

July 31, 2012

Mr. Daniel F. Stenger
Hogan Lovells US LLP
Columbia Square
555 13th Street NW
Washington, DC 20004

SUBJECT: REGULATORY BASIS FOR REGULATORY GUIDE 3.74

Dear Mr. Stenger:

I am responding to your letter to the Executive Director of Operations, dated June 11, 2012, in which you expressed concerns regarding the U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide (RG) 3.74, "Guidance for Fuel Cycle Facility Change Processes," issued in January 2012. Specifically, you state that Sections C.5.b through e of RG 3.74 establish new requirements (*i.e.*, new change control processes) that were "not properly vetted through the rulemaking process or otherwise lack an appropriate regulatory basis and raise backfitting concerns." You also assert that establishing a change control process independent of current regulations is inconsistent with the NRC's good regulation principle that "regulatory actions should always be fully consistent with written regulations." You request that the NRC staff (staff) reconsider Sections C.5 b through e of RG 3.74.

The staff views your letter as raising the following concerns:

1. Whether, in issuing the draft and final RG (and in comment responses), the staff established a new requirement or articulated a regulatory basis for the proposed guidance (on a licensee-initiated license condition addressing licensee document change controls);
2. Whether the staff properly addressed backfitting concerns with respect to the proposed guidance as part of the process of issuing the final RG; and
3. Whether the optional change control process described in RG 3.74 is consistent with the NRC's principle that regulatory actions are to be fully consistent with written regulations.

A draft of RG 3.74 was issued for public comment as DG-3037, dated May 2011. 76 FR 41527 (July 14, 2011). Comments on the draft RG were received and addressed by the NRC prior to issuance of the final RG 3.74, dated January 2012. 77 FR 823 (January 6, 2012).¹

¹ The first draft of DG-3037 (ML091200493) was issued for public comment in 2009. 74 FR 31073 (June 29, 2009). The staff's response to public comments on the 2009, draft RG are set forth in ML100890028. As stated in the *Federal Register* notice announcing a second draft of RG 3.74/DG-3037 for public comment, the earlier RG was revised "as a result of considerations raised by stakeholders during the earlier public comment period, and ongoing NRC policy development." 76 FR 41527 (July 14, 2011). Responses to comments received in response to that notice are in ML113050428.

Sections C.5 b through e of RG 3.74 (quoted in note 2, below) indicate that the staff would consider approving a licensee's request for a license condition which (1) establishes a change control process containing features as described in RG 3.74 and (2) identifies criteria for determining what changes to licensee documents may be made without prior NRC approval.

The staff has reviewed the documents which led to the issuance of RG 3.74, and concludes that the RG does not establish a new requirement, the staff's regulatory basis was articulated in sufficient detail at each stage of the RG development process, and that backfitting concerns were considered in the course of issuing the proposed and final guidance. The staff further concludes that the change control process is fully consistent with existing NRC regulations, and thus meets the NRC's good regulation principle that you cite. In reviewing your concerns, however, the staff identified an error in Section D of RG 3.74. That error will be corrected to clarify the reasons why the guidance is not a backfit. Each of your concerns is addressed below.

I. Voluntary Change Process and Regulatory Basis

RG 3.74, Items C.5.b through e are guidance only. They do not establish new requirements, are not legally binding, and do not constitute a new change control process. They describe a possible option for a licensee to seek regulatory certainty via a shared understanding with the NRC regarding the types of changes that need prior NRC approval.

A discussion of the bases for the draft regulatory guide was provided when the draft guide was originally published in 2009, as well as when the revised draft was again published for comment in 2011. As your letter recognizes, Title 10 of the *Code of Federal Regulations* (CFR) Part 70 does not explicitly specify when certain changes to *licensing documents* require prior NRC approval, nor does Part 70 prescribe a specific mechanism for controlling such changes to *licensing documents*. RG 3.74 similarly notes (at 7) that C.5 changes are not governed by 10 CFR 70.72, which applies to changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. As discussed further below, the absence of 10 CFR Part 70 regulations specifying when changes to licensing documents must have prior NRC approval does not support your position that Items C.5.b through e of RG 3.74 lack an appropriate regulatory basis.

To approve an application, the staff must determine, in part, that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property [10 CFR 70.23(a)(3)] and that the applicant's proposed procedures to protect health and minimize danger to life or property are adequate [10 CFR 70.23(a)(4)]. NRC determinations in this regard rely on documents submitted with and supporting an application (including evaluation methods used to establish the design basis), and constitute the NRC-approved safety basis for the facility. In the absence of a regulation that specifies what changes to such documents may be made without prior NRC approval, licensees and applicants have no regulatory certainty as to whether the NRC would agree that such changes were properly made (*i.e.*, that such changes did not adversely affect the NRC approved safety basis). Although the NRC comment response you quote only noted that the license condition option was consistent with the broad terms of 10 CFR 70.34, the provisions of C.5.b through e of RG 3.74 conveyed the NRC's regulatory concern that changes which, for example, could modify NRC licensing determinations, reduce licensee commitments or conflict with existing license conditions or other

regulatory requirements, warrant prior NRC approval.² RG 3.74 facilitates a shared understanding between NRC and applicants/licensees by describing an option to voluntarily request NRC approval of a license condition which describes a change control approach for licensing documents. This option is consistent with 10 CFR 70.34, which allows a licensee to request a license amendment which specifies the “respects in which the licensee desires his license to be amended and the grounds for such amendment.” The staff regularly approves (or imposes) license conditions to assure that the commitments that support the approved safety basis of the facility are maintained and that regulatory requirements are met.

In the case of the voluntary change process license condition for licensing documents, the staff is assuring that the NRC-approved safety basis used to meet regulatory requirements and the commitments associated with that basis are preserved. These regulatory requirements are 10 CFR 70.22, Contents of Applications; 10 CFR 70.23, Requirements for the Approval of Applications; 10 CFR 70.65, Additional Content of Applications; and 10 CFR 70.66, Additional

² The text of C.5.b through e (reformatted below) conveys this regulatory concern:

b. Additionally, the NRC would consider license amendment requests that a license condition be added to allow changes to licensing documents (*e.g.*, to the license application, or to supporting documents referenced in the license) without prior NRC approval. Requests for license conditions of this type should contain the following information:

- (1) criteria for determining whether prior NRC approval is required,
- (2) documentation requirements for the licensee’s evaluation that supports the finding that preapproval is not required, and
- (3) reporting frequency for providing changes to the NRC after implementing changes.

c. Considerations for the need for prior approval include the following: (1) whether the change decreases the level of effectiveness of the design basis as described in the license application, (2) whether the change results in a departure from the methods of evaluation described in the license application and used in establishing the design basis, (3) whether the change results in a degradation in safety, (4) whether the change affects compliance with applicable regulatory requirements, and (5) whether the change conflicts with an existing license condition.

d. Changes to licensing documents that would not require prior NRC approval would generally be administrative changes such as the following:

- (1) modifications to facility and process descriptions,
- (2) enhancements or clarifications of text,
- (3) grammatical corrections, or
- (4) reformatting of text.

e. Changes to licensing documents that would require prior NRC approval would generally be for the following types of changes:

- (1) reduction in the effectiveness of commitments,
- (2) modifications to methodologies and associated assumptions used in developing the safety basis, such as the Integrated Safety Analysis and criticality methodologies,
- (3) modifications to the NRC-approved safety bases, or
- (4) changes that conflict with an existing license condition.

Requirements for Approval of License Application. The fact that the C.5.b through e guidance in RG 3.74 and the comment response did not cite these regulatory requirements does not mean that the guidance lacks an adequate regulatory basis. Items C.5.b through e narrowly focus on a procedural vehicle to promote a shared understanding, and to achieve greater regulatory certainty as to which non70.72 changes need prior NRC approval. The substantive content of C.5.b through e combined with the NRC's comment response identified the regulatory bases for the change control process described in RG 3.74, Items C.5.b through e in a manner sufficient to inform and respond to public comment. Hence, the staff has a sound regulatory basis for the voluntary change process license condition described in RG 3.74 at C.5.³

The staff recognizes that § 70.34 was not referenced as an authority in the draft RG 3.74 (designated at that time as DG-3037). However, the staff assumed that licensees are aware of the regulatory provisions in § 70.34, given that license amendment requests are submitted under the authority of that section and it is self-evident that licensees may voluntarily seek a license amendment to address a licensee's issue – such as regulatory certainty issues which are the focus of RG 3.74. The *Federal Register* notices (FRN) announcing the original 2009 draft RG and the revised 2011 draft RG, as well each version of the RG, include a discussion of the regulatory framework under 10 CFR 70.72. In addition, the FRN announcing issuance of the 2011 draft RG and final RG discussed the regulatory framework associated with the importance of a screening process for changes and their associated impacts.

II. Backfitting

The staff considered backfitting issues when it developed the draft RG and when it issued RG 3.74 in its final form, and concluded that the RG did not represent backfitting.

Section 5.b. of both the draft and final RG states that the NRC “would *consider* license amendment requests that a license condition be added to allow changes to licensing basis documents...” (Emphasis added). Moreover, Section D of both the draft and final RG states:

If an existing licensee voluntarily seeks a license amendment or change and (1) NRC staff consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 70.76 (a)(1).

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless

³ RG 3.74 merely presents one possible licensee option for requesting the establishment of a change control approach for the subject licensing documents, viz. through a voluntarily-initiated licensee request for a license condition. As your letter recognizes (p.3, first full paragraph), the Commission has discretion under the Administrative Procedure Act (APA) to issue binding, prospectively applicable legal requirements through rulemaking or through orders (which, under the APA, includes licensing). Rather than imposing binding requirements on licensees through rulemaking, the NRC elected to issue non-binding guidance after soliciting and evaluating public comments.

the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require adherence to this regulatory guide.

In the staff's view, Section C.5.b reflects a licensee's currently-available option to voluntarily submit a license amendment request under 10 CFR 70.34. A licensee may voluntarily use the guidance to seek NRC review, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action. The guidance is modeled after a license condition that the staff approved for an existing licensee during a license renewal review in August 2007. To date, all new applicants have opted to include a license condition similar to the one described in RG 3.74 in their license applications and other existing licensees have also applied to include a condition in their license for making changes to their licensing documents without the need for prior NRC approval.

Your June 11, 2012, letter does not explain why, given the discussion in Section D and in Section C.5.b, the staff's consideration of backfitting for RG 3.74 is inadequate or is otherwise inconsistent with language in other portions of the RG or in the FRN.

Moreover, to the extent your letter suggests that the guidance, read reasonably, connotes more than guidance and in fact implies an NRC expectation or new requirement, the staff disagrees. The RG 3.74 guidance has none of the language that industry stakeholders have previously suggested raise backfitting concerns. For example, the guidance does not use the words, "recommends," "suggests," "requires," "should," or (with one exception) "expects" in connection with a licensee decision to seek the proposed license conditions. See, e.g., RG 3.74 at 8-9. Your letter highlights, however, that the phrase containing the word "expects" in section D. "Implementation," is not accurate.

The section incorrectly states, "The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis." RG 3.74 at 9. The final RG should have read, "The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis to adopt a change control process as described in this regulatory guide." The NRC staff has started the process to correct this language.

After careful re-review of the language of RG 3.74, the staff continues to believe that the guidance is properly characterized as such, and does not set forth or imply any NRC intent or expectation that licensees seek approval for a change process through the license amendment described in the guidance.

III. Consistency with Written Regulations

As noted above, the staff views the RG 3.74 guidance as being consistent with agency principles for good regulation and written regulations. Item C.5 is fully consistent with 10 CFR 70.34 and the other requirements discussed in section I, above. The change evaluation process described in Item C.5 is also consistent with providing regulatory transparency, predictability and certainty, enabling the NRC and its licensees to have a shared understanding regarding which changes to licensing documents need prior NRC approval.

IV. Conclusion

The staff discussion of the overall importance of a 70.72 change process, the availability of the 70.34 amendment process, and the suggested criteria in RG 3.74, sections C.5.b through e provided an adequate regulatory basis to allow public comment and staff responses. These provisions are aimed at providing licensees predictability and regulatory certainty regarding changes to licensing documents. As discussed above in section II, the staff properly considered sections C.5.b through e for backfitting concerns under 10 CFR 70.76, but plans to correct the backfitting statement in section D to clarify the staff's expectations with regard to voluntary use of the change control process.

If you have further questions regarding this matter, please contact Kevin Morrissey of the Office of Nuclear Materials Safety and Safeguards at (301) 492-3130, or Kevin.Morrissey@nrc.gov. You may also contact John Hull of the Office of the General Counsel at (301) 415-1573, or John.Hull@nrc.gov.

Sincerely,

/RA/

John D. Kinneman, Director
Division of Fuel Cycle Safety
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Office of Nuclear Materials Safety
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IV. Conclusion

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Sincerely,

/RA/

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