

PUBLIC SUBMISSION

SUNSI Review Complete
Template = ADM-013
E-RIDS=ADM-03
ADD: Robert Schaaf,
Carleen Parker

COMMENT (2)
PUBLICATION DATE:
3/23/2020
CITATION 85 FR 16278

As of: 6/30/20 6:54 AM
Received: June 26, 2020
Status: Pending Post
Tracking No. 1k4-9hha-6v4a
Comments Due: July 22, 2020
Submission Type: Web

Docket: NRC-2018-0142
Backfitting, Forward Fitting, and Issue Finality Guidance

Comment On: NRC-2018-0142-0001
Backfitting, Forward Fitting, and Issue Finality Guidance

Document: NRC-2018-0142-DRAFT-0003
Comment on FR Doc # 2020-06081

Submitter Information

Name: Blake Bixenman
Address:
P.O. Box 1789
Eunice, NM, 88231
Email: andrew.bixenman@urencos.com

General Comment

See the attached comments on Draft NUREG-1409, Revision 1, submitted on behalf of Louisiana Energy Services, LLC, dba Urenco USA

Attachments

LES-20-00063-NRC URENCO USA Comments on Draft NUREG-1409, Revision 1

LES-20-00063-NRC

6-26-2020



Docket ID NRC-2018-0142

U.S. Nuclear Regulatory Commission
Electronic submission to Regulations.gov

Louisiana Energy Services, LLC
NRC Docket No. 70-3103

Subject: URENCO USA Comments on Draft NUREG-1409, Revision 1

On March 23, 2020, the U.S. Nuclear Regulatory Commission (NRC) issued for public comment draft NUREG-1409, "Backfitting Guidelines", Revision 1. Pursuant to 85 FR 29358, Louisiana Energy Services, LLC, dba Urenco USA, herewith submits comments on Draft NUREG-1409,, "Backfitting Guidelines", Revision 1 (NRC-2018-0142).

Should there be any questions concerning this submittal, please contact Wyatt Padgett, UUSA Licensing and Performance Assessment Manager, at 575-394-5257.

Sincerely,

A handwritten signature in blue ink that reads "Stephen R. Cowne".

Stephen R. Cowne
Chief Nuclear Officer and Compliance Manager

Enclosure: URENCO USA Comments on Draft NUREG-1409, Revision 1

LES-20-00063-NRC



Enclosure
URENCO USA Comments on Draft NUREG-1409, Revision 1
“Backfitting Guidelines” (NRC-2018-0142)

**URENCO USA Comments on Draft NUREG-1409,
“Backfitting Guidelines”, Revision 1 (NRC-2018-0142)**

Summary

URENCO USA (UUSA) submits the following comments on the NRC staff's draft Revision 1 of NUREG-1409, *Backfitting Guidelines* (published March 2020, Docket ID NRC-2018-0142). UUSA appreciates the Staff's effort to update the comprehensive guidelines of NUREG-1409 and assist the understanding of the backfitting process by licensees and other stakeholders. UUSA's comments focus on key points in the draft NUREG that we believe warrant additional clarification. We also offer practical suggestions for improving the process. UUSA offers a broader set of comments below and we emphasize the following:

- Two key issues with NRC's application of the backfitting rule are: (1) how to determine the “applicable staff position” that establishes the baseline for identifying a potential backfit; and (2) how to apply the “compliance exception.” If the NRC can clarify these two key points, it will go a long way towards improving the understanding of the rule and reducing the uncertainty over how the rule is applied.
 - To help ensure clarity as to “applicable staff positions,” we suggest that the NRC use a technique similar to the commitment management process developed by industry and NRC where licensees list regulatory commitments in an attachment to a licensing request. The NRC could include such an attachment as part of its Safety Evaluations in order to list findings and conclusions that represent “staff positions.”
 - Regarding the compliance exception, many issues that arise are due to a lack of clarity in how to apply generally worded performance standards in the NRC's regulations – for example, General Design Criteria (GDC) and Quality Assurance standards. The draft NUREG indicates that some performance standards can serve as the basis for invoking the compliance exception. To promote clarity, we recommend that NRC publish an illustrative list of such performance standards that can be a basis for a compliance exception.
- The NRC should publish all backfit decisions on its website in a central location, to promote a better understanding of the process and precedent, as well as consistency in implementation.

UUSA recommends that, due to the many subtleties involved in these backfitting issues, the NRC should provide an additional opportunity to meet with stakeholders and seek further comment once the staff has considered the first round of comments and before finalizing the draft NUREG.

Commented [KA1]: UUSA-01

Commented [KA2]: UUSA-02

Commented [KA3]: UUSA-03

Commented [KA4]: UUSA-04

UUSA Comments

1. The Scope of NRC's Backfitting Provisions Should Be Broadly Applied

Draft Revision 1 of NUREG-1409 ("NUREG"), in several locations, points out that the backfit rule (hereinafter also generally referring to forward fit as well) only applies to certain licensees and situations, indicating that certain ones fall within the scope of backfit rules such as 10 CFR 50.109 (for power reactors) and 10 CFR 70.76 (for fuel cycle facilities) while others fall outside the scope of the rule. In fact, as Section 2.1 of the draft NUREG indicates (see also Section 2.3), determining whether a matter or proposed action would "affect any entity that is within the scope of a backfitting" provision is a crucial preliminary question that must be addressed before the NRC staff moves forward in the backfit screening process. Notwithstanding, Section 2.3 of the NUREG (at p. 2-5) clearly acknowledges that entities *not* within the scope of one of the specific backfit rule provisions listed by the staff may also be affected. Yet, the NUREG (at p. 2-6) simply indicates that the NRC staff "can exit" the screening process if it determines the matter is not within scope, but may still take the proposed action. Although the NUREG indicates that under these circumstance the "staff can consider other agency processes" (at p. 1-7), our experience indicates this rarely occurs. Thus, this approach raises serious questions about why the backfit rule is restricted only to certain licensees and situations.

The position that such an approach is based on policy considerations (see Section 1.2.1 and 2.3), or is due to "technical problems" or "potentially significant resource burdens for the staff" (at p. 2-5), is not logical, given, as admitted in the NUREG, substantive impacts can befall other types of licensees who are outside the scope of an existing backfitting provision. For example, a regulatory action in one part of the regulations without a backfit rule provision can affect licensees that are protected by backfit provisions under other parts of the regulations (e.g., Part 50 or Part 70). Moreover, the NUREG acknowledges that historically the backfit rule only applied to reactors, but as history shows, the rule's scope of application has been expanded multiple times (see Section 2.3). If the backfitting rule reflects good administrative policy, the rule should apply to all licensees that are substantively affected by a new requirement, this would provide fairness and parity. Alternatively, the NRC should at least issue guidance specifying exactly how new requirements in areas outside the scope of a specific backfitting rule but affecting licensees covered by backfitting protections will be addressed.

Commented [BH5]: UUSA-05

Commented [BH6]: USSA-06

In UUSA's view, new requirements should be treated as backfits whenever they have a substantive impact on licensees, even if the new requirements relate to parts of the NRC's regulations that do not contain backfitting provisions. As the Commission explained in adopting the 1985 backfitting rule, a backfit is defined in terms of both the "cause" and the "effect" of the NRC action. Under 10 CFR 50.109(a)(1) and 10 CFR 70.76(a)(1), "backfitting" is defined to include the "modification of, or addition to, systems, structures, or components, of a facility" or changes to "the procedures or organization required to operate a facility" any of which "may result from a new or amended provision in the Commission rules." The definition is broadly worded to include any new or amended regulation that has the effect of causing such changes for Part 50 or Part 70 licensees. As the definition indicates, a backfit can result not only from a change that modifies or interprets Part 50 or Part 70, but by "any new or amended provision in the Commission rules."

Commented [KA7]: UUSA-05.a

Commented [KA8]: UUSA-05.b

In rulemakings with wide-ranging impacts, the Commission has reviewed how the proposed new requirements would burden different types of licensees. In a rulemaking to adopt new Part 71 quality assurance requirements for transportation of radioactive materials, the Commission

stated that the backfit rule will apply "where the activity regulated under other parts without backfitting or issue finality provisions [e.g., Part 71] is an *inextricable part* of the regulated activity subject to backfitting or issue finality [e.g., Part 50 and Part 70]."¹

Commented [KA9]: UUSA-05.c

Under this Commission precedent, if a regulatory action would cause a substantive impact on licensees who are covered by a backfitting provision, it should be subjected to the backfit rule's cost/benefit standard, even if the action involves a change to a part of the regulations that does not contain a backfitting provision. For example, new requirements for reactor operator licensing under 10 CFR Part 55 could be a backfit for Part 50 reactor licensees who are covered by 10 CFR 50.109, since they would be affected by any new Part 55 requirements (e.g., for operator training, or plant-referenced simulators). The current 10 CFR Part 61 rulemaking is another example where the Commission apparently is considering impacts on licensees, including power reactors and fuel cycle facilities, even though Part 61 does not include a specific backfitting provision for low-level waste (LLW) disposal facilities (see Item 5 in SRM-SECY-16-0106, dated Sept 8, 2017). The Commission's action on the Part 61 rulemaking recognizes that NRC actions affecting one type of licensee (e.g. LLW disposal facilities) can have a "domino" effect on other licensees that is often unforeseen or unintended. In fact, the primary impact of the proposed Part 61 rulemaking would fall on reactor and fuel cycle licensees who would face new requirements and procedures for LLW storage and disposal, leading to higher waste burial costs.

Commented [KA10]: UUSA-05.d

The NUREG-1409 guidance should clearly explain this principle to help ensure a broad application of the Commission's backfitting policy. Backfitting provisions should be used to protect all licensees that are affected by NRC actions.

2. NUREG-1409 Guidance Should Be Coordinated with Management Directive 8.4

The NUREG refers often to Management Directive 8.4 ("MD 8.4" or "MD"), which was most recently approved as of September 19, 2019. First, NRC needs to ensure that the NUREG completely squares with MD 8.4, in particular the Handbook portion of the MD (e.g., regarding the use of "safety margin" – see p. 14 footnote 10). Simply stating that safety margin – which the MD considers an important part of a compliance backfitting analysis – "may not be quantifiable" is like stating that the NRC staff will know it when they see it.² Given the extreme importance of *how* the backfit rule, and the compliance exception in particular, is implemented, it is respectfully submitted that clearly articulating and defining critical concepts like safety margin are essential and demand objectivity.³ Accordingly, UUSA urges the NRC to clarify the concept of safety margin as applied in the backfitting context, with a focus on providing an objective definition of safety margin.

Commented [KA11]: UUSA-07

Second, MD 8.4 indicates that "transparency" and public availability of NRC's evaluation and analyses are part of good regulatory practice (at p. 4). Therefore, it makes good regulatory sense to require that NRC promptly publish all backfit decisions on its website (in a location

Commented [KA12]: UUSA-03.a

¹ Final Rule, *Establishing Quality Assurance Programs for Packaging Used in Transportation of Radioactive Material*, 78 Fed. Reg. 29016, 29017 (May 16, 2013)(emphasis added).

² An idea much like Supreme Court Justice Potter Stewart's famous line in the 1964 *Jacobellis v. Ohio* case regarding obscenity, which as initially set forth in the 1973 *Miller v. California* decision ultimately *required* a more objective standard (3-prong test).

³ While "safety significance" (see Section 1.4 of the NUREG) appears to be a more "defined" and/or "definable" concept, NRC should strongly consider making clear the metes and bounds of this terminology as well.

easily identified and in a searchable form) in order for licensees and other stakeholders to evaluate them for applicability and precedent purposes. This would not only enhance the efficiency of licensee/NRC interactions on backfit matters, but very likely conserve NRC resources by eliminating unnecessary back-and-forth correspondence (such as requests for additional information), teleconferences and/or in-person meetings. Moreover, in the same vein, NRC should periodically audit these decisions to ensure that they demonstrate consistency in application (the results of such audits should be made publicly available as well).

Commented [KA13]: UUSA-03.a cont'

Commented [KA14]: UUSA-08

3. The Critical Discussion of "Staff Positions" Should Be Clarified

The determination of a "previously applicable staff position" is fundamental to the backfitting process, as it establishes the baseline by which to evaluate whether a backfit is being imposed. UUSA urges the NRC to pay special attention to the guidance on what constitutes a staff position for purposes of the backfitting rule.

The discussion in Section 1.2.2.2, "Staff Positions," requires some re-evaluation. Specifically, the terminology "regulatory bases" for NRC staff decisions and interpretations that support staff positions is not defined (nor is the phraseology used in MD 8.4). The only clue as to a possible definition is found in Section 1.2.2.2 (and 5.18), indicating that staff positions in safety evaluations are not requirements but rather "provide the *staff position* on whether a licensee's proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement." (Emphasis supplied.) The reason a definition is needed is because, in practice, the NRC staff has often referred to other types of documents and correspondence as the "bases" for its position.⁴ Thus, a clearly articulated definition (e.g., whether bases must be documented and, if so, in what form) would provide clarity and certainty as to how NRC staff positions are formed – a clearly needed understanding when attempting to determine whether there has been an omission or mistake of fact as related to application of the compliance exception (see Section 2.5.2.2).

Commented [KA15]: UUSA-09

Commented [KA16]: UUSA-09.a

A similar ambiguity arises with the NUREG's discussion of NRC inspection reports. Section 1.2.2.2 includes a "caution" that states in part:

Inspection reports can contain staff positions, but the staff must not use inspection reports to create staff positions about the adequacy of the licensing basis (e.g., "the licensee is in compliance"), although some exceptions may apply depending on the type of inspection.

As with the provisions on NRC safety evaluations, this discussion of NRC inspection reports should be clarified. If an NRC inspection reviews the adequacy of a system, structure, or component (SSC), or a licensee program established to meet NRC requirements, the findings and conclusions of the inspection report should be at least substantial evidence of a staff position. Any other result would create great uncertainty for licensees as to whether they are in compliance, even after the NRC has reviewed SSCs or licensee programs during inspections.

Commented [KA17]: UUSA-10

⁴ In certain prior circumstances NRC staff members have also referred to recollection of telephone calls and/or face-to-face meetings to support the "bases" for their positions. Although the NUREG cautions against such situations (i.e., "[t]he NRC staff should not attempt to impose or suggest requirements through informal communications" – see p. 1-13), this has not always been the case. Frankly, instead of a caution, given the principles of good regulation, there should be an absolute prohibition against such behavior.

Commented [KA18]: UUSA-09.b

Another consideration regarding staff positions should be how a licensee can know for certain that particular language in documented “staff decisions and interpretations” is, in fact, intended as a staff position. How might this be accomplished? When proposing a licensing action a large number of licensees have chosen to specifically identify the regulatory commitments they are making, and list those formal written commitments in a separate attachment to the licensing action request. Licensee written commitments serve as a baseline to assess backfitting issues in the same manner as staff positions (see, e.g., 10 CFR 50.109(a)(4)(i)).

NRC should consider a similar protocol for staff positions – for example, require the NRC staff to list the staff positions specifically in the safety evaluation or inspection report. The additional time it would take to make this clarification in applicable documentation on the front end would likely be more than made up for on the back end by avoiding unnecessary correspondence and interface with a licensee as to whether a finding or conclusion in a safety evaluation or inspection report represents a staff position for purposes of the backfitting rule.

Commented [KA19]: UUSA-01.a

4. Administrative Exceptions Create Uncertainty and Should Be Avoided

Section 1.2.4 of the NUREG states: “If the Commission needs to impose an action that meets the definition of ‘backfitting’ but cannot meet the backfitting requirements, then the Commission can exempt itself from the applicable backfitting provisions.” This section goes on to state: “As a practical matter, an administrative exemption should be considered only when none of the criteria for justifying the backfitting action can be met and either the Commission or the EDO has indicated a desire to proceed with the proposed backfitting after being informed by the NRC staff that it was unable to justify the proposed backfitting in accordance with any of the applicable backfitting provisions.”

While it is perhaps laudable that the NRC has only used this administrative exception very sparingly (according to the NUREG only twice), allowing such unfettered discretion for the Commission to exempt itself from the backfitting rule at any time really tears at the underlying reasoning for how the backfit rule should be implemented and, frankly, could lead to the type of uncertainty that the rule was designed to prevent. Allowing such unfettered administrative discretion does not comport with the recent limitations on an agency’s interpretation of its own regulations set forth by the Supreme Court in *Kisor v. Wilkie*, 139 S.Ct. 2400 (2019).

Commented [KA20]: UUSA-11

In *Kisor*, the Supreme Court addressed the concept of *Auer* deference (taken from *Auer v. Robbins*, 519 U.S. 452 (1997)), whereby courts generally defer to an agency’s reasonable interpretation of its own genuinely ambiguous regulation. The Court declined to overrule this deference in *Kisor*, but it also expounded on the strong limits of that deference, which include:

- 1) *Auer* deference should only apply when an agency regulation is *genuinely* ambiguous, meaning it eludes clarity even after a court has applied all of the standard tools of construction.
- 2) If there is genuine ambiguity, the agency’s reading must still be reasonable (i.e. it must come within the zone of ambiguity after the court applies its interpretive tools).
- 3) The court must make independent inquiry into whether the “character and context” of the agency interpretation gives it controlling weight. The Court gave some factors that should be used to make this inquiry, including that the agency interpretation:

- a. Is the agency's "authoritative" or "official position," not an *ad hoc* statement;
- b. Implicates the agency's substantive expertise; and
- c. Reflects the "fair and considered judgment" of the agency.

Given these limitations on deference to an agency's interpretation of its own regulations, it is clear that an administrative exception from the backfitting rule is not the type of agency interpretation of a genuinely ambiguous regulation that the courts would countenance under *Kisor*. At a minimum, the discretion reserved by the NRC to exempt itself from the backfitting rule should at least be limited to situations where the public has the opportunity for notice and comment on the proposed action (recognizing that emergency health and safety and security situations are already accommodated under the adequate protection exception).

Commented [KA21]: UUSA-11.a

5. The Backfit Screening Process Should Be Expanded

Section 2.1 of the NUREG indicates that the staff should ask itself six (6) questions when performing a backfit screen. One question that seems to be missing is whether there has been a prior licensee-specific or generic backfit decision or similar precedent (e.g., an initial claim or appeal) that would bear on the screening being done at the time. Like the comment above about publication of prior backfit decisions, the principles of good regulation logically demand that each time a backfit (or for that matter an exception to the rule) is considered, such a question should be part of the screening. The response to this question on whether a relevant precedent exists should likewise be part of the documented decision. Without consideration of prior precedent, there really is an inadequate check-and-balance mechanism to ensure consistent implementation of the backfit rule.⁵

Commented [KA22]: UUSA-12

6. Discussion of the Compliance Exception Should Be Clarified

One of the most difficult issues associated with the backfitting rule has been the use of the "compliance exception" of 10 CFR 50.109(a)(4)(i) and 10 CFR 70.76(a)(4)(i) and (ii). Section 2.5.2.2 of the draft NUREG discusses compliance exception determinations in some detail. UUSA appreciates the NRC staff's effort to focus on this issue and to try to make the guidance on use of the compliance exception as clear and objective as possible.

In particular, UUSA agrees with the draft NUREG's emphasis on the standard articulated by the Commission in the Statement of Considerations (SOC) to the 1985 backfitting rule. As the draft NUREG notes (at p. 2-13), the Commission made clear in the 1985 SOC (emphasis added):

The compliance exception is intended to address situations in which the licensee has failed to meet *known and established standards* of the Commission because of *omission or mistake of fact*.

⁵ As regards forward fitting, Section 2.2 of the NUREG states: "Because the backfitting and issue finality provisions do not expressly identify these exclusions, the staff should consult the NRC Backfitting and Forward Fitting Community of Practice to assist with determining whether the proposed action would be excluded from backfitting considerations." This apparent informal and internal consultation would be made more certain by adding the steps for documenting, publishing and consulting prior precedent.

Commented [KA23]: UUSA-12.a

We agree that this is the correct standard and should be highlighted in the NUREG. We would urge the NRC staff to work with industry to add examples to illustrate the proper use of the compliance exception under the standard articulated in 1985 by the Commission. As the draft NUREG notes (at p. 2-13), the 1985 SOC emphasized that “new or modified interpretations of what constitutes compliance would not fall within the [compliance] exception.....”

Commented [KA24]: UUSA-13

Many of the issues that have arisen over the years with respect to the use of the compliance exception have involved situations where the licensee believes the NRC may be imposing a new or modified interpretation of what constitutes compliance with a particular regulatory requirement. As the draft NUREG recognizes (at p. 2-15):

A change in the NRC’s position as to whether a licensee’s design conforms to a performance standard is likely to be met with the argument that the new position does not reflect consistency with a ‘known and established standard,’ but rather is a new or modified interpretation of what constitutes compliance. . . .

UUSA believes it would be useful for the NRC staff and industry to develop some common examples to illustrate this key principle, in particular by listing examples of such “performance standards.” One concern has been the NRC’s reliance on general standards such as the General Design Criteria (GDC) for power reactors or Quality Assurance standards for reactors or fuel cycle facilities (e.g., 10 CFR Part 50, Appendix B) as the basis for invoking the compliance exception. Many of the compliance exception issues have arisen due to a lack of clarity in how to interpret and apply generally worded, non-prescriptive provisions of the GDC or QA standards. Section 5.6 of the draft NUREG indicates that such general provisions of the regulations can serve as the basis for invoking the compliance exception if they provide “more than just a performance standard.”

Commented [KA25]: UUSA-02.a

To promote clarity, we suggest that NRC actually publish an illustrative, non-exhaustive list of the GDC or QA provisions that meet this criterion – “more than just a performance standard” – for serving as the basis for a compliance exception. An illustrative list would improve understanding of when the compliance exception may apply, thereby promoting certainty and predictability for licensees and the staff.

Commented [KA26]: UUSA-02.b

Further, with respect to the factor of an “omission or mistake of fact,” the NUREG should recognize that when the NRC, with full and correct information, has accepted a licensee’s design or program as conforming to applicable standards, the licensee is entitled to a presumption of compliance. Such acceptance could occur during initial licensing, in response to a licensing action (e.g., license amendment request), or as part of the NRC’s review or inspection of a licensee’s implementation of an NRC regulatory requirement. This presumption of compliance promotes regulatory stability and should be the starting point for any compliance exception evaluation. Only if the NRC can clearly show an omission or mistake of fact should it be allowed to revisit its prior acceptance and the licensee’s continued compliance. It follows that if the NRC develops new guidance in an area, even in response to generic findings or lessons learned within the industry, such guidance, in the vast majority of cases, should be treated as reflecting a “new or modified interpretation of what constitutes compliance,” which the Commission said in the 1985 SOC would fall outside the compliance exception.

Commented [KA27]: UUSA-14

Commented [KA28]: UUSA-15

Commented [KA29]: UUSA-16

UUSA also appreciates the NRC staff’s recognition that the Supreme Court’s 2015 decision in *Michigan v. Environmental Protection Agency*, 135 S.Ct. 2699, requires consideration of costs for new rulemakings as well as compliance backfitting issues. See draft NUREG-1409 at p. 2-

15 to 2-16. The Supreme Court in *Michigan v. EPA* stressed that cost impacts on regulated entities are always a relevant consideration in reviewing proposed new agency requirements.

UUSA appreciates the opportunity to comment on this important initiative to develop comprehensive updated guidance on backfitting. We look forward to working together with the NRC staff to develop valuable and lasting guidance that will benefit all stakeholders and achieve the Commission's policy reflected in the backfitting rule.