



# Graded Approach in Rulemaking

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## **Development of Regulations in U.S.**

- Example – Fukushima accident 2011
- Japan Lessons Learned Report recommendations
  - Requiring reliable hardened vent designs in BWR facilities with Mark I and Mark II containments.
  - Enhancing spent fuel pool makeup capability and instrumentation for the spent fuel pool.

## **Development of Regulations in U.S.**

- Step 1 - Identify the decision associated with the development or revision of regulations and/or guidance required.
  - Decision was whether to accept the recommendations in the Japan lessons learned report, and if accepting the recommendations, what were the appropriate regulatory tools to implement the recommendations.

## **Development of Regulations in U.S.**

- Step 2 - Determine which factors are applicable to the decision.
  - type of facility – BWR Mk I and II containments
  - industry experience based on significant events - unprecedented
  - urgency with respect to the issue being addressed – public health and safety
  - regulatory tools available - generic communications, orders, new regulation

## **Development of Regulations in U.S.**

- Step 3 - Integrate the applicable factors into the decision-making process. Commission decision to approve recommendations. What tools to use?
  - Urgency – overriding factor. Quickest tool = bulletin
  - Bulletins (1) request licensee actions and/or information to address significant issues regarding matters of safety, security, safeguards, or environmental significance that have great urgency, and (2) require a written response.

## **Development of Regulations in U.S.**

- **Bulletin 11-01 (Mitigating Strategies) – issued prior to lessons learned report.**
  - require verification of compliance with the regulatory requirements of 10 CFR Section 50.54(hh)(2).
  - need for information associated with licensee mitigating strategies under 10 CFR 50.54(hh)(2).
  - require that addressees provide a written response to the NRC in accordance with 10 CFR 50.54(f).



## **Development of Regulations in U.S.**

- Orders
  - Orders were issued due to urgency; determined to be significant enhancement to the protection of public health and safety .

## Development of Regulations in U.S.

- Orders
  - [NRC Order on Mitigation Strategies \(EA-12-049\)](#)
    - required provisions for mitigation strategies for beyond-design-basis external events.
  - [NRC Order on Spent Fuel Pool Instrumentation \(EA-12-051\)](#)
    - requiring all licensees have a reliable means of remotely monitoring wide-range spent fuel pool levels.
  - [NRC Order for Containment Venting Systems \(EA-13-109\)](#)
    - Required licensees with BWR Mk I and II containments to implement requirements for reliable hardened containment vents capable of operation under severe accident conditions at their facilities.



## **Development of Regulations in U.S.**

- Rulemaking – codify requirements described in the orders.
  - Rulemaking plan – Commission approval
  - Regulatory basis
  - Regulatory analysis
  - Stakeholder interactions

## **Development of Regulations in U.S.**

- In August 2019, the NRC issued a new rule, 10 CFR 50.155, "Mitigation of beyond design basis events," makes NRC Order EA-12-049, "Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis Events" (Mitigation Strategies Order), and Order EA-12-051, "Order Modifying Licenses With Regard to Reliable Spent Fuel Pool Instrumentation" (Spent Fuel Pool Instrumentation Order), generically applicable
- The final rule was published in the *Federal Register* on August 9, 2019 ([84 FR 39684](#)) with an effective date of September 9, 2019.

## References

- Management Directive 6.3, “Rulemaking Process”  
<https://www.nrc.gov/docs/ML0516/ML051680185.pdf>
- Public web page – Fukushima enhancements:  
<https://www.nrc.gov/reactors/operating/ops-experience/post-fukushima-safety-enhancements.html>