced participatory process

April 2000 Workshop

- Developed draft Screening Criteria
- Consensus to use a Case Study approach

Why the Case Study Approach

- Show what has been and what could be done
- Test the draft Screening Criteria
- Find safety goals

Case Study Plan

- Developed by Risk Task Group and NMSS Risk Steering Group
- Presented to stakeholders on September 21
- Issued on October 27, 2000

Screening Criteria

1. Resolve a question with respect to maintaining or improving the activity's safety?
2. Improve the efficiency or the effectiveness of the NRC regulatory approach?
3. Reduce unnecessary regulatory burden?
4. Help to effectively communicate a regulatory decision or situation?

➡ *If YES to any of the above, proceed to additional criteria; if NO to all, the activity is screened out.*

Screening Criteria (continued)

5. Do information (data) and analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

➡ *If the answer to criterion 5 is YES, proceed to additional criteria; if NO, the activity is screened out.*

Screening Criteria (continued)

6. Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit?

➡ *If the answer to criterion 6 is YES, proceed to additional criteria; if NO, the activity is screened out.*

Screening Criteria (continued)

7. Do other factors exist (e.g., legislative, judicial, adverse stakeholder reaction) which would preclude changing the regulatory approach in an area and, therefore, limit the utility of implementing a risk-informed approach?

➡ *If the answer to criterion 7 is NO, a risk-informed approach may be implemented; if the answer is YES, the activity may be given additional consideration or be screened out.*

Case Study Areas

- Gas Chromatographs ✓
- Static Eliminators ✓
- Fixed Gauges ✓
- Site Decommissioning
- Radioactive Material Transportation
- Uranium Recovery
- Part 76
- Spent Fuel Interim Storage

Case Study Questions

- Screen Criteria Analysis Questions ✓
- Safety Goal Analysis Question
- Questions Upon Developing Draft Safety Goals

Schedule

For Gas Chromatographs, Static Eliminators, and Fixed Gauges

- Issue draft reports for comment - Spring 2001
- Second stakeholder meeting - Summer 2001
- Issue final case study reports - Late Summer 2001

Case Study in Gas Chromatographs



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Gas Chromatographs

Screening Criteria/Risk Analysis Questions

1. What risk information is currently available in this area? (Have any specific risk studies been done?)

- NUREG/CR-6642
- Draft NUREG-1717
- Applicants for a specific license to manufacture or initially transfer GC's for use under 10 CFR 31.5 must show that the GC meets 10 CFR 32.51

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

2. What is the quality of the study? (Is it of sufficient quality to support decision-making?)
 - NUREG 6642, draft NUREG 1717, and the individual sealed source and device registration certificates should be of sufficient quality to support decision-making

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

3. What additional studies would be needed to support decision-making and at what cost?

■ None

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

4. How is/was risk information used and considered by the NRC and licensee in this area?
- SS&D reviews have been used to determine that sources and devices pose little risk
 - NUREG-1717 has not been finalized
 - NUREG/CR-6642 has not been used in decision-making; could be used to propose that these devices be manufactured and distributed under an exemption similar to 10 CFR 32.22, by meeting the safety criteria in 10 CFR 32.23

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

5. What is the societal benefit of this regulated activity?
- In industrial and laboratory settings, to detect small amounts of organic compounds
 - In the military, as chemical agent monitors and explosive detectors
 - In forensics, to determine time and cause of death

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

6. What is the public perception/acceptance of risk in this area?

■ None

Gas Chromatographs

Screening Criteria/Risk Analysis Questions

7. What was the outcome when this application was put through the draft screening criteria? Did this application pass any of the screening criteria? Does the outcome seem reasonable? Why or why not?
- Passes all of the screening criteria with the possible exception of Criterion 7

Application of Draft Screening Criteria

Gas Chromatographs

- | | |
|--|-----|
| 1. Resolve a question with respect safety? | YES |
| 2. Improve efficiency or effectiveness? | YES |
| 3. Reduce unnecessary regulatory burden? | YES |
| 4. Help to effectively communicate a decision? | YES |

➡ *If YES to any of the above, proceed*

Application of Draft Screening Criteria

Gas Chromatographs

5. Do information and analytical models exist that are of sufficient quality or could they be reasonably developed ...?

YES

➡ *If YES, proceed*

Application of Draft Screening Criteria

Gas Chromatographs

6. Can startup of a risk-informed approach be realized at a reasonable cost ...?

YES

➡ *If YES, proceed*

Application of Screening Criteria

Gas Chromatographs

7. Do other factors exist which would preclude changing the regulatory approach ...?

UNKNOWN

➡ *If NO, a risk-informed approach may be implemented; if YES, activity may be given additional consideration or screened out.*

Gas Chromatographs

Safety Goal Analysis Questions

1. What is the basis for the current regulations in this area ...?

- To exempt materials or to issue general licenses, the quantities of material must not constitute an unreasonable risk to common defense and security and to health and safety of the public (Section 81. Domestic Distribution, Atomic Energy Act of 1954)

Gas Chromatographs

Safety Goal Analysis Questions

2. Are there any explicit safety goals or implicit safety goals embedded in the regulations ...?
 - Explicitly, manufacturers must comply with 10 CFR 30.32(g), 32.210, 32.51, and 31.5(6)
 - Safety criteria in 32.23, related to the exemption under 32.22, contain implied safety goals with respect to consequences and probability of occurrence

Gas Chromatographs

Safety Goal Analysis Questions

3. What was the basis for the development of the strategic goals ...? How would they relate to safety goals ...?

- 10 CFR 30.33(a)(2)
- 10 CFR 20.1801 and 20.1802

Gas Chromatographs

Safety Goal Analysis Questions

4. Are there any safety goals, limits, or other criteria implied by decisions or evaluations that have been made ...?
- Generically, Section 81 of the Atomic Energy Act of 1954
 - Specifically, see answer to Safety Goal Analysis question 2

Gas Chromatographs

Safety Goal Analysis Questions

5. If safety goals were to be developed in this area, would tools/data be available for measurement?
- Yes, NMED data lists incidence of leaking sources over the past eight years.
 - With radiological hazards information from these incidents and the methodologies in NUREG 6642 and radiological assessments in draft NUREG 1717, the magnitude of the risk could be determined for decision-making purposes

Gas Chromatographs Safety Goal Analysis Questions

6. Who are/were the populations at risk?

- Licensees (approx. 160) and their employees
- Manufacturers, servicers of sources and devices
- Individuals involved in the transport of the device
- Individuals involved in the disposal of the device

Gas Chromatographs

Safety Goal Analysis Questions

7. What are/were, and what could be/have been, the various consequences to the populations at risk?
- Draft NUREG-1717, for accidents and misuse scenarios, assumes up to 10 times the rate normally experienced in leaking source
 - Highest dose would be to users of the device
 - ▶ 200 mrem for H-3 devices
 - ▶ 300 mrem for Ni-63 devices
 - Best estimates of expected doses under such conditions less than 100 mrem

Gas Chromatographs

Safety Goal Analysis Questions

8. What parameters should be considered for the safety goals ...?
- Need to address reliance on the linear-no-threshold model for latent fatalities
 - Acute effects are not plausible

Gas Chromatographs

Safety Goal Analysis Questions

9. On the basis of the answers to the questions above, would it be feasible to develop safety goals in this regulatory area?

Gas Chromatographs

Safety Goal Analysis Questions

10. What methods, data results, safety goals, or regulatory requirements would be necessary to make it possible to risk-inform similar cases?

Case Study in Static Eliminators



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Static Eliminators

- Types of Static Eliminators
- Radiological characteristics

Issue

- Manufacture, distribution regulated under Part 32
- Use regulated under Part 31 general license
- Can it be classified as exempt device?
- Will a risk-informed approach support this action?

Static Eliminators

Screening Criteria/Risk Analysis Questions

1. What risk information is currently available in this area? (Have any specific risk studies been done?)

- NUREG/CR-1775
- NCRP Report No. 95
- Draft NUREG-1717
- NUREG/CR-6642

Static Eliminators

Screening Criteria/Risk Analysis Questions

2. What is the quality of the study? (Is it of sufficient quality to support decision-making?)

- NUREG/CR-1775 may be outdated
- NCRP Report No. 95 may be outdated
- NUREG-1717
 - ▶ Worst case analyses
 - ▶ May not reflect current industry information
- NUREG/CR-6642
 - ▶ Limited information specific to static eliminators
 - ▶ May not reflect current industry information

Static Eliminators

Screening Criteria/Risk Analysis Questions

3. What additional studies would be needed to support decision-making and at what cost?
 - Compilation of current manufacturer information
 - Compilation of consequence analyses from recent studies
 - Develop realistic probabilistic risk assessment with quantification of uncertainties
 - Identify regulatory framework for moving from generally licensed to exempt

Static Eliminators

Screening Criteria/Risk Analysis Questions

4. How is/was risk information used and considered by the NRC and licensee in this area?
- Available information indicates that risks are low
 - Risk information has not been used directly in decision-making

Static Eliminators

Screening Criteria/Risk Analysis Questions

5. What is the societal benefit of this regulated activity?

- For reducing electric charge buildup on equipment and materials
- Commercial - printing, electronics, photographic, paint shops
- Consumer - photographic and phonographic
- Used in hazardous environments

Static Eliminators

Screening Criteria/Risk Analysis Questions

6. What is the public perception/acceptance of risk in this area?

- Limited use nationwide
- Minimal public awareness of static eliminators

Static Eliminators

Screening Criteria/Risk Analysis Questions

7. What was the outcome when this application was put through the draft screening criteria? Did this application pass any of the screening criteria? Does the outcome seem reasonable? Why or why not?
- Passes the screening criteria with the possible exception of Criterion 7

Application of Draft Screening Criteria

Static Eliminators

- | | |
|---|-----|
| 1. Resolve a question with respect safety? | NO |
| 2. Improve efficiency or effectiveness? | YES |
| 3. Reduce unnecessary regulatory burden? | YES |
| 4. Help to effectively communicate a decision ? | YES |

➡ *If YES to any of the above, proceed*

Application of Draft Screening Criteria

Static Eliminators

5. Do information and analytical models exist that are of sufficient quality or could they be reasonably developed ...?

YES

➡ *If YES, proceed*

Application of Draft Screening Criteria

Static Eliminators

6. Can startup of a risk-informed approach be realized at a reasonable cost ...?

YES

➡ *If YES, proceed*

Application of Screening Criteria

Static Eliminators

7. Do other factors exist which would preclude changing the regulatory approach ...?

UNKNOWN

➡ *If NO, a risk-informed approach may be implemented; if YES, activity may be given additional consideration or screened out.*

Case Study in Fixed Gauges



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Fixed Gauges

Brief Description

- Types of Gas Chromatographs
- Radiological Characteristics

Issue

- Inconsistent Regulatory Structure

Fixed Gauges

Screening Criteria/Risk Analysis Questions

1. What risk information is currently available in this area? (Have any specific risk studies been done?)

- NUREG/CR-6642
- NUREG-1669
- NUREG-1551
- PNNL-11905

Fixed Gauges

Screening Criteria/Risk Analysis Questions

2. What is the quality of the study? (Is it of sufficient quality to support decision-making?)

- **NUREG-1669**

- ▶ Focuses on gauges in the scrap/recycling stream only
- ▶ Insufficient data for an accurate assessment of risk

- **NUREG/CR-6642**

- ▶ Provides generic risk information about fixed gauges

- **PNNL-11905**

- ▶ Provides criteria for a useful study

Fixed Gauges

Screening Criteria/Risk Analysis Questions

3. What additional studies would be needed to support decision-making and at what cost?
 - Examine the design dose criteria of 10 CFR 32 and define “unlikely”
 - Complete surveys from NUREG-1669 to quantify risks from devices in scrap and recycling stream
 - Examine current device population

Fixed Gauges

Screening Criteria/Risk Analysis Questions

4. How is/was risk information used and considered by the NRC and licensee in this area?
- General License Registration Program uses criteria based on consequence analysis and professional judgement
 - Devices must pass a Sealed Source and Device Review.
 - Accidents that cause doses in excess of 10 CFR 32.24 criteria must be “unlikely”

Fixed Gauges

Screening Criteria/Risk Analysis Questions

5. What is the societal benefit of this regulated activity?
- Used in many industries to improve quality and lower cost of products
 - Used in areas inhospitable to humans, such as tanks or other dangerous locations
 - Use of gauges in hazardous locations may reduce immediate safety risk to workers at the facility

Fixed Gauges

Screening Criteria/Risk Analysis Questions

6. What is the public perception/acceptance of risk in this area?

- Public is generally unaware of devices
- Public concern over radioactive material in metals is increasing

Fixed Gauges

Screening Criteria/Risk Analysis Questions

7. What was the outcome when this application was put through the draft screening criteria? Did this application pass any of the screening criteria? Does the outcome seem reasonable? Why or why not?
- Passes some criteria, unclear on others

Application of Draft Screening Criteria

Fixed Gauges

- | | |
|---|------|
| 1. Resolve a question with respect safety? | YES |
| 2. Improve efficiency or effectiveness? | YES |
| 3. Reduce unnecessary regulatory burden? | YES* |
| 4. Help to effectively communicate a decision ? | NO |

➡ *If YES to any of the above, proceed*

* May increase requirements on more hazardous gauges

Application of Draft Screening Criteria

Fixed Gauges

5. Do information and analytical models exist that are of sufficient quality or could they be reasonably developed ...?

DATA LACKING IN MAY AREAS

➡ *If YES, proceed*

Application of Draft Screening Criteria

Fixed Gauges

6. Can startup of a risk-informed approach be realized at a reasonable cost ...?

UNCLEAR

➡ *If YES, proceed*

Application of Screening Criteria

Fixed Gauges

7. Do other factors exist which would preclude changing the regulatory approach ...?

UNCLEAR

➡ *If NO, a risk-informed approach may be implemented; if YES, activity may be given additional consideration or screened out.*

Schedule

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