



NUCLEAR ENERGY INSTITUTE

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Mr. Daniel M. Gillen  
Branch Chief  
Fuel Cycle Facilities Branch  
Division of Fuel Cycle Safety and Safeguards  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Please Docket  
(no docket #)  
Thank you  
Jm

Dear Mr. Gillen:

**REFERENCE: Follow-up Remarks on the 2002 NMA-NRC Uranium Recovery Workshop**

*I wish to compliment you and Katie Sweeney for organizing, yet again, a very informative and thought-provoking Uranium Recovery Workshop. These workshops provide an excellent forum for licensees to interact with one another and with state and federal regulators to discuss generic issues of concern, proposed regulatory changes and cooperative actions amongst the EPA, DOE, NRC and the States. The workshops are very valuable and we hope that the meeting you are planning for 2003 in Denver will be as enjoyable and productive as this year's gathering!*

*The final workshop presentation by John Lusher of the NRC's Uranium Processing Section entitled 'Change, Test and Experiment License Condition and SERP' addressed a very important topic that has major ramifications for uranium recovery licensees. Unfortunately, many workshop attendees had already departed for the airport before the start of the presentation, and thereby missed an important discussion on a new facility change process for Part 40 licensees. The Nuclear Energy Institute (NEI)<sup>1</sup> commends the efforts of the Fuel Cycle Facilities Branch*

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<sup>1</sup> 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 nuclear companies licensed to operate commercial nuclear power plants in the United States, nuclear plant designers,

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staff to adapt the Commission's risk-informed, performance-based regulatory philosophy to licensing, inspection and enforcement actions for Part 40 licensees. NEI has worked closely with the NRC for the last decade to 'risk-inform' regulations applicable to commercial power reactors and, most recently, to the uranium enrichers and fabricators of nuclear fuel. We, therefore, have a strong interest in broadening the applicability of this new Commission regulatory philosophy to include Part 40 licensees.

In his presentation Mr. Lusher outlined a new Standard License Condition that he seeks to incorporate into uranium recovery licenses as they are renewed. This new condition outlines a process that enables a licensee to establish when a change can be made to the facility without first obtaining NRC pre-approval or a §40.44 license amendment. While the intent of this Standard License Condition is admirable – granting licensees more latitude to implement changes that do not adversely affect safety and reducing the number of non-safety significant license amendment applications that the NRC must review – the details of the proposed condition are highly prescriptive, incompatible with the NRC's risk-informed philosophy and internally inconsistent. Simply put, no Part 40 license should ever accede to incorporation of the proposed Standard License Condition as drafted, for it imposes unnecessary and burdensome restrictions on a licensee's operations. NEI does strongly support having each license develop and use a corrective action program and operate within the bounds of a risk-informed facility change process. However, the draft, proposed Standard License Condition must be significantly modified to be truly risk-informed and to be consistent with the licensing requirements and regulations in 10 CFR 40. NEI raised similar concerns with the NRC's draft NUREG-1569 ('Standard Review Plan for In Situ Leach Uranium Extraction License Applications') in a letter dated April 24, 2002 to the Commission. If you have not had an opportunity to do so, I would encourage you to read the covering letter of our submission to more fully understand our concerns.

The proposed Standard License Condition contains language that appears to have been selectively excerpted from 10 CFR Parts 50, 60 and 72 among others. (Why no reference is made to the newest facility change mechanism developed for fuel fabrication facilities -- 10 CFR 70.72 'Facility Changes and Change Process' – is, however, particularly puzzling). Drafting a change process for Part 40 licensees by cutting and pasting statements excerpted from change processes for other classes of licensee without examining the regulatory bases underlying each change process and considering the risks posed by such licensees to human health and safety and the environment is inappropriate and constitutes poor regulatory policy. There is no provision comparable to 10 CFR 50.59 or 70.62 in the Part 40 regulations. The change process for each class of license is distinct, is consistent with the corresponding

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*Title 10 regulations and must reflect the risks to health and safety and the environment posed by the licensed operations.*

*Our first concern arises with the statement [Slide 8] that the staff attempted to make the Standard License Condition consistent with the regulations applicable to nuclear power plants, the high-level waste repository and fuel fabricators. This assertion is incompatible with the risk-informed philosophy. The criteria for making a change to a power reactor can not be compared to those for a uranium recovery licensee, for the permissible margin of error for the former is miniscule compared to that for an ISL mine where an operational accident (e.g. airborne release of yellowcake dust, wellfield excursion, release of pregnant lixiviant, spillage of loaded resin) would have comparatively negligible health and safety or environmental impacts. While the facility change processes for all classes of licensee may share a common structure and certain elements (e.g. need to first evaluate potential risks of the change), the details of each process will be unique to each class of licensee in accordance with risks posed by facility operations in that class. While a power reactor licensee may need to perform a complex probabilistic risk analysis of a proposed change, an LEU fuel fabricator needs only to perform a qualitative evaluation due to the lower inherent risk of the facility, and a uranium recovery licensee might only have to document the change. The breadth and complexity of the facility change process must reflect the potential risks of the facility operations. As the proposed Standard License Condition fails to address risk and as it far exceeds the regulatory requirements of 10 CFR 40, we have concerns with the staff's intention to require its inclusion as a license condition.*

*The eight components of the Standard License Condition [Slides 2 & 3] imply that the licensee has conducted far more exhaustive pre-licensing safety analyses than have ever been required for Part 40 licensees. For example, the conditions imply that process hazards analyses and accident sequence analyses will have been performed, that the likelihood of such accidents will have been quantified, that safety systems will have been designated and that accident consequences will have been established. The criteria [Slide 8] also reference 'margins of risk' and other terms that are not pertinent to uranium recovery licensee operations. Ignoring for the moment that the Commission has clearly stated that quantitative analyses are not required for lower-risk classes of licensee (e.g. uranium recovery, fuel fabrication, uranium conversion), the Standard License Condition is inconsistent with the licensing requirements of 10 CFR 40. Uranium recovery license applicants are not required to perform the equivalent of an Integrated Safety Analysis, such as is required for Part 70 fuel fabrication applicants, and they do not need to quantitatively (or qualitatively) establish an accident's consequences of likelihood. Thus, in the absence of such hazard and accident analyses, the licensee is unable to address the first six of the criteria (changes in the likelihood or consequences of accidents or safety systems). But even for the hypothetical case in which the licensee performs an analysis comparable to the Integrated Safety Analysis, the proposed criteria would be inconsistent with a*

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*risk-informed approach. Most criteria use the prescriptive term "any" – such as "any increase in consequence", "any increase in likelihood" or simply "any accident sequence". Surely an increase in the likelihood of an accident that has minimal health, safety or environmental consequences should not be of concern to the NRC (e.g. a release of CO<sub>2</sub> gas, spillage of acid or resin).*

*The specifications for the licensee panel, referred to as the Safety and Environmental Review Panel (SERP), that will evaluate proposed facility changes [Slide 6] is unnecessarily prescriptive. The NRC should not dictate the numbers, qualifications or responsibilities of members of this internal panel, but should instead limit its attention to the accuracy and adequacy of licensee analyses of proposed changes. For comparison, 10 CFR Part 70 regulations neither specify the name of this panel nor its composition or functions, but focus solely on its change reviews and assessments.*

*The record-keeping criteria [Slide 7] appear unnecessarily prescriptive, again by requiring information pertaining to any facility change to be maintained until license termination. The criteria also dictate that 'written safety and environmental evaluations' must be performed for any change, regardless of its safety significance. To be risk-informed, the proposed license condition should not direct a Part 40 licensee to perform a formal safety or environmental analysis for changes that have little safety-significance.*

*The breadth of the "required" NRC review [Slide 12] to encompass '...procedures conditioned in the license or outlined, summarized or included in the application...' is worrisome and inconsistent with the risk-informed approach. The condition could, conceivably, be applied to 'tests and experiments' that the licensee may conduct as part of an ongoing research effort. Bench-scale tests of new processes, lixiviants or reagents should not be included in application of the condition.*

*In summary, NEI strongly supports the staff initiatives to make Part 40 licensing actions more risk-informed and performance-based. We also support the reduction in regulatory burden that can be achieved by allowing licensees to make changes to their facilities without NRC pre-approval or license amendments when such changes have minimal impacts on health and safety and the environment. This improvement will significantly reduce the staff's workload by no longer requiring reviews of applications for routine and non-safety significant license amendments. We also endorse the staff's recommendation that Part 40 licensees adopt and use a corrective action program to internally resolve facility safety and operational issues.*

*NEI can not, however, support the draft Standard License Condition, as proposed, for it is unnecessarily prescriptive, places significant new burdens on the licensee to conduct formal, quantitative safety analyses that have never been required by 10 CFR 40 regulations, and fails to incorporate the risk-informed, performance-based*

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*regulatory approach. Before the Standard License Condition (as drafted) could be adopted, significant changes would be required to 10 CFR 40, such as a requirement to conduct operational safety analyses (analogous to the Integrated Safety Analysis for Part 70 licensees), a formal facility change mechanism (analogous to 10 CFR 70.72), and provisions to rank the comparative risks of potential accident sequences and to designate appropriate safety controls (analogous to IROFS or SSCs) to mitigate the consequences of such accidents. In the absence of such regulations, the eight change process criteria in the Standard License Condition are inappropriate for a Part 40 licensee. As drafted, a licensee would be far more likely to simply request a license amendment rather than to apply a very confusing and nebulous change process whose use would require an enormous commitment of resources to perform the required safety analyses, accident sequence evaluations, quantification of likelihoods and consequences and formal analysis of risk. In other words, the proposed Standard License Condition offers more of a disincentive to use a facility change process intended to give the licensee greater operational flexibility than to continue use of the existing §40.44 license amendment approach. This is neither the intent of the Commission nor a good demonstration of how the Commission wishes to achieve reduced regulatory burden and risk-based license oversight.*

*NEI appreciates the opportunity to comment upon this proposed Standard License Condition. We certainly encourage you to proceed with development of a facility change process appropriate to Part 40 licensees. As an interested stakeholder, we should be pleased to assist the NRC in drafting a risk-informed facility change process for Part 40 licensees and to develop supporting Standard Review Plan and inspection and enforcement guidance documents to facilitate its implementation.*

Sincerely,



Dr. Clifton W. Farrell

cc: *Katie Sweeney, Assistant General Counsel, National Mining Association  
John H. Lusher, Uranium Processing Section, Fuel Cycle Facilities Branch,  
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