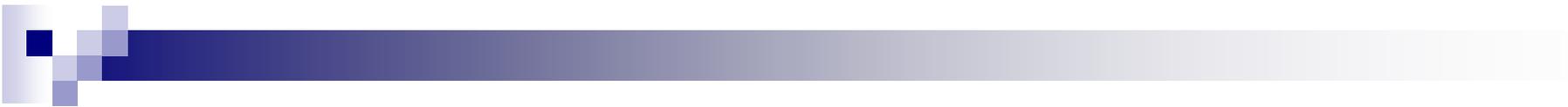




10 CFR 70.72 Facility Changes and Change Process

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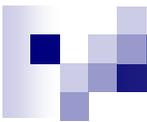
Purpose and Background of 10 CFR 70.72:

- 70.72 was intended to capture, for NRC pre-approval, “changes that are considered major and could have a significant impact on health and safety.” (SECY-99-147)
- 70.72 was modeled after 10 CFR 50.59 in that NRC wanted to allow licensees to make changes that do not increase risk (which was the 50.59 criteria in effect at the time).
- The language in 70.72 and 50.59 is similar to the Department of Energy’s Unreviewed Safety Question (USQ) program - not a new concept.
- Prior to Subpart H, fuel cycle licensees committed (either through license condition or license application) to an internally authorized change program with language similar to 70.72.



■ Requirements of 10 CFR 70.72

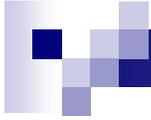
- Establish a configuration management system;
- Evaluate changes to determine if license amendment is required;
- Make certain changes without Commission approval;
- Submit an amendment application (when necessary), submit an annual update, and maintain an updated ISA.



■ **70.72(a) - Establish a Configuration Management System**

- Requires licensee to establish a system to evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

- System must be documented in written procedures and must address the following:
 - technical basis for change;
 - impact of change on safety and health or control of material;
 - modifications to procedures (training);
 - authorization requirements;
 - duration of temporary changes;
 - impacts on ISA, ISA summary.



- **70.72(b) - Evaluation of changes by licensee to determine if license amendment is required.**
 - Licensee must evaluate the change before it is implemented

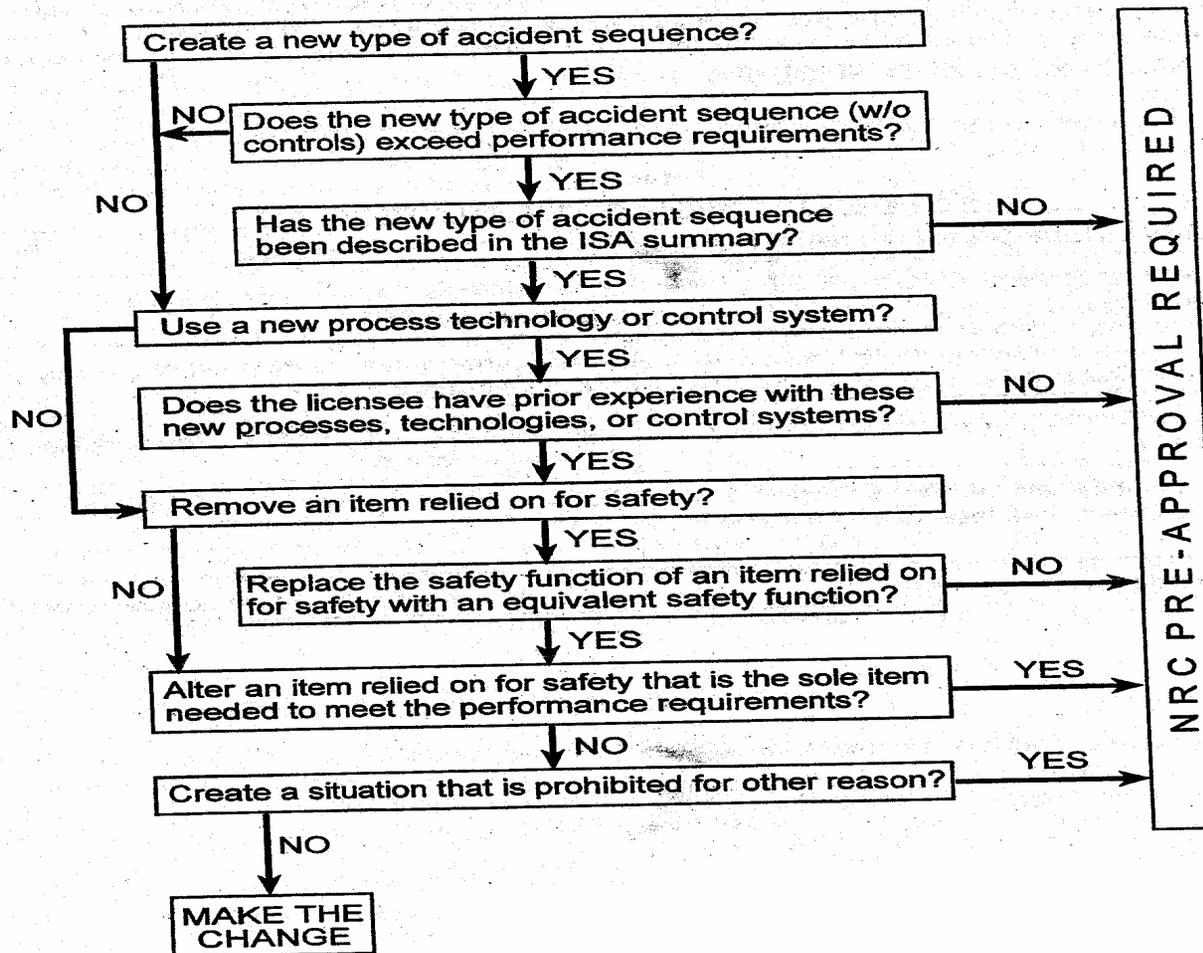


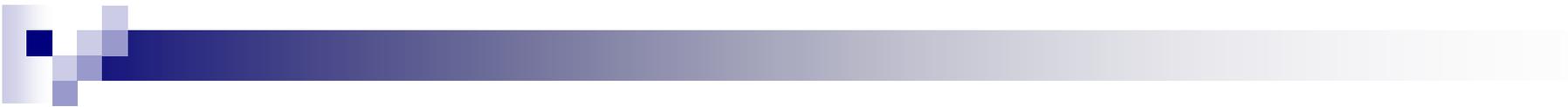
- **70.72(c) - Allow licensee to make certain changes without Commission approval.**

- Licensee may make changes without prior Commission approval if the change does not:
 - Create new type of accident;
 - Use new processes, technologies, or control systems;
 - Remove, without an equivalent replacement of the safety function, an IROFS;
 - Alter a sole IROFS;
 - Is not otherwise prohibited by license condition or order.

Flow Diagram for 70.72 Change Process

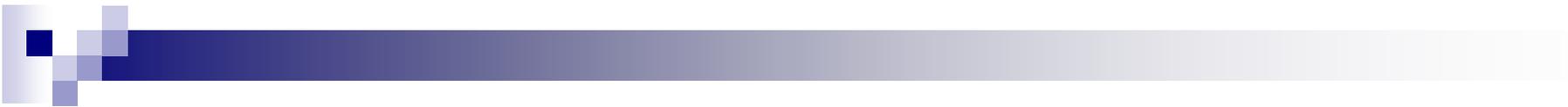
Does the change:





- **70.72(d) - Require licensee to submit an amendment application (when necessary), submit an annual update, and maintain an updated ISA.**

- For changes that require an amendment, submit amendment application in accordance with 70.34;
- For changes that do not require an amendment, submit a brief summary of changes annually;
- For all changes that affect the ISA Summary, submit an annual update
- Maintain records of changes, including basis for not needing prior approval.



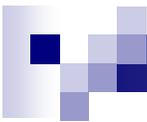
■ Case Study - Changes to IROFS

- The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval) if it *from 70.72(c)(2) - Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary.*
- For a new process, licensee submitted an amendment application, with accompanying ISA Summary and had it approved by the NRC.
- After approval of amendment, the licensee re-analyzed an accident sequence and found that what was previously identified as an intermediate consequence is now a low consequence.
- For low consequence accidents, IROFS are not required, so the licensee deleted the IROFS (no replacements) associated with the accident sequence.



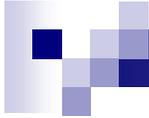
Changes to IROFS (cont.)

- NRC staff considered whether or not licensee needed to re-submit the new analysis for review and approval.
- Conclusion - licensee did not need review and approval because it was considered an equivalent replacement of the safety function.
- NRC inspection staff will review changes on-site to determine that licensee has a sound technical basis for the change (appropriate methodology was applied).
- NRC licensing staff will review annual list of changes to determine that licensee has a sound technical basis for the change (appropriate methodology was applied).



■ Case Study - Altering a Sole IROFS

- The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval) if it *from 70.72(c)(3) - Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of 70.61.*
- For a new process, licensee submitted an amendment application, with accompanying ISA Summary and had it approved by the NRC.
- After approval of the amendment, the licensee re-analyzed an accident sequence and found that what was previously identified as an intermediate consequence is now a low consequence.
- For low consequence accidents, IROFS are not required, so the licensee deleted the sole IROFS (no replacements) associated with the accident sequence.



■ Case Study - Altering a Sole IROFS (continued)

- NRC staff considered whether or not licensee needed to re-submit the new analysis for review and approval.
- Conclusion - licensee did not need review and approval because licensee continues to meet performance requirements following the alteration (removal) of a sole IROFS
- NRC inspection staff will review changes on-site to determine that licensee has a sound technical basis for the change (appropriate methodology was applied).
- NRC licensing staff will review annual list of changes to determine that licensee has a sound technical basis for the change (appropriate methodology was applied).