

December 22, 1998

Dr. Carl A. Paperiello, Director  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Two White Flint Center  
Washington, D.C. 20555-0001

**REFERENCE:      10 CFR Part 70: Integrated Safety Analysis (ISA), Preliminary ISA and Decommissioning ISA**

Dear Dr. Paperiello:

At the December 3-4, 1998 *NRC Public Meeting on Amendment to 10 CFR Part 70*, the Nuclear Energy Institute (NEI)<sup>1</sup> discussed the role of both the Integrated Safety Analysis (ISA) and the Preliminary ISA in the Part 70 licensing process. In response to NRC's request for written comments on industry's recommendations for using these documents, I am pleased to provide you with this letter and the accompanying enclosure. Also included are comments on a proposed Part 70 licensing concept introduced by Drew Persinko at the public meeting.

NEI and NRC agree on the need to perform, document, maintain and update an ISA for a fuel cycle facility. NEI concurs with the recommendation contained in the December 1, 1998 *Staff Requirements Memorandum (SRM) on SECY-98-185* that the results of the ISA should not be included in the license. NEI recommends that the onus be placed on a licensee to perform and implement an ISA, that the licensee commit to maintaining an updated and complete version of the ISA at the licensed facility and that only a summary of the ISA results be provided to the NRC for placement on the docket. The ISA is, therefore, to be used in the Part 70 licensing process as follows:

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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 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.

- **Materials License:** would contain the licensee's commitments to conduct, maintain, implement and update the ISA
- **ISA Summary:** a synopsis of the results of the ISA would be submitted to the NRC for placement on the docket. This synopsis would outline the ISA methodology, identified high-risk accident sequences, implemented mitigative safety controls and control assurances.
- **Complete ISA:** would be maintained at the licensed facility for NRC inspection and for updating as the facility (or its processes) are modified.

Under this approach both NRC and licensee objectives can be met. NRC would have the ability to verify that an ISA was properly performed and updated as changes to the facility and processes are made, that vulnerabilities are identified, that items relied on for safety are implemented and that appropriate measures are maintained to ensure their availability and reliability. Enforcement actions could be taken for failure to properly conduct the ISA or to address any identified vulnerabilities. Licensees would be free to change their facility configurations in accordance with their approved internal change control process without prior NRC approval or through license amendment.

The SRM recommends that a preliminary ISA be prepared for new processes and new facilities. A preliminary hazards analysis, which closely resembles the analysis contemplated by the NRC in a Preliminary ISA, constitutes an integral component of the conceptual design and feasibility study phases of a new process or facility. Industry's current practice of first consulting with the NRC on a proposed new facility, identifying significant hazards, assessing issues that impact regulatory compliance and evaluating the overall technical and economic feasibility of a new facility constitutes a *de facto*, preliminary ISA. This type of analysis is referred to by the American Institute of Chemical Engineering (AIChE) as a preliminary Process Hazards Analysis (PHA). NEI recommends that this PHA terminology be used in the Part 70 revisions. A preliminary PHA would be submitted to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo refinements and redesigns prior to its eventual construction and commissioning. The licensee's ISA would be based on the "as-built" facility and would incorporate some, if not all, of the results of the preliminary PHA.

Dr. Carl A. Paperiello  
Nuclear Regulatory Commission  
December 22, 1998  
Page 3

The Enclosure to this letter addresses these and other proposed modifications related to the ISA provisions in the draft Part 70 revisions. NEI will provide specific comments and recommendations on the ISA chapter of the Standard Review Plan after agreement on the proposed rule changes is achieved.

NEI looks forward to continuing our dialogue with the NRC on the Part 70 rulemaking. We should be pleased to address any questions which you or your staff may have on the industry's concerns and positions.

Sincerely,  
/signed/  
Marvin S. Fertel

Enclosure

cc: The Honorable Shirley A. Jackson, Chairman, NRC  
The Honorable Greta J. Dicus, Commissioner, NRC  
The Honorable Nils J. Diaz, Commissioner, NRC  
The Honorable Edward McGaffigan, Jr., Commissioner, NRC  
The Honorable Jeffrey S. Merrifield, Commissioner, NRC  
Dr. William D. Travers, Executive Director for Operations, NRC

## ENCLOSURE

### NUCLEAR ENERGY INSTITUTE (NEI) RECOMMENDED LANGUAGE CHANGES TO PART 70 CONCERNING INTEGRATED SAFETY ANALYSIS (ISA) AND A PRELIMINARY PROCESS HAZARDS ANALYSIS (PHA)

#### Proposed Changes to the Draft Language

##### **(a) *Risk-Informed Regulation***

An ISA provides a systematic and integrated approach to assessing the *risk* of potential accident sequences. Based upon this assessment, appropriate safety controls to mitigate (or prevent) the risk can be implemented. As NEI has commented previously, all of the Part 70 revisions should discuss the *risk* of an accident sequence rather than separately its consequences and likelihood. The proposed revisions contain language that could be construed to establish a consequence-based, rather than risk-based, regulatory framework. Such language should be corrected to make the rule consistent with a risk-informed, performance-based regulatory framework.

##### **(b) *Inclusion of ISA in License Application***

As currently written, proposed parts 70.62 and 70.65 require a license to include, among other things, the "...*results of the ISA*..." in a license application. The breadth of this requirement could be interpreted to require submittal and inclusion in the license of a large amount of documentation from the ISA process. This requirement would create an unnecessary administrative burden in managing commercially sensitive documents, would drastically increase the number of requests for license amendments (via a 10 CFR 50.59-like change process), would require appreciable administrative support and would force both the NRC and licensee to allocate significant resources away from safety at the facilities.

NEI concurs with the SRM's directive that the results of the ISA should not be included in the license. NEI recommends that the onus be placed on a licensee to perform and implement an ISA, that the licensee commit to maintaining an updated and complete version of the ISA at the licensed facility and that only a summary of the ISA results be provided to the NRC for placement on the docket. The ISA should, therefore, be used in the Part 70 licensing process as follows:

- ***Complete ISA***: The detailed results of the ISA would be retained by the licensee at the facility to be used to safely manage it and to be available for NRC licensing reviews and compliance inspections. The ISA would be updated under the facility's Configuration Management Program as modifications to the facility or

to processes are implemented.

- **ISA Summary:** A synopsis of the results of the ISA would be prepared and submitted to the NRC for placement on the docket. The ISA summary would identify the disciplines of expertise and minimum qualifications of the individuals who performed the ISA, outline the approach and methodologies used in performing it, describe any identified, credible accident sequences whose unmitigated consequences could exceed the consequences of concern in §70.60(b), the safety controls implemented to reduce the risk of such accidents and the measures used to ensure the availability and reliability of such controls. The ISA summary would be maintained as a reference on the licensing docket or as the safety demonstration in Part II of a traditional two-part license. It would be revised on an annual basis.
- **Materials License:** A license applicant's commitments to conduct, maintain, implement and update the ISA would be the only commitment required to be included in the license.

Under this approach both the NRC and licensee objectives can be met. The license would require the licensee to conduct ISAs, prepare and maintain the ISA results, identify potential, credible accident sequences, identify items relied on for safety and maintain measures to assure those items are available and reliable. Through these clear license conditions, NRC would have the regulatory bases to inspect and verify that an ISA is properly performed and updated as changes to the facility and processes are made, that vulnerabilities are identified, that items relied on for safety are implemented, and that appropriate measures are maintained to ensure the availability and reliability of such items. The ISA results and documentation would be fully available for NRC staff licensing reviews and compliance inspections. If appropriate, enforcement actions could be taken for failure to properly conduct the ISA or to address vulnerabilities identified by it. Licensees would be free to change their facility or process configurations in accordance with their approved internal change control process without prior NRC approval or license amendment.

NRC licensing activities should focus on those credible accident sequences whose uncontrolled (unmitigated) outcomes could exceed consequences of concern referenced in §70.60(b). Such accident sequences would be identified by the ISA and reported in the ISA summary along with implemented safety controls and control assurances. The complete ISA, including the licensee's analysis the relative risks of all analyzed credible accident sequences, would be available at the licensed facility for the NRC to review.

The following definition of an ISA summary is proposed for inclusion in §70.4 of the proposed revisions to Part 70:

*"ISA summary means a synopsis of the results of the ISA that succinctly describes the facility or its processes, identifies the disciplines of expertise and minimum qualifications of the individuals who performed the ISA and outlines the approach and methodologies used in performing it. The ISA summary identifies and describes those credible accident sequences, whose unmitigated consequences could exceed the consequences of concern elaborated in §70.60(b), the safety controls (or items relied on for safety) to mitigate the risk of such accidents to an acceptable level and the measures to ensure the availability and reliability of such controls. The ISA summary shall be placed on the docket and shall be updated annually by the licensee, but shall not constitute part of the license."*

**(c) Decommissioning ISA:**

The proposed §70.62(b) requires a license applicant to perform an additional ISA for facility decommissioning if any "...*potentially hazardous activities...*" are anticipated. The results of the decommissioning ISA are to be submitted to the NRC for approval prior to the onset of decommissioning.

The SRM supports the requirement of a decommissioning ISA, but only if it can be justified on a health and safety or cost-benefit basis. NEI believes that a separate decommissioning ISA is not warranted. Decommissioning should be viewed as simply one, albeit the last, phase of operation of a licensed facility. As such, the facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. Any required changes to the ISA and facility operations to protect the health and safety of workers and the public during decommissioning can be implemented within the framework of the existing ISA program. The ISA would be updated, as required, and changes to the ISA summary would be submitted to the NRC as currently practiced. There is, therefore, no need for a separate decommissioning ISA in the Part 70 rule.

The decommissioning plan submitted to the NRC in accordance with the schedule and requirements of §70.38(g) will include an ISA evaluation of the hazards posed by activities or procedures proposed for use in the decommissioning and recommendations for implementation of items relied on for safety and assurances to be placed on such controls.

The example cited in the draft language for §70.62(b)-- "*...potentially hazardous activities such as chemical treatment of wastes...*" -- may be inappropriate as the NRC-

OSHA MOU<sup>2</sup> does not grant NRC jurisdiction over management of purely chemical wastes.

NEI recommends that §70.62(b) be deleted from the proposed Part 70 revisions.

- ***Reporting of ISA Results:***

The table on the following page lists the contents of a typical Part 70 license application. This table graphically illustrates how the ISA is to be used in the Part 70 licensing process. The commitment to perform, maintain, update and implement an ISA is an integral part of the license. The results of the ISA are kept at the licensed facility and updated in accordance with the licensee's Configuration Management Program as changes to the facility or processes are effected. The ISA summary is to be submitted to the NRC for placement on the docket.

- (e) ***Preliminary ISA (or Process Hazards Analysis):***

Proposed part §70.62(a)(3)(ii) requires a license applicant to perform a preliminary ISA and to submit its results to the NRC prior to constructing the facility or process. The SRM recommends that a preliminary ISA be prepared for new processes and new facilities.

NEI considers a preliminary hazards analysis, which closely resembles the analysis contemplated by the NRC in a preliminary ISA, to constitute an integral component of the conceptual design and feasibility study phases of a

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<sup>2</sup> Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration: Worker Protection at NRC-Licensed Facilities, 53 Fed. Reg. 43950 (31 October 1988)

## USE OF THE INTEGRATED SAFETY ANALYSIS IN PART 70 LICENSING

Contents of a Typical Part 70 License	In License (Commitment)	On Docket	On Site (Configuration Management)
1.0 <b>General Information</b> (Site, Process)	✓		
2.0 <b>Management Organization</b>	✓		
<ul style="list-style-type: none"> <li>● <b>Conduct of Operations</b> (configuration management, QA, training, maintenance, reporting, audits)</li> </ul>	✓		
<ul style="list-style-type: none"> <li>● <b>Integrated Safety Analysis (ISA)</b> <ul style="list-style-type: none"> <li>(a) <b><i>Programmatic/Administrative</i></b> <ul style="list-style-type: none"> <li>▶ Commitment to Perform, Maintain, Update &amp; Address Vulnerabilities</li> <li>▶ Scope (Processes and Hazards to be Reviewed)</li> <li>▶ Methodologies Available</li> <li>▶ Team Member Qualifications</li> <li>▶ Graded Approach</li> <li>▶ Assurance Criteria</li> <li>▶ Submit ISA Summary &amp; Annual Update</li> </ul> </li> </ul> </li> </ul>	✓		
<ul style="list-style-type: none"> <li>(b) <b><i>ISA Implementation</i></b> <ul style="list-style-type: none"> <li>▶ Process Descriptions</li> <li>▶ Credible Accident Sequences</li> <li>▶ Items relied on for safety (safety controls)</li> <li>▶ Assurance applied to items relied on for safety</li> </ul> </li> </ul>			✓
<ul style="list-style-type: none"> <li>(c) <b><i>ISA Summary</i></b> <ul style="list-style-type: none"> <li>▶ Site Description summary (reference to ¶1 &amp; ¶4(a))</li> <li>▶ Facility Summary (reference to ¶1 &amp; ¶4(a))</li> <li>▶ Process Description Summary</li> <li>▶ ISA Methodology (reference to ¶1 &amp; ¶4(a))</li> <li>▶ Team member qualifications (reference to ¶1 &amp; ¶4(a))</li> <li>▶ High-risk accident sequence descriptions</li> <li>▶ Items relied on for safety (safety controls)</li> <li>▶ Safety Controls (Overview) &amp; Assurances</li> </ul> </li> </ul>		✓	
4.0 <b>Radiation Safety</b> <ul style="list-style-type: none"> <li>▶ Performance Requirements</li> <li>▶ Program Description</li> <li>▶ Implementation through ISA results</li> </ul>	✓		
5.0 <b>Nuclear Criticality Safety</b> <ul style="list-style-type: none"> <li>▶ Performance Requirements</li> <li>▶ Program Description</li> <li>▶ Implementation through ISA results</li> </ul>	✓		
6.0 <b>Chemical Safety</b> <ul style="list-style-type: none"> <li>▶ Implementation through ISA results</li> </ul>	✓		
7.0 <b>Fire Safety</b> <ul style="list-style-type: none"> <li>▶ Implementation through ISA results</li> </ul>	✓		
8.0 <b>Emergency Management Program</b>	✓		
9.0 <b>Environmental Protection</b>	✓		
10.0 <b>Decommissioning</b> <ul style="list-style-type: none"> <li>(a) Funding Plan (§70.25)</li> <li>(b) Decommissioning Plan (§70.38)</li> </ul>	✓		✓
11.0 <b>Management Control Systems</b>	✓		
12.0 <b>Authorizations and Exemptions</b>	✓		



new process or facility. Industry's current practice of first consulting with the NRC on a proposed new facility or process, identifying any potentially significant hazards, assessing issues that impact regulatory compliance and evaluating the overall technical and economic feasibility of a new facility or process constitutes a *de facto*, preliminary hazards analysis. This type of analysis is referred to by the American Institute of Chemical Engineering (AIChE) as a Process Hazards Analysis (PHA). NEI recommends that this PHA terminology be used in place of the "preliminary ISA" designation throughout the Part 70 revisions.

A license applicant would submit a preliminary PHA to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo several refinements and redesigns prior to its eventual construction and commissioning. Based on the results of the submitted, preliminary PHA, the NRC would communicate to the applicant any concerns (e.g. over the proposed design or engineering methodology, inadequate compliance with current baseline design criteria, etc.) and recommendations for improvement. The ISA to be performed by the licensee would be based on the "as-built" facility, but may incorporate some, if not all, of the results of the preliminary PHA.

NEI recommends that the PHA terminology be used throughout the proposed Part 70 revisions and that the following preliminary PHA definition be included in §70.4 of the rule:

*"Preliminary Process Hazards Analysis (PHA) means an analysis undertaken during the design or early development phases of a process to identify the principal potential hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification of potential corrective, mitigative or preventive measures."*

The proposed Part 70 revisions correctly allow a license applicant to decide when to proceed with detailed engineering and construction. Whether a licensee decides to await NRC comments on the submitted preliminary PHA, or not, is not a regulatory agency decision, but rather a risk-informed, business judgment of the applicant.

**(f) Persinko Chart**

The chart introduced at the December 3-4, 1998 public meeting by Mr. Drew Persinko (*Part 70 Concept Under Consideration: On The Docket vs. In the License*) generally supports the approach presented in this letter: the detailed ISA is maintained at the licensed facility and is not included in the license; the ISA summary is placed on the NRC

docket and is not included in the license; the licensee commitments to perform, maintain, update and implement the ISA are included in the license. Some clarification of the wording in the right-hand column of the chart is, however, recommended.

The license should only contain the *commitments* of the licensee to implement adequate and sufficient measures and assurances for items relied on for safety; specific measures and assurances should not be enumerated in the license. For example, a licensee would commit to implementing the double contingency principle for nuclear criticality safety protection, but would not detail in the license the specific safety controls or barriers to be used for each accident sequence.

The term '*measures*' in the Persinko chart requires clarification. In the ISA, 'measures' will include very detailed specifications and/or highly specific technical information for each safety control installed or implemented by the licensee. 'Measures' in the license, however, has a different meaning and only encompasses the specific commitments made by the licensee to conduct, update, maintain and implement the ISA.

The chart suggests that the NRC rely solely on information contained in the ISA summary to establish the safety basis of a facility. The staff can, in fact, avail itself of the entire ISA at the facility for developing the safety basis. Finally, reference is made to "...*other safety analyses/design analyses and measures...*" in the ISA. What additional analyses the NRC is seeking beyond those comprehensive analyses already contained in the ISA is unclear. NEI believes that a properly conducted ISA contains sufficient information and analyses for NRC license application review purposes.

The Persinko chart can be summarized as follows:

PART 70 CONCEPT UNDER CONSIDERATION (ON THE DOCKET vs. IN THE LICENSE)		
Not in the License	Not on the Docket (Information Available to the NRC to Establish Safety Bases)	Complete ISA
Not in the License	On the Docket (Information Available to the NRC to Establish Safety Bases)	ISA Summary
In the License	On the Docket	<ul style="list-style-type: none"> <li>• ISA Commitments</li> <li>• License Conditions and Other Requirements</li> </ul>

## II. Proposed Language Modifications

Some of the language in the proposed Part 70 revisions could be construed to establish a consequence-based rather than a risk-based, regulatory system. For example, in numerous instances the *risk* rather than the "consequence" of an accident sequence should be emphasized. The language should be corrected.

## III. Concluding Remarks

NEI and the fuel cycle industry endorse the ISA concept and concur with the NRC that the ISA should form the cornerstone of a facility's safety program. NEI agrees with the SRM recommendation that the results of the ISA be excluded from the Part 70 license. NEI recommends that the ISA be used in the licensing process in three ways: ISA commitments in the license, ISA summary on the docket and active management of the complete ISA at the licensed facility. NEI also endorses the SRM's recommendation that NRC licensing and regulatory resources be focused on those high-risk accident sequences that could potentially have the greatest impact on the health and safety of workers and the public.

NEI concurs with the SRM requirement that a preliminary hazards analysis be performed for new processes and facilities, but recommends that the AIChE terminology for this analysis be substituted for "preliminary ISA." Finally, NEI believes a separate "decommissioning ISA" is not warranted. The existing ISA mechanism at a licensed facility can adequately address the hazards which may be posed by procedures and approaches proposed for use during decommissioning of the facility. Decommissioning is more simply viewed as one phase in the operation of the facility.

Ref: I:\files\Part 70\ISA and ISA Summary (NRC Ver).msw