

License Amendment Review Process

Patrick G. Boyle

Office of Nuclear Reactor Regulation

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License Amendment Request

- Pre-submittal meeting
 - Category 1 public meeting
 - Encouraged for any complex amendment
 - Allows licensee to discuss proposed amendment with NRC technical and licensing staff
 - Provides opportunity for NRC staff to raise concerns about proposed change that can be addressed in the application

License Amendment Request

- License Amendment Process
 - Acceptance reviews
 - Anticipated request for information (RAI) date
 - Anticipated determination date
 - Increased use of formal audits and site visits

NRC Internal Procedures

- NRC – Office Instructions
 - LIC-101 “License Amendment Review Procedures”
(will include instructions for Non-Power Utilization Facility (NPUF) safety evaluation (SE))
 - LIC-109 “Acceptance Review Procedures”
 - LIC-111 “Regulatory Audits”
 - New LIC-115 “Request for Additional Information”

Acceptance Review

- All NPUF requests for licensing action now receive an acceptance review (LIC-109)
 - Acceptable for review
 - Unacceptable with opportunity to supplement
 - Unacceptable with no opportunity to supplement
- Determination made by technical reviewer
(Licensing Branch, sometimes with input from another Division)

Acceptance Review

- Unacceptable with opportunity to supplement
 - Most common result with current submittals
 - Safety conclusion must be supported with analyses and logical evidence; technical description of change is not sufficient by itself
 - Technical specification (TS) revisions not provided or not fully justified

Acceptance Review

- Unacceptable with opportunity to supplement
(typically 30-60 days for supplement to be provided)
 - Supplement dates matter
 - 10 CFR 50.90 “Application for amendment of license ...”
 - 10 CFR 50.4 “Written communications”
 - 10 CFR 50.34 “Contents of applications; technical information”
 - 10 CFR 2.101 “Filing of application”

Acceptance Reviews

- For an accepted license amendment request, the letter will include milestone dates: **supporting compliance with Nuclear Energy Innovation and Modernization Act (NEIMA)**
 - Anticipated first round of RAI
(only one round is assumed in the schedule)
 - Anticipated determination date for the requested licensing action

Processing Request

LIC-101 provides:

- Guidance to the NRC staff for processing license amendment requests, including development of the safety evaluation
- Instruction to ensure review process remains transparent
- Instruction to engage technical review staff

Processing Request

- Enhanced RAI process
 - Draft safety evaluation (SE) developed before RAIs are sent
 - Anticipated date of RAIs communicated in acceptance review letter
 - Delays in RAI responses will result in rescheduling milestones
 - Excessive delays could result in reports to the Commission or Congress, as required by NEIMA

Processing Request

- Enhanced RAI process
 - Per 10 CFR 2.108, “Denial of application for failure to supply information.” Failure to respond to RAI, by 30 days or the agreed upon date, can result in the denial of the application
 - Once an application is denied you cannot request the same action again
 - Withdrawal of the application is usually the better option

Processing Request

- What can be done to reduce the burden related to RAIs?
 - Pre-submittal meetings to identify all areas of review and the information required
 - Comprehensive information in the initial application
 - Logical arguments and complete analyses that justify the change versus only a description of the change

Role of Audits

Visiting the site improves the reviewer's understanding of the facility layout and the requested change:

- Each research reactor, even those with the same fuel type, has unique characteristics
- Technical reviewers may not be familiar with the details of a specific technology and can understand better through direct observation
- On site review of reference material may improve technical reviewer's understanding

Role of Audits

- Once the draft SE is prepared and RAIs are developed, a site visit may allow some questions to be addressed through direct observation
- Once the reviewer has observed the site, clarification related to the expected RAI response is possible, which is communicated through revision to the RAI itself

Role of Audits

- Information reviewed during the audit that is required to make a regulatory finding, must be submitted formally under oath or affirmation
- Audits can enhance understanding, but are not a replacement for information required on the docket
- Audit results must remain transparent to the public

Role of Audits

- Anticipated outcomes:
 - Enhanced facility understanding by the reviewer reduces time for processing the amendment
 - Enhanced understanding of the proposed facility change
 - Enhanced understanding of information needed by the reviewer to complete the safety evaluation
 - Potential reduction in the number of RAIs and the burden of responding

Wrap Up

- Processing amendment requests for NPUFs tend to take longer than nuclear power plants because of the unique aspects of the facilities
- The NPUF license amendment process at the NRC is included in NEI/MA reporting requirements
- Enhancements to the review process should result in a more predictable timeline, reduced rounds of RAI, and reduced overall time for making a determination

Questions?



References

- List of applicable Office Instructions
 - LIC-101, Rev. 5 “License Amendment Review Procedures,” ML16061A451
 - LIC-109, Rev. 2 “Acceptance Review Procedures,” ML16144A521
 - LIC-111, Rev. 0 “Regulatory Audits,” ML082900195
 - LIC-115, pending “Request for Additional Information Procedures,” to be determined

Acronyms

- List of Acronyms used in this presentation:
 - 10 CFR: Title 10 of the *Code of Federal Regulations*
 - NEIMA: Nuclear Energy Innovation and Modernization Act
 - NPUF: Non-Power Utilization Facility
 - NRC: Nuclear Regulatory Commission
 - RAI: Request for Additional Information
 - SE: Safety Evaluation
 - TS: Technical Specification