Regulatory Analysis

Advanced Reactors and Regulatory Effectiveness Assessment Branch

Division of Systems Analysis and Regulatory Effectiveness

Office of Nuclear Regulatory Research

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Principal NRC Guidance

- **Regulatory Analysis Guidelines – NUREG/BR-0058 (Rev. 3, July 2000)**
- **Regulatory Analysis Technical Evaluation Handbook – NUREG/BR-0184 (January 1997)**

Regulatory Analysis

A formal, highly-structured, reasoned analysis of a proposed government agency requirement containing estimates of benefits and costs that are quantified to the fullest extent possible.

Coverage

- **A regulatory analysis should accompany any proposed action that establishes or communicates requirements, guidance, requests or staff positions that would result in a change in resources by our licensees**
- **Regulatory analysis requirements for any given action can be modified or eliminated at the discretion of the Office Director or above**

Historical Perspective

- **Executive Orders - Ford, Carter, Reagan, Bush, Clinton, Bush**
- **1930s - Corps of Engineers**
- **Abraham Lincoln - 1848**

  “The true test in determining to embrace or reject anything is not whether it have any evil in it; but whether it have more of evil than of good.”

Why government uses cost-benefit analysis

- **Adam Smith's Invisible Hand of Competition**

  The market decides whether a good or service is needed, and if so, establishes price and quantity.

  Under perfect competition, intersection of supply and demand curves leads to an optimal use of society's scarce resources

Why government uses cost-benefit analysis

- **Market failure distorts market solution. Major types of market failure are:**
  - **Natural monopoly**
  - **Market power**
  - **Inadequate information**
  - **Externalities**

Market failure – Externalities

- **Externality occurs when one's actions impose uncompensated benefits & costs on another.**

- **Cost-benefit analysis is a means by which we explicitly consider these externalities in order to more closely approximate a pure market decision.**

Market failure – Externalities

- **Examples of externalities:**
  - **Nuclear Power Plant discharges heat into a body of water... causes uncompensated costs on others.**
  - **NRC licensee imposes safety risks on others without compensating them for that risk.**

Historical perspective on the role of cost-benefit analysis - NRC

- Early 1970s – Value impact analysis
- Nuclear power plant licensing – NEPA
- Generic safety issues program
- License renewal – Severe Accident Mitigation Alternatives (SAMA)

Assigning dollar value to person-rem of exposure

- 1974 rulemaking concerning design criteria for nuclear power reactors' radwaste systems
  - Applied to routine emissions
  - Adopted $1000 as a conservative estimate to encompass the full range of values under consideration

Use of $1000 per person-rem conversion factor

- Routine emissions – power reactors
- Accidental releases
  - Regulatory analyses
  - Unresolved safety issues, generic issues
  - SAMDA/SAMA analyses

Use of $1000 per person-rem conversion factor

- Part 20 ALARA program, occupational exposure
- Applicable to radiological releases from all licensees, materials and power reactors alike

Reasons for revisiting the conversion factor

- $1000 value was of questionable origin
- Developed in 1974 and reflects 1974 dollars
- Updated risk coefficients

Reasons for revisiting the conversion factor

- Simplistic adjustment to account for inflation and updated risk coefficients suggests 15-fold increase
- Certain applications of $1000 value pose technical difficulties
  - An allowance for offsite property damage is assumed in all applications

Criteria for changing the conversion factor

- 1995 reassessment
  - Suitable for a wide range of regulatory applications
  - Provide an understandable and straightforward basis for new value

Dollar per person-rem conversion factor

- **Only captures health effects**
  - **If offsite property consequences are involved, they need to be calculated separately**

- **Basis for conversion factor**

probability of health detriment per person-rem

(times)

value of health detriment

Dollar per person-rem conversion factor

- **Probability of health detriment per person-rem**

Fatal cancer	**5.0×10^{-4}**
Nonfatal cancer	**1.0×10^{-4}**
Severe genetic effects	**1.3×10^{-4}**
Total risk coefficient	**7.3×10^{-4}**

- **Value of health detriment**

Representative value of statistical life
3 million dollars

Dollar per person-rem conversion factor

- **Probability of health detriment = 7×10^{-4}**
- **Value of health detriment = $3 million**

7.0×10^{-4}/person-rem x $3 million = $2100/person-rem

Figure of merit
$2000 per person-rem

Format and content of an NRC Regulatory Analysis

- Statement of the problem
- Identification of alternatives
- Safety goal evaluation*
- Estimation of costs and benefits
- Presentation of results
- Decision rationale
- Implementation

* This is unique to NRC Regulatory Analyses. Another unique feature is inclusion of backfit and CRGR considerations.

Table 2.2 Checklist for specific backfit regulatory analysis requirements

CFR Citation (Title 10)	Information Item to be Included In a Backlit Regulatory Analysis	Section of the Regulatory Analysis Where Item Should Normally be Discussed
50.109(a)(3)	Basis and a determination that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for the affected facilities are justified in view of this increased protection.	Basis - Presentation of Results Determination - Decision Rationale
50.109(c)(1)	Statement of the specific objectives that the proposed backfit is designed to achieve.	Statement of the Problem and Objectives
50.109(c)(2)	General description of the activities that would be required by the licensee or applicant to complete the backfit.	Identification of Alternatives
50.109(c)(3)	Potential change in the risk to the public from the accidental offsite release of radioactive material.	Estimation and Evaluation of Values and Impacts

Statement of the Problem

- Describe nature of the problem
- Relevant history
- Boundaries of the problem
- Interfaces with other NRC activities
- Clear statement of the objective of the proposed action

Identification of Alternatives

- Performance-based vs. prescriptive
- Different requirements for different segments of the regulated population
- Alternative levels of stringency
- No-action alternative

No-Action Alternative

- Importance
  - No-action is a viable option
  - Serves as baseline from which all consequences are measured

- Issue
  - Voluntary initiatives

Voluntary Initiatives

- How one treats voluntary initiatives can effect one's definition of the baseline
  - Revision 3 of the Guidelines, July 2000 established new Commission Policy
- Industry initiates a voluntary program in lieu of new regulatory requirement

Voluntary Initiatives

- **Costs and benefits of proposed regulatory action are diminished because the voluntary initiative is now part of the baseline and it gets credit for some of the benefits and costs**

- **Our ability to justify imposing a new requirement is weakened because it is less likely to pass the "substantial safety improvement" standard of the backfit rule**

Voluntary Initiatives

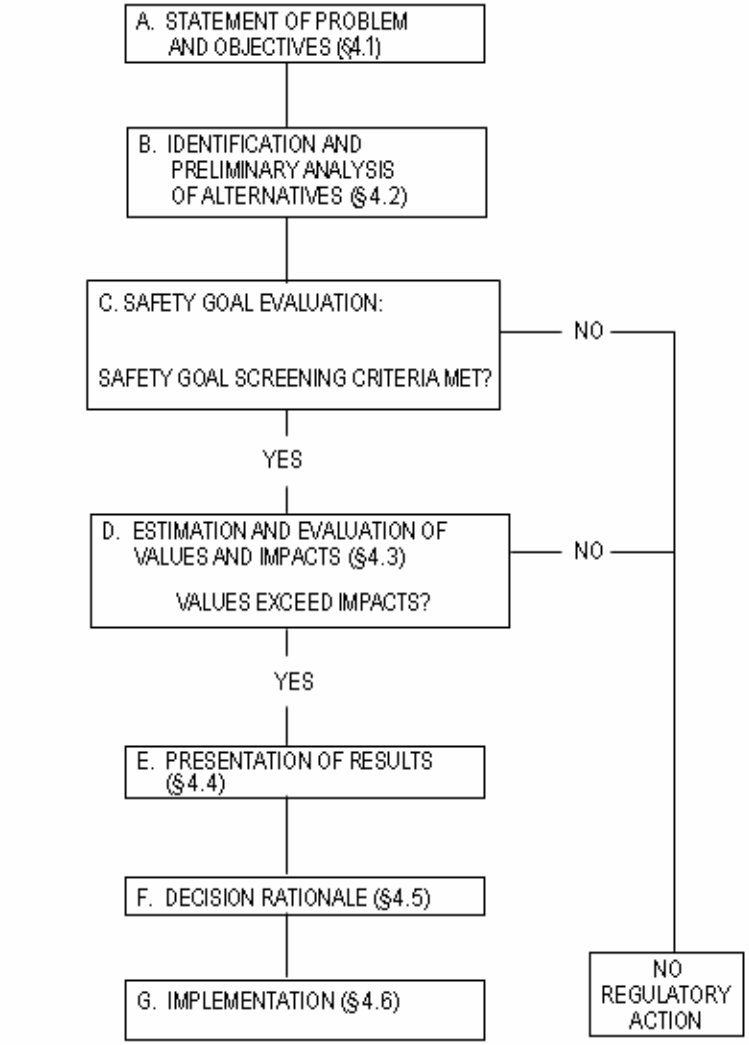
- **Commission concern - although Commission encourages voluntary initiatives, they can be problematic**
  - **Can be vague and discretionary**
  - **Non-uniform**
  - **Lack enforcement**
  - **Subject to backsliding or future elimination**

Voluntary Initiatives

- **Commission Policy**
  - **perform sensitivity analysis**
    - **compare results with full credit and no credit, and if necessary, measured credit**

Safety Goal Evaluation

- **Determines, from a regulatory analysis perspective, whether the proposed requirement constitutes a substantial improvement in public heath and safety.**
  - **Change in core damage frequency per R/Y**
  - **Conditional containment failure probability**
- **Applies to generic preventative safety enhancements involving nuclear power plants**



REGULATORY ANALYSIS FOR NUCLEAR POWER PLANT

COST-JUSTIFIED SUBSTANTIAL SAFETY ENHANCEMENTS

FIGURE 3.1

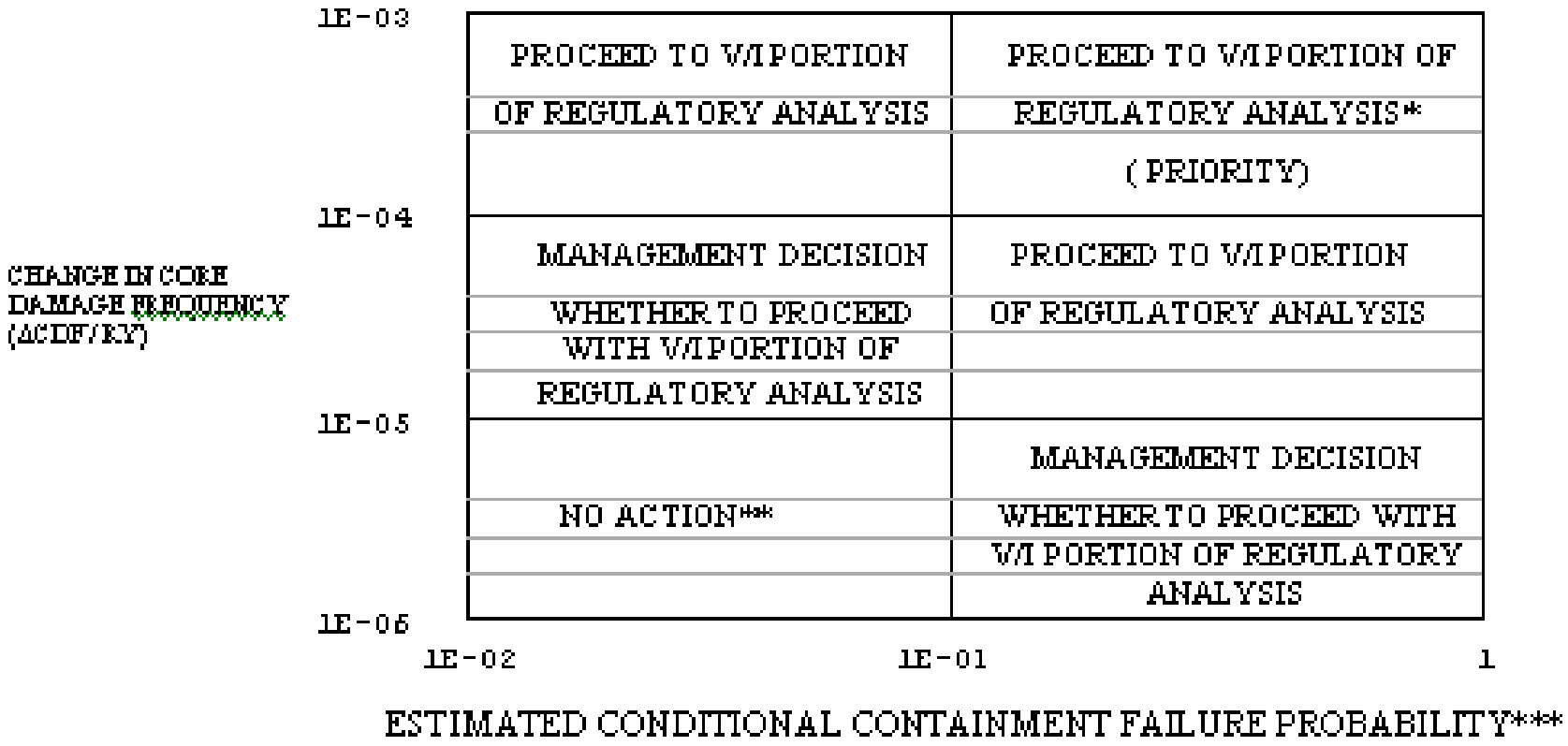


FIGURE 3.2 SAFETY GOAL SCREENING CRITERIA

Estimation of Costs and Benefits

- **Backfit test**
  - **Determine if the direct and indirect costs of implementation for the affected facilities are justified in view of this increased protection**

Estimation of Costs and Benefits

- Typical benefits
  - Public health
  - Averted offsite costs
  - Averted onsite costs
  - Averted occupational exposure (accident)
- Special policy affecting onsite costs

Averted Onsite Costs

- **Accident-related consequences borne directly by licensee: replacement power, decontamination / clean-up, repairs, early decommissioning.**

Averted Onsite Costs

- Industry has continually argued that it should not be included as a benefit - beyond NRC purview - not public health and safety issue; involves NRC in internal investment and operational decisions; already covered by insurance.
- NRC staff maintains it should be included - it is a societal consequence; has public components; inclusion is consistent with OMB guidance and other federal agencies have analogous situations where "internalized benefits" are included in the regulatory analysis.

Averted Onsite Costs

- It is hotly contested because averted onsite costs is likely to be the dominant safety benefit - billions of dollars
- Revision 2 of Guidelines - include averted onsite costs in best estimate of the benefits.
- However because of uncertainties and potential dominance on overall cost/benefit results, also calculate without averted onsite costs. And if result is significantly different, also display these results to the decision-maker for sensitivity analysis purposes.

Estimation of Costs and Benefits

- Typical costs
  - Industry costs (implementation, operation)
  - NRC costs (implementation, operation)
  - Occupational exposure (routine)

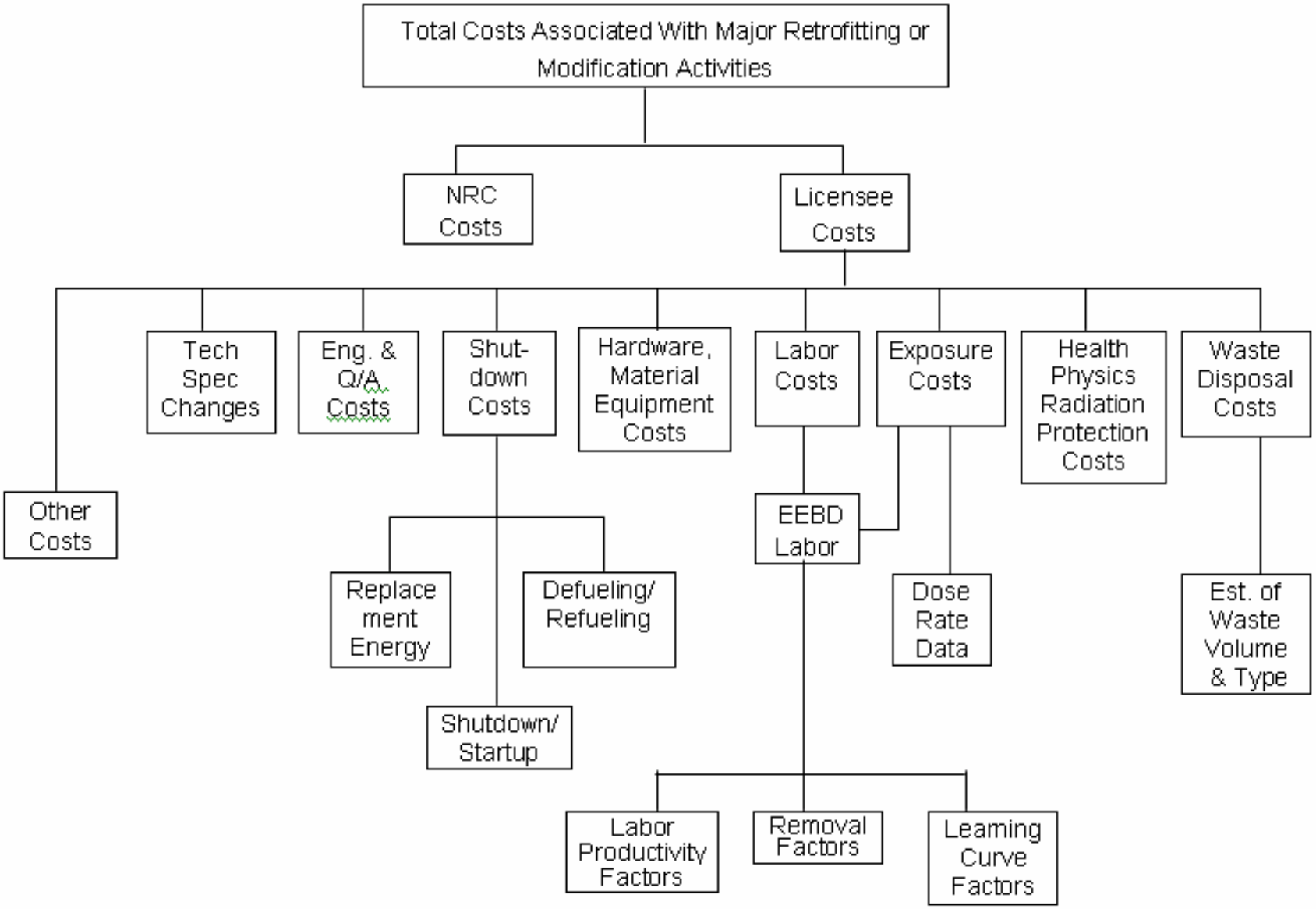

Total Costs Associated With Major Retrofitting or Modification Activities
NRC Costs
Licensee Costs
Other Costs
Tech Spec Changes
Eng. & Q/A Costs
Shut-down Costs
Hardware, Material Equipment Costs
Labor Costs
Exposure Costs
Health Physics Radiation Protection Costs
Waste Disposal Costs
Replace ment Energy
Defueling/ Refueling
Shutdown/ Startup
EEBD Labor
Dose Rate Data
Est. of Waste Volume & Type
Labor Productivity Factors
Removal Factors
Learning Curve Factors

Table 5.1 Checklist for identification or affected attributes

Attribute	Affected
Public Health (Accident)	☐
Public Health (Routine)	☐
Occupational Health (Accident)	☐
Occupational Health (Routine)	☐
Offsite Property	☐
Onsite Property	☐
Industry Implementation	☐
Industry Operation	☐
NRC Implementation	☐
NRC Operation	☐
Other Government	☐
General Public	☐
Improvements in Knowledge	☐
Regulatory Efficiency	☐
Antitrust Considerations	☐
Safeguards and Security Considerations	☐
Environmental Considerations	☐
Other Considerations (Specify)	☐

Presentation of Results

- **Net value**
- **Supplementary considerations (nonmonetary and nonquantified attributes)**
- **Uncertainty analysis and/or sensitivity analysis results**
- **Safety goal evaluation**

Decision Rationale

- Alternative with greatest net value
- Other contributors to decision rationale may include:
  - Attributes quantified in nonmonetary terms or nonquantifiable
  - Relationship to legislative mandates
- Decision not binding

Implementation

- Identify how and when the proposed action is to be implemented
  - Identify proposed NRC regulatory instrument (e.g., rule, regulatory guide, generic letter)
- Identify dates with realistic schedule