Update and Overview of NRC's Regulatory Analysis Guidance

ACRS Full Committee Meeting

June 11, 2014

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Purpose/Outline

- **Purpose:**
  - Provide an overview of SECY-14-0002, "Plan for Updating the U.S. NRC's Cost-Benefit Guidance"
  - Provide an overview of Staff's Regulatory Analysis Practice
- **Outline**
  - Overview of SECY-14-0002 and Status
    - Background
    - Public Interactions
    - Implementation Plan to Update Cost-Benefit Guidance
      - Current cost-benefit initiatives and related activities
      - Two-Phased Approach
    - Timeline of 2014 Cost-Benefit Activities
    - Price-Anderson Act
  - Regulatory Analysis Overview

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Overview of SECY-14-0002

- Staff submitted SECY-14-0002, "Plan for Updating U.S. NRC's Cost-Benefit Guidance" on January 2, 2014
  - Blog post published on January 21: http://public-blog.nrc-gateway.gov/2014/01/21/moving-forward-on-updating-cost-vs-benefit-analysis/
- Information paper
- High level implementation plan for two-phased approach to updating cost-benefit guidance
- No potential policy issues identified in paper but accounts for addressing policy issues in the future

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Background

- Fukushima Dai-ichi accident initiated questions regarding how NRC considers potential economic consequences (EC) of a nuclear accident

- Staff submitted SECY-12-0110, "Consideration of EC within the U.S. NRC's Regulatory Framework" in August 2012
  - Addressed the policy question: *To what extent, if any, should NRC's regulatory framework modify consideration of economic consequences of the unintended release of licensed nuclear materials to the environment?*
  - Described the current offsite property damage considerations in NRC analyses: cost-benefit determinations for regulatory, backfit, and environmental analyses
  - Recommended enhancing cost-benefit guidance (i.e., Option 2 of paper)

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Background cont'd

- SRM-SECY-12-0110 directed staff to provide a notation vote paper so it is clear how Option 2 "would help harmonize regulatory guidance across the agency" in consideration of economic consequences, including items per SRM
  - Identify what activities will be impacted by this work and describe how priorities will be modified
  - Integrate summary and analysis of how federal and international bodies assess EC into its recommendations
  - Address if and how Option 2 may influence future NRC recommendations to Congress regarding renewal of Price-Anderson Act

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Public Interactions

- Four public meetings
  - May 24, 2012 (ML12130176)
  - August 29, 2012 (ML12283A373)
  - July 29, 2013 (ML13227A201)
  - May 28, 2014 (ML14114A034)
- Two ACRS meetings
  - October 2012
  - November 2012
- Commission Meeting
  - September 11, 2012
  - Representatives from U.S. Environmental Protection Agency, Union of Concerned Scientists, American Nuclear Insurers, Health Physics Society, and Nuclear Energy Institute

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Implementation Plan for Updating Cost-Benefit Guidance

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Current Cost-Benefit Initiatives & Related Activities

- Update to Replacement Energy Cost
  - Address costs for replacement energy on short-term and long-term bases
  - Draft NUREG expected later this year
- Update to Dollar Per Person-Rem Conversion Factor
  - Guidance for monetizing health detriment (revised NUREG-1530) and process for updating in the future
  - Draft NUREG expected later this year
- Cumulative Effects of Regulation
  - SRM-SECY-12-0137: Case studies to review accuracy of NRC cost and schedule estimates; insights may inform cost-benefit updates
  - NEI provided final report with recommendations (ML14028A455) during a January 28, 2014 public meeting

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Current Cost-Benefit Initiatives & Related Activities

- Disposition of NTTF Recommendation 1
  - SRM-SECY-13-0132: The staff's proposed Improvement Activities as written were not approved by the Commission. Staff work on the Risk Management Regulatory Framework and other interrelated activities should be treated outside the scope of the NRC's post-Fukushima actions
- Qualitative Factors
  - SRM-SECY-12-0157: Staff is developing a notation vote paper seeking Commission direction on its use of qualitative factors
  - Notation vote SECY due July 2014
- Regulatory Gap Analysis
  - SRM-SECY-12-0110: Identify differences in cost-benefit practices across the NRC prior to developing new guidance*
  - Information SECY due November 2014

*With the exception of the dollar per person-rem and replacement energy updates

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Process for Identifying Gaps

	Regulatory Analyses	Backfit Analyses	Environmental Analyses
Operating Reactors	For each cell: •Regulatory Requirements •Guidance •Practice (e.g., assumptions, data source, use of qual. factors)		
New Reactors			
Materials			
Fuel Cycle Facilities			
Emergency Preparedness			

Differences across business lines

Differences across cost-benefit analyses

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Two-Phased Update Approach

- Phase I- *Administrative Changes*
  - Consolidate and clean up cost-benefit guidance (NUREG/BR-0058, NUREG/BR-0184, and NUREG-1409)
  - Restructure guidance by mid-2015

- Phase II- *Addresses potential changes in policy and methodology*
  - Process for addressing policy issues identified by gap analysis
  - Consequence and probabilistic methodology review
  - MELCOR Accident Consequence Code System (MACCS)
  - Periodic review of cost-benefit guidance
  - Begin after gap analysis; multi-year phase

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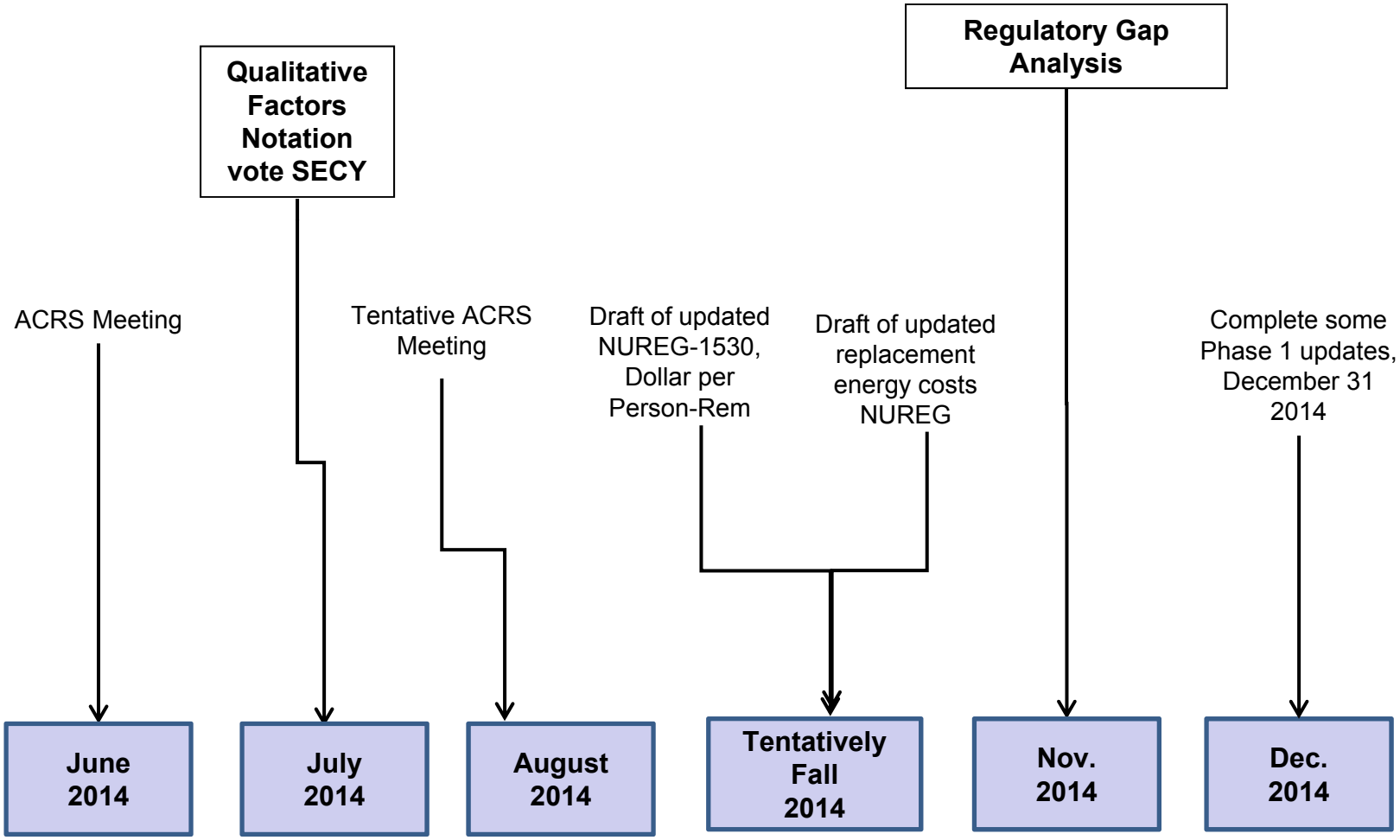
Timeline of 2014 Cost-Benefit Activities



Dates are estimates and subject to resources and Commission direction

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Price-Anderson Act (PAA)

- Commission required to submit a report to Congress by December 31, 2021 on need for continuation or modification to the PAA
- Staff has not historically used cost-benefit analyses as means to inform the Commission's report to Congress
- Enclosure 4 to SECY-14-0002 provides more information

Regulatory Analysis Overview

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Regulatory Analysis Definition

- 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

- Societal cost-benefit analysis

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What is Regulatory Analysis

An analytical tool provided to decision makers that:

- Recommends a preferred alternative from the potential courses of action studied
- Contains estimates of societal benefits and costs with a conclusion whether the proposed regulatory action is cost beneficial
- Documents the analysis in an organized and understandable format

Examples of Regulatory Actions

Regulatory Analyses are performed for:

- Rules
- Bulletins
- Generic Letters
- Regulatory Guides
- Orders
- Standard Review Plans
- Standard Technical Specifications
- Branch Technical Positions

Regulatory Analyses are <u>not</u> performed for:

- Licensing Actions
- Topical Reports
- Regulatory Issue Summaries
- Information Notices
- Policy Statements
- Inspection Reports
- Generic Letters (transmittal of information)

Purpose of a Regulatory Analysis

- Decision tool for policymakers
- Rationale for action
- Transparency of Agency decision making
- Consistency with Executive Orders on regulatory analysis and related issues
- Comply with Office of Management and Budget guidance and Executive Orders

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Regulatory Analysis is Required when a Proposed Action:

- Establishes or communicates requirements, guidance, requests, or staff positions that would result in a change in licensee resources
- Involves backfitting licensed facilities
- Imposes generic requirements on one or more classes of the agency's reactor and materials licensees

NRC Regulatory Analysis Requirements

- No statute, NRC regulation, or Executive Order requires the NRC to perform regulatory analysis
- Voluntarily performed since 1976

Format and content of an NRC Regulatory Analysis

1. Statement of the problem and objective
2. Identification of alternatives
3. Safety goal evaluation*
4. Estimation and evaluation of costs and benefits
5. Presentation of results
6. Decision rationale
7. Implementation

* This is unique to the NRC and not included for other agencies

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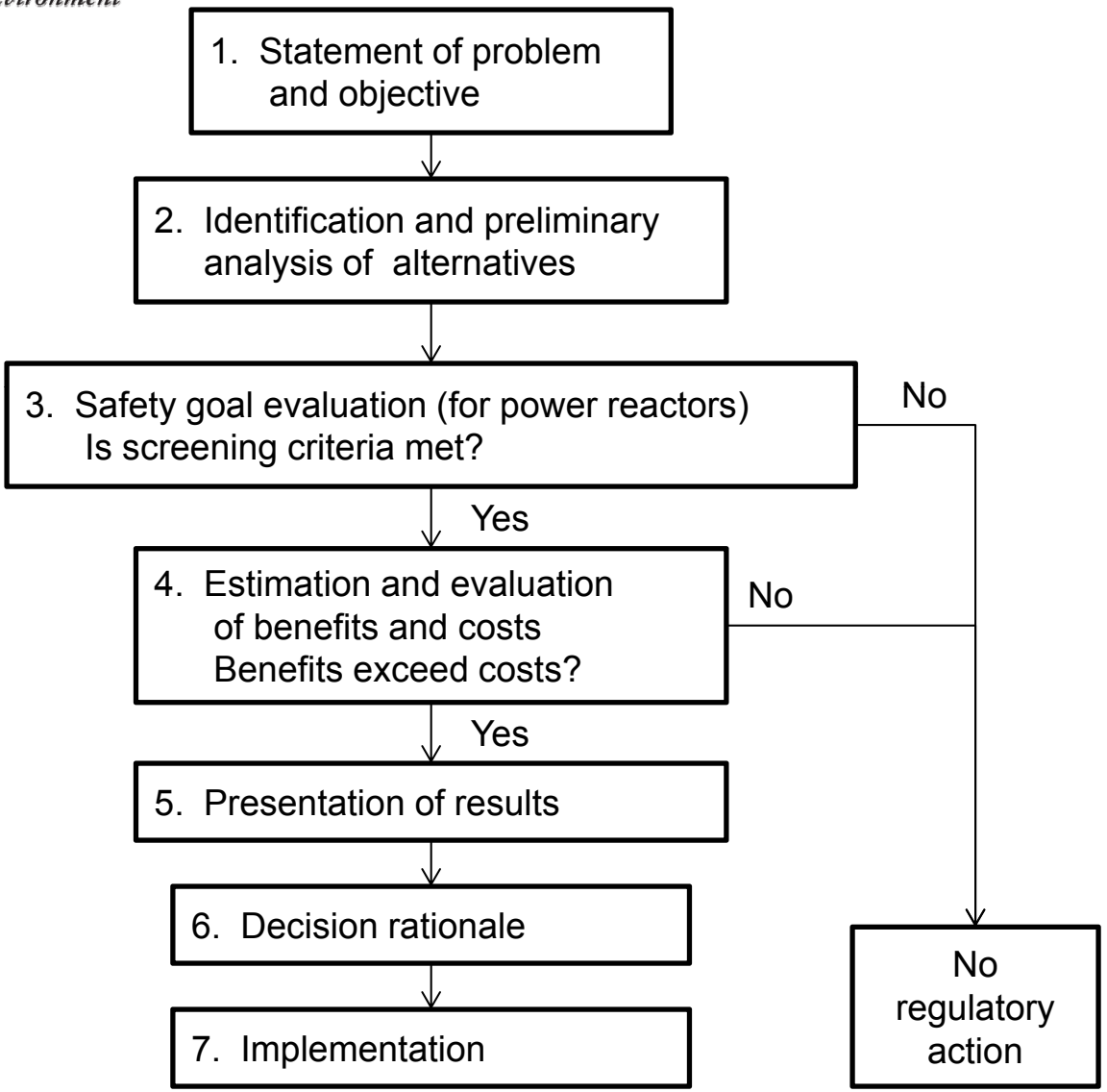
Regulatory Analysis Steps



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Safety Goal Evaluation (for nuclear power reactors)

- Determines whether the proposed requirement constitutes a substantial improvement in public health and safety
  - Change in core damage frequency per reactor-year
  - Conditional containment failure probability
- Applies to generic preventive safety enhancements involving nuclear power plants
- Risks from the nuclear fuel cycle and possible effects of sabotage or diversion of nuclear material are not included in the safety goals

Safety Goal Evaluation (cont'd)

Safety Goal Screening Criteria

Estimated Conditional Containment Failure Probability[3]	1E-02	1E-01
1E-03 to 1E-04	Proceed to benefit-cost portion of regulatory analysis	Proceed to benefit-cost portion of regulatory analysis[1] (Priority)
1E-04 to 1E-05	Management decision whether to proceed with benefit-cost portion of regulatory analysis	Proceed to benefit-cost portion of regulatory analysis
1E-05 to 1E-06	No action taken[2]	Management decision whether to proceed with benefit-cost portion of regulatory analysis

1 A determination is needed regarding adequate protection or compliance; as a result a benefit-cost analysis may not be appropriate.

2 Unless office director decides that the screening criteria do not apply.

3 Conditional upon core damage accident that releases radionuclides into the containment

Attributes Considered in a Regulatory Analysis

- 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 Population
- Improvements in Knowledge
- Regulatory Efficiency
- Antitrust Considerations
- Safeguards and Security Considerations
- Environmental Considerations
- Other Considerations

Estimation of Costs and Benefits

To the extent applicable, attributes to be assessed include the following:

Cost estimates:

- costs to licensees
- costs to the NRC
- costs to State, local, or tribal governments
- adverse effects on health, safety, or the natural environment
- adverse effects on regulatory efficiency or scientific knowledge needed for regulatory purposes
- adverse effects on the efficient functioning of the economy and private markets

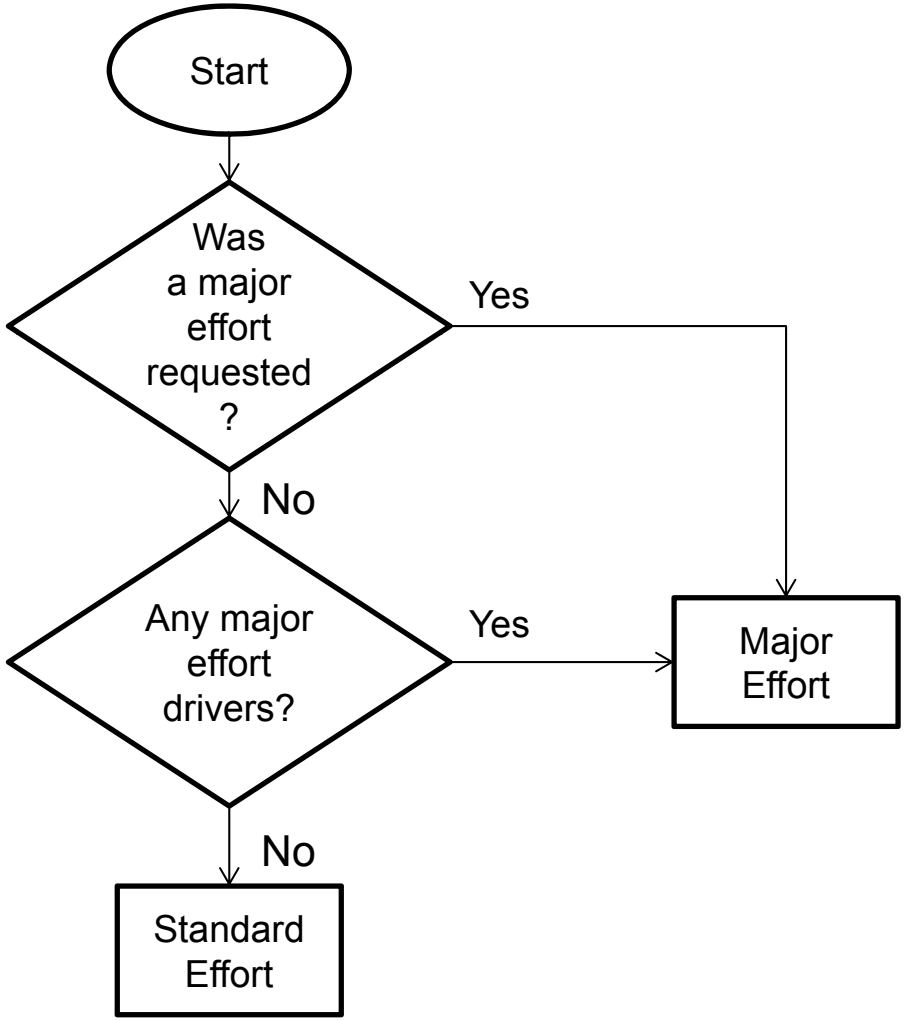
Benefit estimates:

- reductions in public and occupational radiation exposure
- enhancements to health, safety, or the natural environment
- averted onsite impacts
- averted offsite property damage
- savings to licensees
- savings to the NRC
- savings to State, local, or tribal governments
- improved plant availability
- promotion of the efficient functioning of the economy
- reductions in safeguards risks

Regulatory Analysis Level of Effort

Major effort drivers

- Annual effect on economy of $100 million or more
- Major increase in costs or prices for consumers; individual industries; federal, state or government agencies or geographic regions
- Significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets
- Roughly comparable benefits and costs
- Potential for considerable controversy, complexity, or policy significance



Regulatory Analysis Considerations

1. Choose time horizon appropriate for analysis based on when costs and benefits are incurred
2. Consider each group affected by the regulatory action
3. Identify elements that may be difficult to quantify or monetize
   - Develop strategy on how to estimate these costs or benefits
   - Establish depth and breadth of the uncertainty analysis
4. Search for good data
5. Estimate costs and benefits by year for the entire period that groups will be affected by the proposed regulatory action
6. Convert estimated costs and benefits to monetary terms expressed on a present-worth basis using both 3-percent and 7-percent real discount rates

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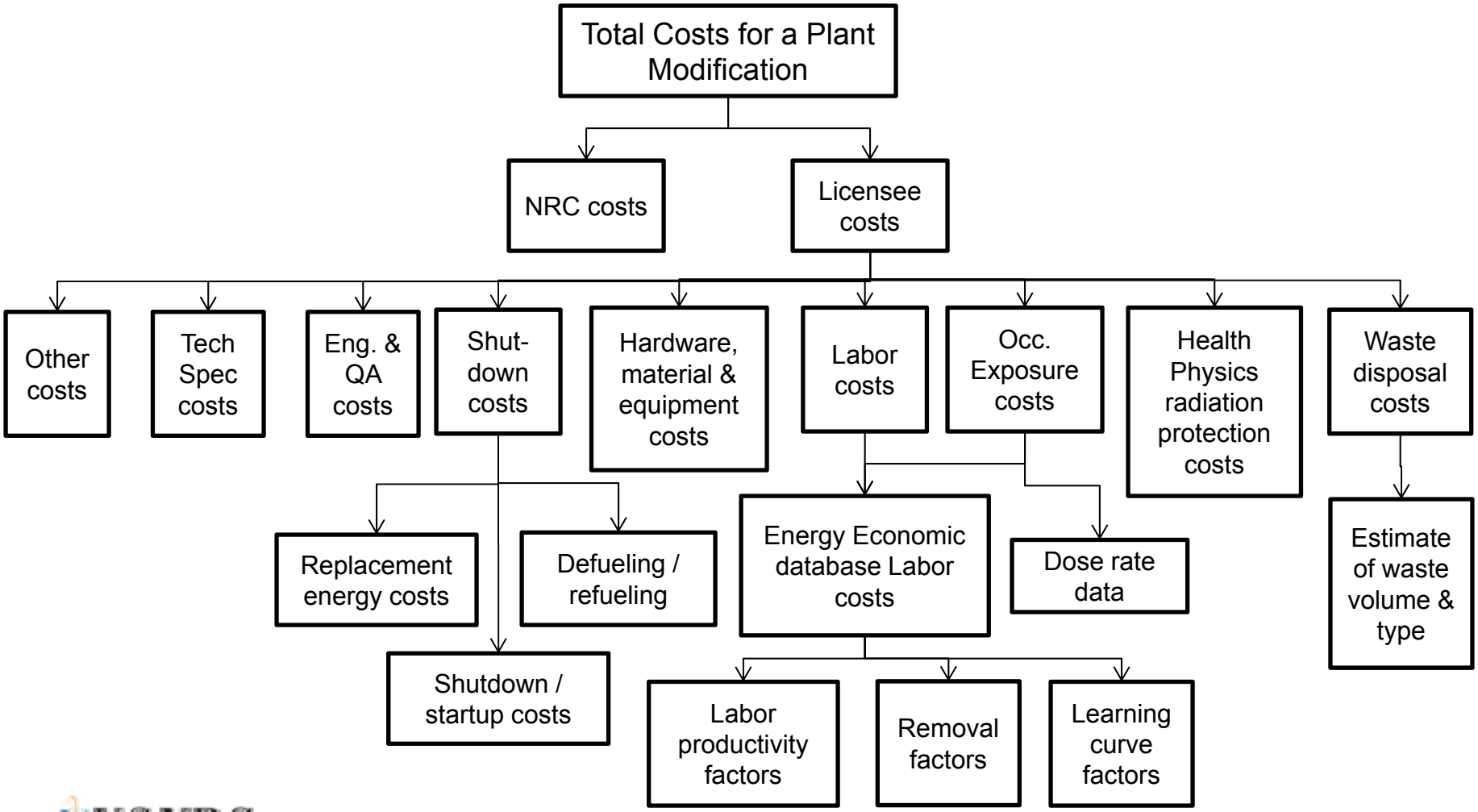
Estimating Costs associated with a Plant Modification



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NRC Guidance on Uncertainty

- Use common sense
- Detail and breadth should be commensurate with the overall policy significance, complexity, level of controversy, and perceived importance of the recommendation
- Use and discuss the best available peer-reviewed studies and data collected by best available methods
- Use and discuss qualitative factors (i.e., increased confidence in the margin of safety), when appropriate

Difference between Uncertainty and Sensitivity Analysis

Uncertainty Analyses:

- Evaluates and quantifies the change in model predictions so that it can be considered when using model predictions for decisionmaking
- More formal than sensitivity analysis
- Explicitly quantifies uncertainties and their relative magnitudes but requires probability distributions for each random variable

Sensitivity Analyses:

- The process of varying model input parameters over a reasonable range and observing the relative change in model response
- Manipulate one parameter at a time unless multiple parameters are affected when one is changed

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Presentation of Results

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

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Decision Rationale

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

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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

Backfit Analysis (10 CFR 50.109)

- Backfit – A change in agency position
- Backfit Rule – Sets the standard for changing the requirements
- Backfit Analysis – Required for all backfits
  - Does an exemption apply (e.g., adequate protection)
  - Assists in determining if the backfit represents a substantial increase in protection of the public health and safety and common defense and security
  - Aids in demonstrating that the costs of the backfit are justified in light of the action's increased protection

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Comparison of Regulatory Analysis with Backfit Analysis

Backfitting and Issue Finality	Regulatory Analysis
NRC-unique policy, voluntarily adopted	Federal agency-wide policy
Protects licensees and other entities who have received or wish to reference certain NRC regulatory approvals (e.g., design certification rules)	Protects society from bad governmental decisions
Applicable only to regulatory proposals affecting current licensees and regulatory approvals	Applicable to all regulatory approvals affecting both current and future licensees and regulatory approvals
Substantial increase which outweighs the cost of the backfitting	Benefit equal to or greater than the cost of the regulatory action
Only health and safety or common defense and security benefits	All benefits, all costs

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Backup Slides

Basic Definitions

- Regulatory change – Any change in agency position requiring licensees to expend resources
- Baseline – Best assessment of the way the world would look absent the proposed regulatory change
  - Includes current statutes and regulations, even if not yet implemented
- Net Present Value (NPV) – Method of taking into account the time value of money and of comparing benefits to costs (or comparing different alternatives), which may not occur in the same timeframe

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Basic Definitions (continued)

- Discounting – Method of bringing costs and benefits occurring at different times to a common time period
  - Cost = $10 in Year 1, Benefit = $100 in Year 2
  - Discount rate is 7%
  - NPV of Cost in Year 0 = $10/(1+0.07)^1 = $9.3
  - NPV of Benefit in Year 0 = $100/(1+0.07)^2 = $87.3
  - Net Effect in Year 0 terms = $87.3 - $9.3 = $78
- Bundling – The aggregation of different requirements within a regulatory action that results in a particular requirement appearing to be cost-beneficial, when it isn't
  - If individual requirement is necessary, it doesn't need to be analyzed separately
  - If individual requirement is supportive but not necessary, it should be included only if it makes the bundled initiative more cost-beneficial
  - If individual requirement is unrelated, it should be included only if it makes the bundled initiative more cost-beneficial and it passes the backfit test

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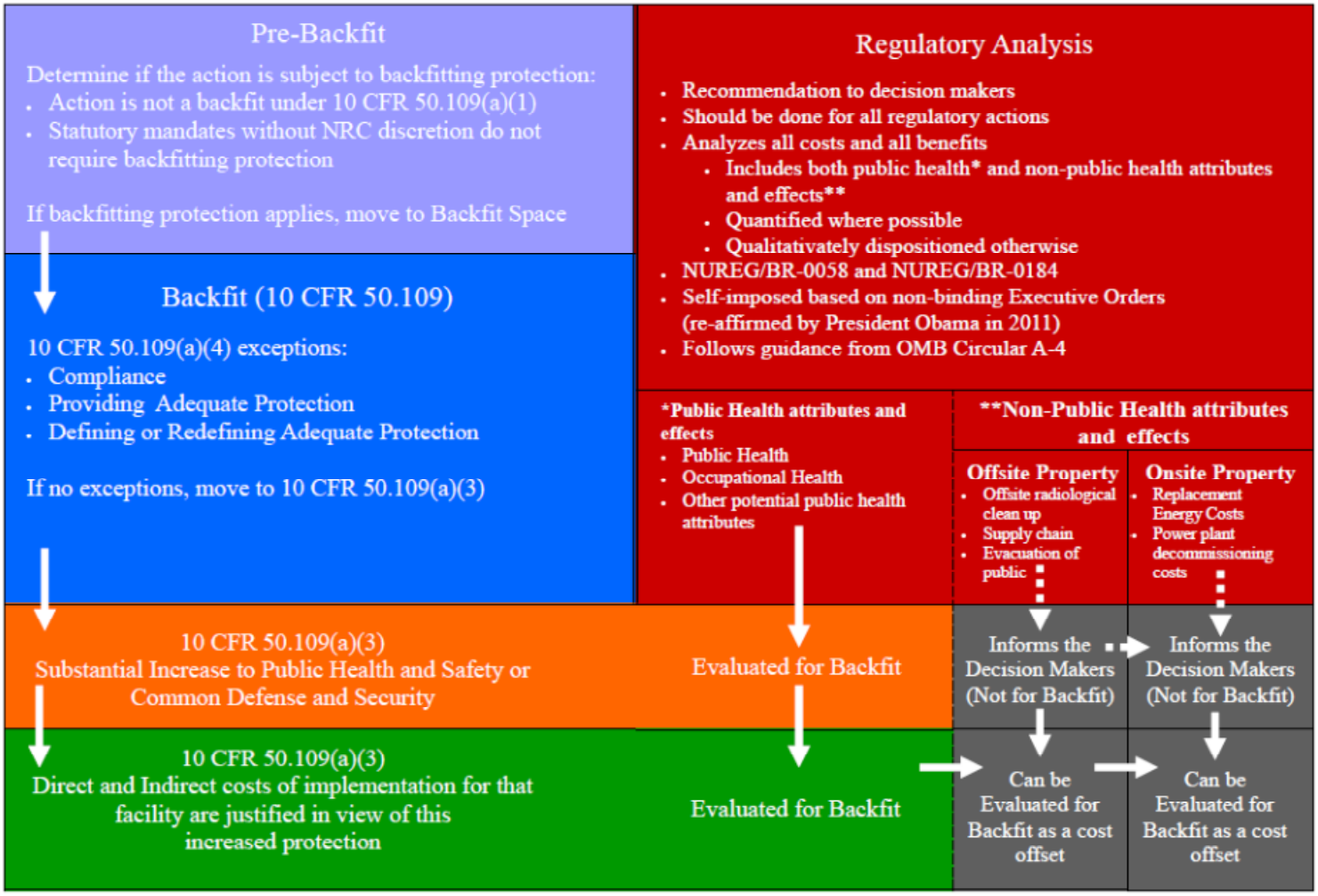
Regulatory Analysis vs. Backfit

REGULATORY ACTIONS (Operating Reactors)



Discussion of Qualitative Factors

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Background

- SRM-SECY-12-0157 directed the staff to “seek detailed Commission guidance regarding the use of qualitative factors [in regulatory analysis and backfit analysis] in a future notation voting paper”

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Background (cont'd)

- Qualitative factors are used in regulatory analysis and backfit analysis
  - NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission", page 24
  - SECY-77-388A, "Value-Impact Guidelines" instructed to consider quantitative and qualitative factors
  - SRM-SECY-93-086 allowed for use of qualitative factors for backfit analysis within the "substantial increase" criterion

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Background (cont'd)

- Documents that require or recommend the use of qualitative factors by other federal agencies
  - Executive Order (EO) 12866, "Regulatory Planning and Review"
  - Office of Management and Budget (OMB) Circular A-4, "Regulatory Guidance"
  - Office of Information and Regulatory Affairs (OIRA), "Regulatory Impact Analysis: A Primer"

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Background (cont'd)

- Use of qualitative factors in risk-informed decisions
- Safety Goal Policy Statement
- Probabilistic Risk Assessment Policy Statement (e.g., Regulatory Guide 1.174)

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Background (cont'd)

- Qualitative factors are considered in adequate protection decisions
  - Only quantitative safety goal measure is the Quantitative Health Objectives (QHOs)
    - Applicable to power reactors only
  - Other adequate protection decisions are made based on a qualitative determination

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Background (cont'd)

- Qualitative factors are used in cost-justified substantial safety enhancement decisions
  - NUREG-1409, "Backfitting," allows for the use of qualitative factors
  - SRM-SECY-93-086 also allows for the use of qualitative factors

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Discussion

- Multiple cases where qualitative factors can be considered within a cost-benefit analysis for a regulatory analysis and backfit analysis
- Case 1:
  - Benefits are difficult to quantify and, thus, are only presented qualitatively
  - Costs are quantified

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Discussion (cont'd)

- Case 2:
  - Some benefits are quantified, but not all
  - Costs are quantified
- Scenario A:
  - Quantitative analysis results are cost-beneficial
  - Qualitative factors strengthen the staff's recommendation

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Discussion (cont'd)

- Scenario B:
  - Quantitative analysis results are not cost-beneficial
  - Qualitative factors are used to support the staff's recommendation
- Scenario C:
  - Identification of relevant qualitative factors
  - No consideration of qualitative factors into the staff's recommendation

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Discussion (cont'd)

- Different evaluation techniques for evaluating qualitative benefits and costs
  - Cost-effectiveness analysis
  - Break-even analysis
  - Internal rate of return
  - Qualitative assessment supplemented with decision analysis tools

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References

- EO 12886, 58 FR 51735 (October 4, 1993) and http://www.whitehouse.gov/omb/inforeg_riaguide/
- NEI Letter (ML14028A455)
- NRC policy statements available at http://www.nrc.gov/reading-rm/doc-collections/commission/policy/
- NUREG/BR-0184 available at ML111290858
- NUREG/BR-0058 available at ML042820192

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- NUREG-1409 available at ML032230247
- NUREG-1530 available at ML063470485
- OMB Circular A-4, available at ML11231A834
- OIRA Regulatory Analysis Primer, http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf
- Regulatory Guide 1.174 available at ML003740133

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- SECY-12-0110 available at ML12173A478
- SECY-12-0157 available at ML12345A030
- SRM-SECY-12-0110 available at ML13079A055
- SRM-SECY-12-0157 available at ML13078A017
- SRM-SECY-13-0132 available at ML14139A104