

January 26, 1999

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: Critique of Reporting Requirements, Change Mechanisms and Baseline Design Criteria

Dear Dr. Paperiello:

At the December 3-4, 1998 *NRC Public Meeting on Amendment to 10 CFR Part 70*, the Nuclear Energy Institute (NEI)¹ offered to comment upon three additional provisions of the proposed revisions to Part 70. In the enclosure to this letter, analyses of the reporting requirements (§70.74), change mechanisms (§70.72) and baseline design criteria (§70.64) are presented.

NEI considers the existing incident reporting provisions in 10 CFR 20 and 10 CFR 70 to be adequate for ensuring that the NRC is promptly informed of all safety-related incidents. Adding a new §70.74 to the existing §70.50 and 10 CFR 20 reporting requirements appears to be unnecessary.

The new proposed change mechanism (§70.72) strives to set the regulatory threshold at which pre-approval by the NRC of a change is required. As written, it will not, however, relieve the NRC of the burden of making determinations on potentially hundreds of operational changes of minor safety impact each year. To keep the NRC aware of important, risk-significant changes that may affect a facility's safety programs, and yet limit reviews to "*...those few significant changes*

Dr. Carl A. Paperiello

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.

Nuclear Regulatory Commission

January 26, 1998

Page 2

that currently would require license amendments...” as stated in the December 1, 1998 Staff Requirements Memorandum (SRM), NEI proposes a new change mechanism. NEI’s approach would require NRC pre-approval only when that change could potentially threaten to degrade the effectiveness of a safety commitment in the license.

Inclusion of baseline design criteria in the Part 70 licensing process is appropriate for new facilities. We do not, however, believe an existing fuel cycle facility should be subject to such criteria, either now or when application is made for renewal of its license. The criteria should, similarly, not apply to new processes or technologies installed at existing facilities. By preparing an Integrated Safety Analysis (ISA) and by making commitments in its license to assure the availability and reliability of all implemented safety controls, a license applicant will, by necessity, have already addressed appropriate design criteria.

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 comments.

Sincerely,

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)
CRITIQUE OF PROPOSED REVISIONS TO PART 70
CONCERNING REPORTING REQUIREMENTS, CHANGE MECHANISMS AND
BASELINE DESIGN CRITERIA

I. Reporting Requirements (§70.74)

Section 70.74 and Appendix C of the proposed revisions to Part 70 identify safety-related incidents of differing severity that are to be reported to the NRC Operations Center within specified timeframes. NEI has five concerns with the proposed §70.74 revisions: (1) reporting requirements for fuel cycle facilities are already adequately addressed in the existing rule; a new rule chapter is unnecessary, (2) the new one-hour reporting timeframe for certain events is too restrictive, (3) a licensee should not be required to report all personnel hazardous chemical exposures, (4) a licensee should not be required to conduct continuous radiological monitoring in the unrestricted or controlled areas of its facility, and (5) emergency reporting of ‘*potential deviations*’ from safe operating practices or ‘*potentially unsafe conditions*’ should not be required. This language is too subjective. Each NEI concern is discussed below:

- (1) ***Adequacy of Existing Rules:*** Appendix C of the proposed Part 70 revisions assigns timeframes within which high and intermediate consequence events in §70.60(b) and certain other events (e.g. deviations from safe operating procedures, external conditions, potentially unsafe conditions) are to be reported to the NRC Operations Center. Reporting procedures, format and information requirements are also detailed. NEI believes that the current reporting requirements of 10 CFR Parts 20 (20.2201-22.06) and 70.50 will keep the NRC apprised of these safety related incidents. Adding a new reporting provision (§70.74) to those of 10 CFR Parts 20 and 70 will be repetitive and unnecessary. The current rule has functioned successfully for over thirty years and should continue to serve as the principal regulatory basis for safety incident reporting. The need for modifying the current Part 20 and 70 reporting requirements and for including §70.74 and Appendix C in the rule, is not apparent.
- (2) ***One-Hour Reporting:*** Proposed Part 70 revisions increase the number of safety-related incidents that must be reported within a one-hour timeframe. The justification for shortening the reporting period to one hour for an incident which §70.50 or §20.2202 now only requires a four-hour notification is not apparent. Indeed, reports to the NRC under NRC Bulletin 91-01 (‘*Reporting Loss of Criticality Safety Controls*’) on ‘significant’ events with criticality safety implications must be filed within four hours of their discovery. The NRC has provided no basis for why the

existing four-hour ‘*immediate report*’ timeframe may be inadequate for most incidents. NEI is particularly concerned with the exhaustive list of information that must accompany a one-hour telephone notification to the NRC Operations Center. Providing the NRC with the added information required by Appendix C, ¶V (e.g. the accident sequence and failure of items relied on for safety (¶V.(c)(1)), quantities of released licensed material (¶V.(c)(2)), analysis of potential health and safety consequences (¶V.(c)(3)), press releases (¶V.(h)), etc.) within such a short timeframe is unreasonable and unnecessary. In fact, some required information such as personnel radiation exposure data and chemical analyses of licensed material or hazardous chemicals produced from licensed materials (¶V.(c)(3)) can not be provided within such a short timeframe. Information accumulated within the first hour of discovery of an incident will likely be based on operators’ impressions rather than on a rigorous analysis of the incident or on confirmed technical data. The risk of providing the NRC with inaccurate preliminary information, which may in turn be publicly disseminated, is increased under the draft rule revisions. Finally, during the first hour following a ‘safety-significant’ event the licensee *must* focus all its efforts on emergency response activities. NEI recommends that the one-hour timeframe be limited to notification of the NRC of serious safety incidents and that all supplemental information be provided within the existing four or twenty-four hour reporting periods.

(3) ***Chemical Exposure Reporting***: Sections I and II of Appendix C require a licensee to report exposures to individuals of “...*hazardous chemicals in concentrations exceeding AEGL or ERPG criteria...*” Corrections to the Part 70 revisions proposed by the NRC in December 1998 have clarified a licensee’s reporting requirements for chemical releases in accordance with the *Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities* (Fed. Reg. 43950 (Oct. 31, 1988). Sections I(a)(2)(ii), I(a)(3)(iii) and II(a)(1)(iii) and II(a)(2)(ii) should be appropriately corrected.

(4) ***Environmental Monitoring Program***: Proposed §70.60(b)(2)(iii) of the rule and ¶II(3) of Appendix C address releases of licensed material to the environment. ¶II(3) requires notification to the NRC Operations Center within 4 hours of the discovery of such a release for “...*concentrations that, if averaged over a period of 24 hours, [would] exceed 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20...*” Compliance with this requirement *could* be interpreted to require explicit, continuous, radiological monitoring and surveying of radiation levels in the unrestricted and controlled areas adjoining a licensed facility. For a fuel cycle facility to release Special Nuclear Material (whether or not as a result of a nuclear criticality accident) and have its concentration exceed this threshold value at edge of the

restricted area is extremely unlikely. In the operating history of fuel cycle facilities such an exceedance has never happened; fuel cycle facilities have very benign impacts on the public. Radiological monitoring and surveying of outside radiation levels should not, therefore, be required along the perimeters of fuel cycle facilities.

(5) ***Subjective Language:*** Appendix C contains several references to plant operating conditions which could be subject to broad interpretation and necessitate non-essential reporting to the NRC Operations Center. For example, ¶II(2)(b), ¶III(a), ¶III(c) and ¶IV(a) require notification to the NRC of “...*deviations from safe operating conditions...*” What constitutes a ‘deviation’ is not defined, and could be broadly interpreted by NRC staff. For example, would the loss of two of six controls for a controlled parameter in nuclear criticality safety protection constitute a reportable deviation even when loss of double contingency is not threatened? An emergency report to the NRC would not seem to be warranted in this case. Similarly, definition and reporting of a “...*potentially unsafe condition...*” (e.g. ¶II(d)) is open to unreasonably broad subjective assessment.

Reports to the NRC should be limited to ‘deviations’ that are safety-significant or that resulted in an accident. Reporting *potential* unsafe conditions should not be necessary. Upon discovery of a potentially unsafe condition (presumably overlooked while performing the ISA), a licensee would rely on the facility’s corrective action program to remedy the deficiency. An *actual*, as opposed to a *potential*, unsafe condition that resulted in an accident would be reported to the NRC’s Operations Center.

II. Change Mechanism (§70.72)

(a) Proposed Change Mechanism

Proposed revisions to Part 70 attempt to set the regulatory threshold at which pre-approval by the NRC is required for changes. Proposed §70.72(b) would authorize changes without NRC pre-approval or license amendment if the changes do not result in at most a *minimal* increase in the likelihood or consequences of an accident previously evaluated in the facility’s ISA, if the changes are unlikely to create the potential for an accident not previously evaluated in the ISA, and if the changes do not violate any license condition.

NEI supports the philosophy of the proposed revisions. We agree in principle with the proposed risk-informed change mechanism based upon qualitative assessment of changes in risk, but we recommend adoption of a different set of criteria to effect a change. A licensee should have the flexibility to operate within the ‘regulatory envelope’ of the commitments and authorized activities contained in its license. A licensee should be able

to implement changes so long as they do not substantially degrade or decrease the effectiveness of any safety commitment in the license, do not approach or exceed a §70.60(b) consequence of concern, do not impair the licensee's ability to meet applicable federal regulations or do not conflict with any license conditions.

NEI is concerned, however, that the proposed §70.72 change mechanism may prove difficult to implement. The inherently qualitative nature of the ISA used to establish whether or not NRC pre-approval is needed for a change makes assessment of what constitutes "...a minimal increase..." a highly subjective call. Exclusion of the results of the ISA from the license application, as recommended by NEI, will reduce NRC's burden to make determinations on potentially hundreds of operational changes of minor safety impact each year. Similar structuring of the change mechanism to limit the number change (and license amendment) requests to the NRC to those that are risk-significant would be consistent with recommendations in the December 1, 1998 *Staff Requirements Memorandum (SRM) for SECY-98-185* that supports decreased involvement of the NRC in the change process. The SRM states "...Part 70 needs to capture for submittal to NRC those few significant changes that currently would require license amendments (underlining added)..."

(b) Recommended Change Mechanism

The Part 70 rule change mechanism should be appropriate to the operating characteristics and risks of fuel cycle facility operation. It should also afford a licensee the flexibility to use risk assessment methodologies to evaluate and implement changes.

The regulatory threshold for change approvals by the NRC should be risk-informed and be consistent with current practices in the regulation of fuel cycle facilities. A licensee will have clearly defined, authorized activities and safety programs for the facility (e.g. nuclear criticality safety, fire safety) and if it operates within the limits of these authorizations and programs as specified in its license, pre-approval of a change by the NRC or a license amendment should not be required. The onus would be placed on the licensee to identify and analyze the significance of potential hazards associated with a proposed change and to seek NRC pre-approval of a change whenever its analysis so dictates. NRC pre-approval would be required for a change to the facility or operating procedures as described in the ISA that entails:

- exceedance of, or approach to, a consequence of concern listed in §70.60(b)
- activities not currently authorized by the license
- substantial degradation or a decrease in the effectiveness of any safety commitment in the license

- significant process or facility changes that either create new types of higher consequence accidents or require significant changes to the facility’s environmental report prepared in accordance with 10 CFR 51
- impairment in the licensee’s ability to meet applicable federal regulations
- a conflict with any license condition

For example, changes in equipment, procedures or processing conditions (other than ‘replacement-in-kind’) such as replacing analog equipment by digital equipment or a mechanical control system by a digital control system should not require NRC approval. Improvements in process technology (new equipment, changes in operating conditions), in equipment (materials of construction, equipment specifications, computer program revisions) or in procedures (replacement, addition or removal of controls on parameters in nuclear criticality safety so long as double contingency is assured) should, similarly, not require NRC pre-approval.

The licensing basis on which the NRC establishes compliance with the rule and base licensing action approvals should be the commitments and authorized activities contained in the materials license. These would include, for example, commitments to protect health and minimize danger to life and property, to protect against nuclear criticalities, to implement fire and chemical safety programs, to conduct personnel and environmental monitoring programs, to implement management control systems and to conduct, implement and maintain an ISA for the facility. The commitment to perform, maintain, update and address vulnerabilities identified by the ISA would constitute an important licensing basis.

For changes to the facility or operating procedures as described in the ISA that do require NRC pre-approval, the licensee would have to file an application for amendment of its license (as specified in §70.34) that would authorize the change.

All changes implemented by the licensee would be incorporated into the facility’s ISA and reported to the NRC in the annual ISA update. For changes not requiring NRC pre-approval the licensee would maintain written internal evaluations that provide the bases for determining that the changes do not require NRC pre-approval.

III. Baseline Design Criteria (§70.64)

Proposed §70.64 requires a license applicant to (generally) address ten baseline criteria in the design of new processes or facilities. In the *Supplemental Background Information to the Proposed Federal Register Notice* (p.26), the NRC states that adherence to such criteria constitutes “*good engineering practice*” and an acceptable method to “*...assure adequate safety for all new processes and facilities...*” These baseline design criteria

establish the design, fabrication, construction, testing, maintenance and performance requirements for all items relied on for safety defined by the facility's ISA. They would constitute part of the licensing base and would be used to validate measures implemented to assure the availability and reliability of such items relied on for safety.

NEI believes the §70.64 baseline design criteria are appropriate for *new* fuel cycle facilities, but that they should not apply to *existing* facilities or to future changes that may be made to such facilities. An existing Part 70 licensee will already have conducted a process hazards assessment (PHA) (referred to as a 'preliminary ISA' in the draft language) and a complete ISA for its facilities. The ISA has two objectives: first, to identify accident sequences with potentially significant risks or impacts; and second, to implement safety controls to prevent or mitigate these risks and assure that the controls remain available and reliable whenever they are called upon to perform their intended safety functions. This second requirement is particularly important to achieving the goal of protecting public health and safety and the environment. It obliges the licensee to apply appropriate design criteria to select equipment or implement procedures that can be demonstrated to satisfy the rigorous 'available and reliable' requirement.

In other words, a properly executed ISA will have already addressed baseline design criteria and other factors to protect against undesirable consequences in a risk-informed manner. There is, therefore, no need for a current licensee to address or adhere to the baseline design criteria of §70.74. The license commitment to perform, implement, update and maintain an ISA is a broad licensing basis which encompasses, by reference, stringent baseline design criteria. NEI further believes that changes to an existing facility (e.g. process technology) should not be subject to the §70.64 baseline design criteria. Proposed revision §70.74 should be revised to exclude existing licensees from adherence to these baseline design criteria, both for their existing facilities and for changes in process technology or operating procedures that may be implemented in the future to ..

NEI Recommendation: The December 1, 1998 *Staff Requirements Memorandum (SRM) for SECY-98-185* supports the need for a license applicant to *address* baseline criteria in the design of a new facility or process. NEI recommends that this requirement remain in the proposed Part 70 revisions, but that it not apply to existing licensees.