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Mr. Michael D. Tschiltz
Deputy Director
Division of Fuel Cycle Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Comments Following March 10 Public Meeting on 10 CFR 70.72

Project Number: 689

Dear Mr. Tschiltz:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)[1] offers the following comments relevant to the Nuclear Regulatory Commission (NRC) public meeting held on March 10 to discuss clarifying guidance on 10 CFR § 70.72 being considered by the staff. The meeting aided industry's understanding of NRC's position on this matter and provided an opportunity to discuss rule implementation, past practice and relevant precedents in this area, as well as potential impacts of NRC further implementing its current interpretation of section 70.72. Although the meeting was productive, we offer the following comments for your further consideration.

As was stated during the March 10 meeting, industry believes that NRC staff has changed its interpretation of section 70.72 in several respects and is implementing these new interpretations through both its licensing and inspection activities. Further, these new interpretations are being implemented ten years after promulgation of Subpart H to 10 C.F.R. Part 70, without an opportunity prior to March 10 for public discussion or adequate explanation of the staff's regulatory or technical bases and, apparently, without considering the backfitting provisions contained in 10 C.F.R. § 70.76.

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[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

For example, recent staff interpretations regarding the timing of change "implementation" are inconsistent with accepted past practice in this area. In addition, 10 C.F.R. § 70.72 does not differentiate between changes occurring during facility construction or significant plant modifications, and changes occurring at operating facilities. Therefore, on its face, the regulation would apply similarly to all changes and has been consistently implemented in this manner by licensees under NRC's oversight for the past 10 years. However, current NRC staff practice indicates that a different change control standard applies during new plant construction, particularly to structural changes during facility construction. This approach appears inconsistent with section 70.72(c) which is relatively clear regarding changes to sites and structures that can be made without prior Commission approval. Specifically, section 70.72(c) clearly allows changes involving new construction, provided that such changes do not create new types of unmitigated accident sequences; use new processes, technologies, or control systems with which the licensee has no prior experience; remove or alter items relied on for safety, and are not otherwise prohibited.

Consistent with the concerns described above, industry believes that there are significant problems associated with Examples 1, 3 and 5 on the NRC slides used during the March 10 meeting. We believe that the examples need to be carefully reevaluated in light of past practice and precedent before any draft guidance is issued. Specifically, in Example 1, continuation of construction does not equal implementation and should not be a driver for enforcement at this stage. The important point in Example 1 is whether the licensee followed the requirements of 70.72 in evaluating the change and if not, enforcement is potentially appropriate. Further, the seemingly broad interpretation provided in Example 1 seems to be at odds with the Commission's order in *Nuclear Fuel Services, Inc*. (Erwin, Tennessee), CLI-03-03, 57 NRC 239 (2003). *Nuclear Fuel Services* involved a request to enjoin construction activity to enable down-blending of highly enriched materials at a Part 70 facility while the required license amendment requests were pending. In that case, the Commission explicitly recognized its limited authority over construction activities in this area. Specifically, the Commission stated:

> [I]t is questionable whether the Commission has authority to halt NFS's pre-licensing construction activities in the circumstances of this case. The record before us does not reveal any statute or regulation that requires NFS to obtain a construction permit or similar authorization prior to beginning construction. The Atomic Energy Act provisions authorizing NRC construction permits in some settings do not apply here.
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> We do not understand the applicable NRC regulations or statutes to prohibit outright NFS's construction activities.
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> In short, NFS *proceeds at its own risk with construction activities*. If NFS begins or continues to construct buildings associated with license amendments for which the staff's environmental review is incomplete, NFS's construction may prove grounds for denial of one or more of the license amendments.[2]

The Commission reached these conclusions, despite the fact that sections 51.101(a) and 70.23(a)(7) "contemplate that construction should not begin until the NRC has completed its environmental review."[3] Thus, contrary to the position taken in Example 1, the Commission's regulations do not prohibit construction activities pending NRC approval of license amendment requests for *all types* of Part 70 facilities. Further, contrary to bullet number 3 in the staff's slide entitled "Regulatory Position," the Commission has explicitly recognized the concept of "at risk" construction in this area (see discussion of NFS above).

In Example 3, the critical point comes when nuclear material is introduced into the new system because until that point, that part of the system is not operating in a nuclear environment. In Example 5, there are cases where a licensee can make decisions to operate new or changed operations. If the licensee is operating consistent with section 70.72 then enforcement action is not appropriate. On the other hand, if the licensee made an error in the application of 70.72, then enforcement may be considered appropriate. Further, the staff's reference to deliberate misconduct on the Example 5 slide is inappropriate in a situation such as this where licensees are attempting to engage NRC to address evolving staff concepts of compliance, some of which appear to be inconsistent with controlling precedent (i.e., Commission Orders) in this area.

If the NRC staff continues to implement new interpretations of 10 CFR§ 70.72 then, at the very least, the agency must explain the regulatory basis for such changes and must apply such changes in light of the backfit provisions contained in 10 C.F.R. § 70.76. The impact of such changes must be thoroughly evaluated and analyzed, and any modifications to the rule to impose a revised NRC expectation should be conducted through a rulemaking in accordance with the Administrative Procedure Act. Further, although courts generally give substantial deference to an agency's interpretation of its own regulations,[4] they have also held that the Administrative Procedure Act requires notice and comment rulemaking when an agency substantially modifies such interpretations.[5]

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[2] CLI-03-03, at 10-11 (emphasis added).
[3] CLI-03-03, at 10 (footnotes omitted).
[4] *See* Thomas Jefferson Univ. v. Shalala, 512 U.S. 504 (1994).
[5] *See* Paralyzed Veterans of America v. D.C. Arena L.P., 117 F.3d 579, 586 (DC Cir. 1997); National Family Planning & Reproductive Health Assn. v. Sullivan, 979 F.2d 227, 240 (DC Cir. 1992).

Finally, NRC suggested during the meeting that a rulemaking may be needed to clarify NRC's expectations on licensee implementation of 70.72. Industry does not believe that modification of section 70.72 is necessary based on ten years of implementing it in a safe manner as overseen by NRC; therefore, industry does not plan to subject a petition for rulemaking. Rather, of concern to industry is NRC's new interpretation of the rule which was the cause for and subject of the March 10 meeting.

On a related matter, industry continues to be concerned with the inordinate delay in issuance of the final version of DG-3037, "Guidance for Fuel Facility Change Process" issued in June 2009 for comment. This guide is particularly significant since it is a direct product of an NRC-Industry working group formed in 2007 to provide additional guidance on the facility change process allowed by section 70.72 and relevant to the March 10 discussions. Industry supported the working group, assisted in drafting the guidance, provided timely comments on it during the public comment period, and remains available to discuss it. This is particularly important since NRC has stated that it may further modify DG-3037 to address the issues discussed on March 10, rather than issuing a separate guidance document. We encourage continued active engagement with affected stakeholders on this matter and request a timeline for its resolution including a publication date for DG-3037 or other draft guidance.

We look forward to additional dialogue on these matters to help ensure their timely resolution and provide for increased regulatory stability for fuel cycle facilities. If you have any question or concerns regarding this matter, please feel free to contact me at 202-739-8098; jrs@nei.org.

Sincerely,

Janet R. Schlueter

c: Mr. Daniel H. Dorman, NMSS/FCSS, NRC
Mr. Michael F. Weber, NMSS, NRC
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