

Quality of Application

A discussion of License Amendment Request (LAR) detail and quality.

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What We'll Discuss

What do we mean by 'quality of application'?

Discussion on initial submittal process

- Regulatory Requirements
- Regulatory Guidance

Thought Experiment!

Key Takeaways

License Amendments – The Regulations



10 CFR 50.59(C)(1):

A LICENSE AMENDMENT IS REQUIRED IF:

- 1) TS CHANGES ARE REQUIRED; AND/OR
- 2) ANY OF THE EIGHT CRITERIA IN 10 CFR 50.59(C)(2) ARE MET



10 CFR 50.90:

LICENSE AMENDMENT REQUIRES APPLICATION TO NRC, “**FULLY DESCRIBING THE CHANGES DESIRED**”, AND FOLLOWING, AS FAR AS APPLICABLE, THE FORM PRESCRIBED FOR ORIGINAL APPLICATIONS” (50.36, NUREG-1537)



10 CFR 50.92(A):

IN DETERMINING WHETHER TO ISSUE AN AMENDMENT, NRC IS “**GUIDED BY THE CONSIDERATIONS WHICH GOVERN ISSUANCE OF INITIAL LICENSES** ... TO THE EXTENT APPLICABLE AND APPROPRIATE”

Summarized



License Amendment are sometimes required.



License Amendment requests must be detailed.



The NRC holds license amendment request to the same pedigree as the initial license.

The LAR Process.

- Let's look at the first part of the process:
- Step 1: Pre-Submission
- Step 2: Initial Submission
- Step 3: Initial Acceptance Review.

License Amendment Requests (LARs) – Pre-Submission and Initial Submission



Pre-Submission

Early communication with NRC Project Manager

Public meetings (e.g., “phase zero” meetings)



Initial Submissions:

Send to NRC Document Control Desk, or use NRC Electronic Information Exchange system (10 CFR 50.4(a))

Must submit under oath or affirmation (10 CFR 50.30(b))

Cover letter may include requested priority/timeframe/schedule (with basis), if appropriate

Now the NRC has the License Amendment Request....



Is there is sufficient technical information in both scope and depth to allow NRC to begin detailed technical review?



Does the LAR have any readily apparent information sufficient with respect to regulatory requirements or characterization of licensing basis?

After the initial acceptance review.....

1. The LAR is accepted for review

2. The LAR is not accepted for review, and an information supplement is required.

3. The LAR is not accepted for review.

Let's do a thought experiment!

- We are now the regulators of housing! And we will have to do some initial acceptance reviews.

Let's do a thought experiment...

“Your neighbor is doing an amendment on their house.”

- The initial submission tells you that they are going to remove a wall from their house which is a more than minimal increase in consequence of an accident.

1. Good. You accept the amendment to enter the review process.

2. Unsure. The LAR is not accepted for review, and an information supplement is required.

3. Bad. The amendment is not accepted for review based on major issues.

Let's do a thought experiment...take #2

“Your neighbor is doing an amendment on their house.”

- The initial submission tells you that they are going to remove the interior wall that divides the dining room and the living room which is a more than minimal increase in consequence of an accident.
- Blueprints are provided to you as a reference.
- The letter additionally explains how the wall is not a load bearing wall, and it will not affect the integrity of the house.

1. Good. You accept the Amendment to enter the review process.

2. Unsure. The LAR is not accepted for review, and an information supplement is required.

3. Bad. The is not accepted for review based on major issues.

Let's do a thought experiment...take #3

“Your neighbor is doing an amendment on their house.”

- The initial submission tells you that they are going to remove the interior wall that divides the dining room and the living room which is a more than minimal increase in consequence of an accident.
- Blueprints are provided to you as a reference.
- A licensed contractor's inspection report is attached, confirming no ceiling joists or structural members bear on this wall. Additionally, a calculation was performed to show that the increase in consequence of an accident is still within the margins of safety that the home was built with and it is included in the report.
- The original 1978 permit records are also attached showing it was built as a non-structural partition, which confirms the licensed contractor's inspection report.

1. Good. You accept the Amendment to enter the review process.

2. Unsure. The LAR is not accepted for review, and an information supplement is required.

3. Bad. The is not accepted for review based on major issues.

Now the NRC has the License Amendment Request....



Is there is sufficient technical information in both scope and depth to allow NRC to begin detailed technical review?



Does the LAR have any readily apparent information sufficient with respect to regulatory requirements or characterization of licensing basis?

Why The Quality of Application Matters



Timeliness

A complete and organized submittal moves through review faster. Gaps and ambiguity are exactly what generate Requests for Additional Information (RAIs) and each RAI cycle adds time.



Shared Resources

NRC review resources are finite and shared across every applicant in the queue. A submittal that requires excessive ret pulls resources from everywhere else.



Better Outcomes

Investing time upfront in a complete, self-contained submittal reduces total RAIs and hours.

Now that your application has been accepted...

Following acceptance review, NRC staff may use several tools to effectively resolve information gaps identified during the technical review, including:

- **Regulatory Audits**
 - Help efficiently gain understanding, verify information, and/or identify information that will require docketing
 - May be conducted on-site or virtually
- **Public Meetings**
- **Requests for Additional Information (RAIs)**
 - May provide draft RAIs to ensure understanding
 - NRC/applicant discussions of RAIs before and after transmittal (clarification calls)

Important considerations

1

Contact your NRC PMs early and often about scheduling and regulatory clarification.

Clear, early communication helps with resource alignment and sets shared expectations.

2

If there is information already on the docket, and it is necessary information to establish the technical basis, then reference it!

NOTE: Cite the exact document, revision, and ADAMS accession number, and point to the specific section or page being relied on.

3

All License Amendment Requests must be fully encapsulating.

Tell the full story.

- Why the change is needed
- Technical basis supporting the change
- How it satisfies the applicable criteria

The NRC cannot fill in the blanks and make assumptions based on prior knowledge or discussions.



Questions