

10 CFR 50.59

The meaning behind Changes, Tests, and Experiments

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What We'll Discuss

The Regulatory Framework

- What 10 CFR 50.59 is...
- Screenings
- The Eight Criteria

Diving into Screening Examples!

- Screening Example
- Evaluation Example

Key Takeaways

- Recordkeeping
- Best Practices

What 10 CFR 50.59 Is...

- **50.59 Changes, tests, and experiments.**

(a) Definitions for the purposes of this section:

(1) **Change** means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) **Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses** means:

(i) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) **Facility as described in the final safety analysis report (as updated)** means:

(i) The structures, systems, and components (SSC) that are described in the final safety analysis report (FSAR) (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(4) **Final Safety Analysis Report (as updated)** means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with [§ 50.34](#), as amended and supplemented, and as updated per the requirements of [§ 50.71\(e\)](#) or [§ 50.71\(f\)](#), as applicable.

(5) **Procedures as described in the final safety analysis report (as updated)** means those procedures that contain information described in the FSAR (as updated) such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

(6) **Tests or experiments not described in the final safety analysis report (as updated)** means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses or descriptions in the final safety analysis report (as updated).

What 10 CFR 50.59 Is...

SELF-GOVERNED CHANGE CONTROL

LICENSEES EVALUATE THEIR OWN FACILITY
AND PROCEDURE CHANGES AGAINST
DEFINED CRITERIA.

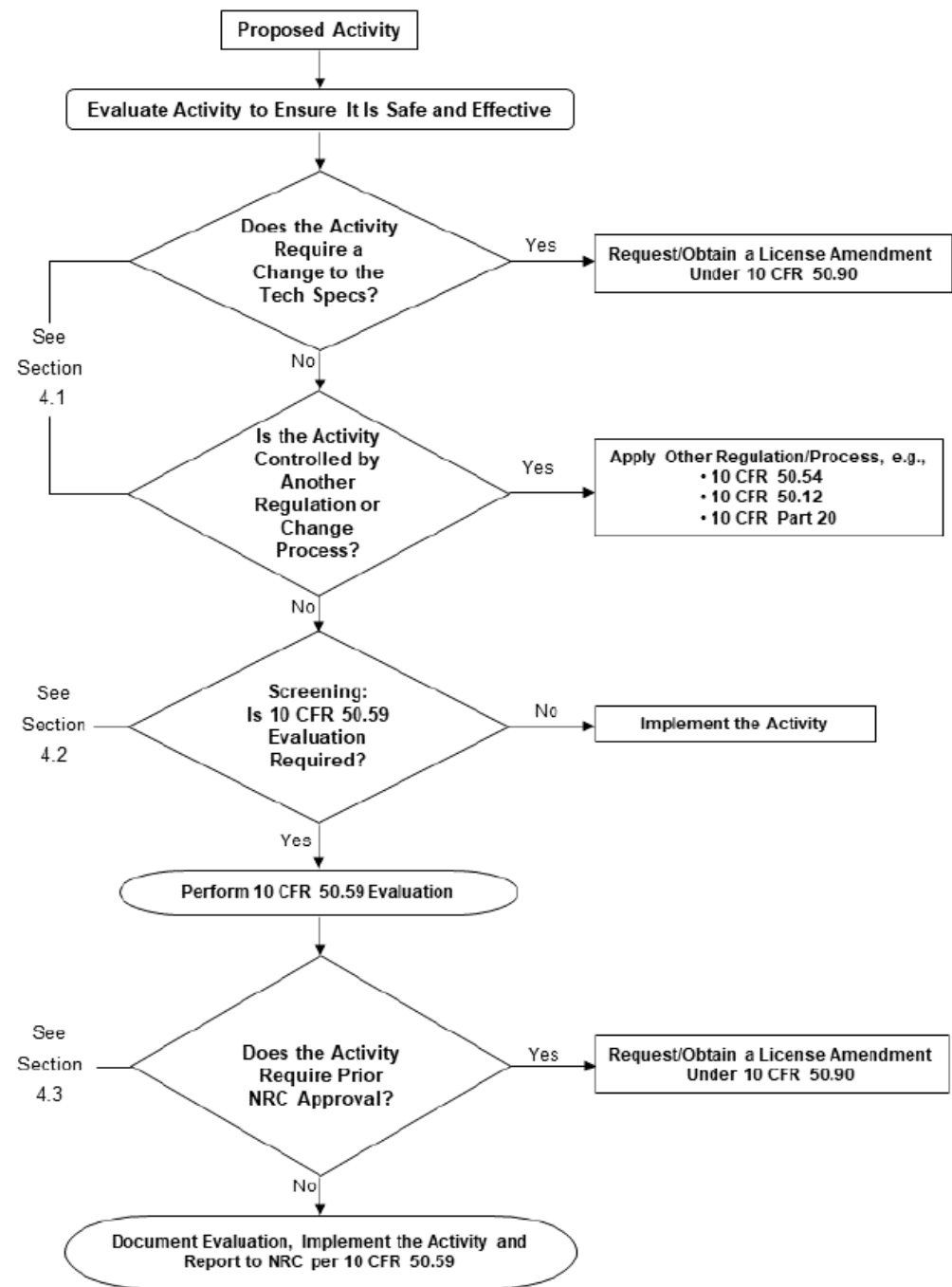
A THRESHOLD TEST

THE RULE DOESN'T PROHIBIT CHANGE.
IT DEFINES WHEN A CHANGE IS
SIGNIFICANT ENOUGH TO REQUIRE NRC
REVIEW PRIOR TO IMPLEMENTATION.

APPLIES TO THE FSAR BASELINE:

CHANGES ARE MEASURED AGAINST WHAT
IS DESCRIBED IN THE FINAL SAFETY
ANALYSIS REPORT (AS UPDATED)

The Process of 50.59 (according to NEI 21-06)



The “Adverse Effect” Screening Test

According to the guidance utilized in NEI 21-06, a 50.59 evaluation is required only for changes that adversely affect a design function, how it's performed, or the evaluation that demonstrates it works. Positive or neutral changes may screen out — regardless of size.

- | | |
|--|--|
| • Does it decrease the reliability of an SSC design function? | • Does it reduce existing redundancy, diversity, or defense-in-depth? |
| • Does it add or delete an automatic or manual design function? | • Does it convert an automatic feature to manual, or vice versa? |
| • Does it introduce an unreviewed system or materials interaction? | • Does it adversely affect response time for required actions? |
| • Does it degrade seismic or environmental qualification? | • Does it affect a method of evaluation used in the design bases or safety analyses? |

A “yes” to any question screens the activity in — the evaluation (not the screening) is where magnitude gets assessed.

Worked Example for Screening: Screening a Timing Change

The UFSAR credits building ventilation dampers with closing within 12 seconds of detecting abnormal effluent activity, so the release doesn't escape.

10 → 12 seconds

SCREENS OUT

Still meets the credited 12-second design function — no adverse effect, even though the actuation relay changed.

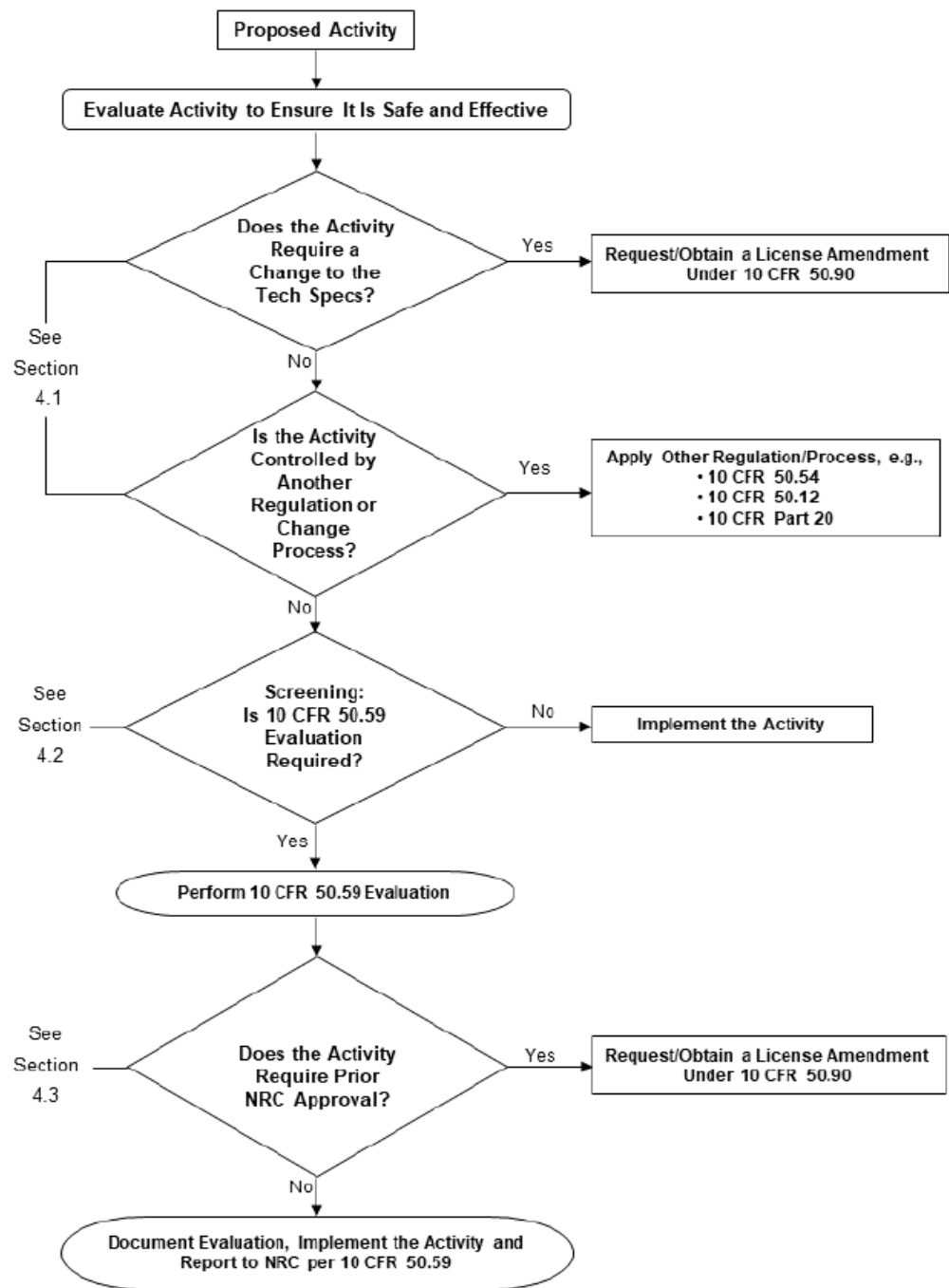
10 → 13 seconds

SCREENS IN

Exceeds the 12-second design function — adversely affects the credited function, regardless of any revised analysis showing dose limits are still met.

The lesson: screening questions asks whether the credited function is still met. It does not ask whether the outcome is still “safe.” A revised analysis showing acceptable dose doesn't change a screen-in.

The Process of 50.59 (according to NEI 21-06)



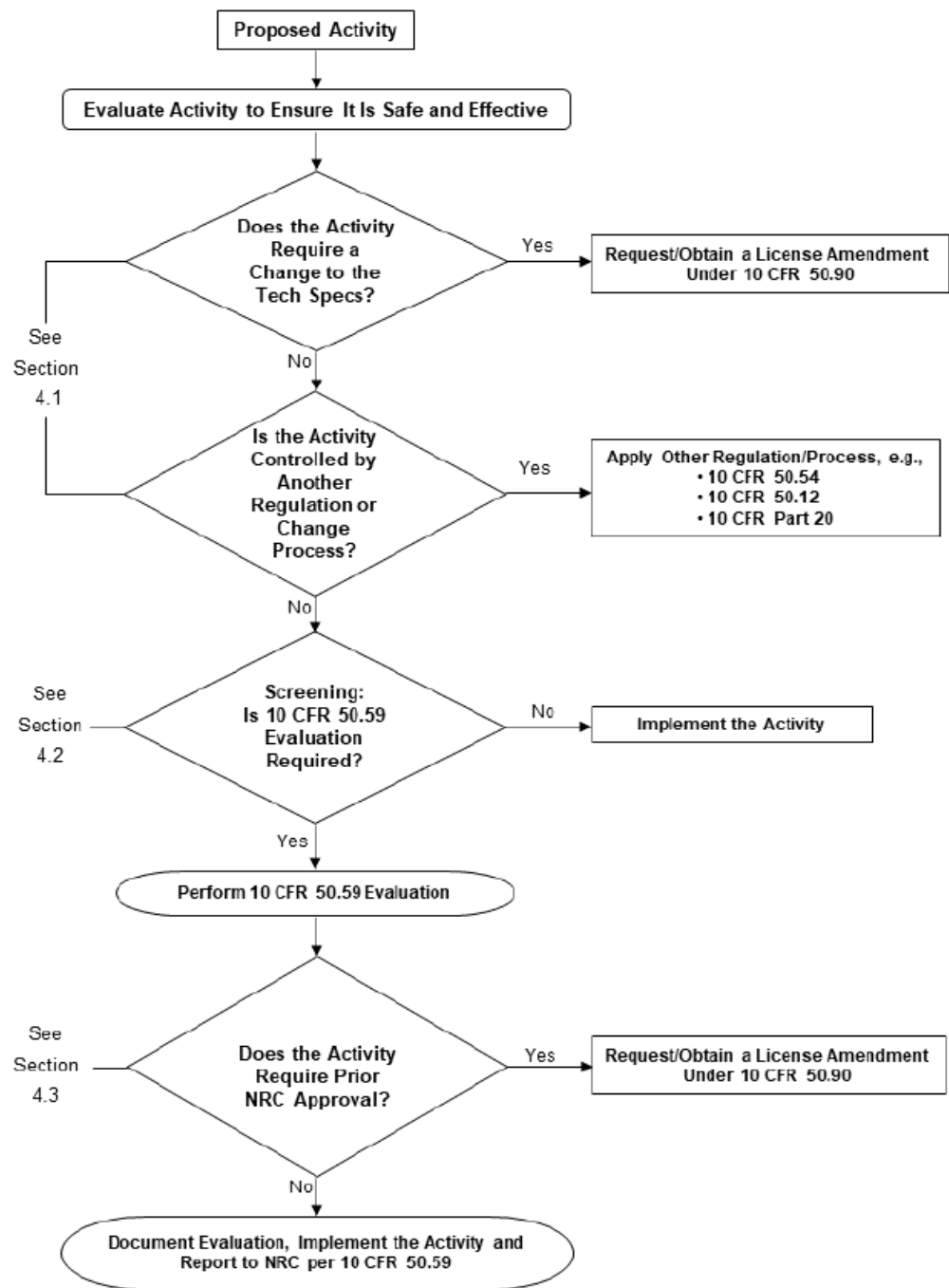
50.59(c)(2): The Eight Evaluation Criteria

- A license amendment is required if the activity results in a more than a minimal increase in any of the following:
 - i. Frequency of occurrence of an accident previously evaluated
 - ii. Likelihood of occurrence of a malfunction of an SSC important to safety
 - iii. Consequences of an accident previously evaluated
 - iv. Consequences of a malfunction of an SSC important to safety
 - v. Possibility for an accident of a different type than previously evaluated
 - vi. Possibility for a malfunction of a different type than previously evaluated
 - vii. Design basis limit for a fission product barrier is exceeded or altered
 - viii. Departure from a method of evaluation described in the FSAR (used in safety analyses)

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The Process of 50.59 (according to NEI 21-06)



Worked Example for Evaluating Criterion (i): Malfunction of an SSC

Ventilation damper closure: The proposed change replaces a mechanically operated actuator with an air-operated actuator. The Damper is an SSC with a design function to close and fail in the closed position.

Adverse Effect Screening Test: screens in because it changes the method of performing the design function (NEI 21-06, 2.2.1.2).

Evaluation focus (criterion i): does the change increase the probability of occurrence of a malfunction of an SSC important to safety?

Fails CLOSED on loss of air

NO ADVERSE EFFECT — NO APPROVAL NEEDED

The new actuator's failure mode still performs the design function (building closure) on loss of instrument air. No new malfunction is created, and the probability of a malfunction with a different result than previously evaluated is not increased.

Fails OPEN on loss of air

ADVERSE EFFECT — PRIOR NRC APPROVAL REQUIRED

A loss of instrument air now defeats the design function instead of preserving it — a new failure mode with worse consequences than the original mechanical actuator. This meets criterion (i): more than a minimal increase in the likelihood of a malfunction with a different result than previously evaluated.

The Process of 50.59



Identify The Activity

A change to the facility or a procedure, or a test/experiment not already described in the FSAR.



Screen It

Does the activity affect an FSAR-described design function, method of evaluation, or procedure?



Screened Out?

If no FSAR-described function is affected, no further 50.59 evaluation is needed — document and proceed.



Evaluate

If screened in, apply the eight evaluation criteria in 50.59(c)(2) to determine if NRC approval is required.

Recordkeeping and Reporting

1

What Must Be Recorded

Changes to the facility, changes to procedures, and tests/experiments performed under paragraph (c) that **screened in and were evaluated.**

2

Written Evaluation Required

Records must include a written evaluation providing the basis for concluding a license amendment under (c)(2) is not required.

3

Reporting: Rule vs. Practice

10 CFR 50.59(d) requires reporting to NRC at least every 24 months — but current NPUF technical specifications typically require ANNUAL reporting of major changes and new tests/experiments, with a summary of the safety evaluation.

4

Retention Period

Records of procedure changes and of tests/experiments **must be maintained for 5 years.**
Screening-out records aren't subject to this requirement but should still be kept per facility procedure.

50.59 Considerations and Best Practices

1

Detailed 50.59 screenings allow 3rd party reviewers to understand the basis for each change.

2

Involvement of the Reactor Oversight Committee helps ensure changes are completed with accuracy and rigor.

3

50.59 screenings reviewed by a qualified, senior individual catch more errors and support stronger technical rigor in the proposed changes.



Questions