March 26, 1999

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

REFERENCE: **Review of Proposed Revisions to 10 CFR Part 70**

Dear Dr. Paperiello:

The Nuclear Energy Institute (NEI)[1] has reviewed the most recent revisions to 10 CFR Part 70 proposed by the Nuclear Regulatory Commission's (NRC) Staff on March 1 and 4, 1999. We commend the NRC for addressing issues raised by the affected parties including industry and NEI. Improvements made by the staff as represented by the proposed revisions in SECY-98-185 enhance the Rule's risk-informed, performance-based philosophy, ensure that the Rule realistically addresses the potential health, safety and environmental risks posed by fuel cycle facilities and reduce its prescriptiveness. We are encouraged with the progress achieved to date in revising the Part 70 Rule and with the receptiveness of the Staff to NEI's recommended improvements to the proposed revisions which were presented at the March 23, 1999 *Public Meeting on Staff Revision to 10 CFR Part 70*.

NEI wishes, however, to address several outstanding concerns with the proposed Rule revisions. NEI strongly supports selection of Option 1 in §70.72 as modified in the enclosure to this letter for the facility change mechanism. This change process is straightforward, unambiguous and provides a licensee the latitude to operate within the constraints of its license conditions without submission of a cumbersome

---

[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.

number of license amendments for facility changes that are not safety-significant. Option 1 complies with the direction contained in the December 1, 1998 Staff

Requirements Memorandum (SRM) that " *…only those few significant changes that currently would require license amendments…*" should still be brought to the Commission for pre-approval..

NEI believes that a licensee's 'safety program' (§70.62(a)) consists of 'management measures' that would provide reasonable assurance that items relied on for safety will be available and reliable when needed. We believe the proposed Rule needs to be clarified to state that the baseline design criteria in §70.64(a) should only apply to new facilities or to new processes at existing facilities that require a license amendment under §70.72.

Section 70.65(b) specifies in great detail the information to be incorporated into the Integrated Safety Assessment Summary. In a number of cases significant amounts of information are requested that have already been provided elsewhere in the facility license (or license application). These multiplicative requirements should be removed. The discussion of 'items' in this section is unclear and confusing due to both the way this term is defined and the way it is used in detailing the requirements for performing the ISA. The term 'items' needs to be replaced with a less confusing term such as that proposed in the detailed comments attached to this letter. While §70.65(b) explicitly states that the ISA Summary is not to be incorporated into the license, we believe a comparable statement should be placed in the Rule (§70.62(c)(1)) clarifying that the full ISA is neither to be docketed with the NRC nor incorporated into the license.

We reiterate our concern that the proposed Part 70 revisions should include an immediately-effective backfit provision. The contention that knowledge of the safety bases of fuel cycle facilities is so inadequate that a backfit provision could not be implemented for several years is erroneous. In fact, there is a very thorough and comprehensive understanding of Part 70 facility safety bases. The NRC has reviewed and recommended granting licenses for the facilities, has supported license renewals for several fuel fabrication facilities, has prepared Safety Evaluation Reports (SERs) favorable to the facilities and, through frequent inspections and facility visits, knows plant and process operations intimately. The NRC also has experience working with several facilities in the preparation of the new ISAs. The Staff arguments for delaying implementation of the backfit provision do not, therefore, appear necessary or justified. NEI recommends, therefore, that an additional section (§70.76) entitled 'Backfitting Provision' with contents similar to those presented in NEI's letter of September 30, 1996 to the NRC be added to the proposed revisions to Part 70

In addition to the above comments, NEI has identified other minor changes that will clarify the intent of Rule provisions, simplify the language and reduce its repetitiveness or prescriptiveness. The Enclosure to this letter presents a red-lined version of the NRC's Part 70 revisions on which such changes are noted.

NEI trusts that our comments in this letter and the discussions held at the March 23, 1999 NRC Public Meeting will be useful in further revising the draft Part 70 Rule. As NEI's fuel cycle industry members shall be meeting in Washington on April 15-16, 1999, it would be very helpful if the NRC could post on its Webpage the next set of revisions to draft Part 70 prior to that meeting.

We appreciate being able to participate in the revision process for the Part 70 Rule.
We look forward to achieving consensus on those few outstanding issues in the Rule and to achieving similar progress on making changes to the Standard Review Plan that are necessary for it to be consistent with the Rule and the direction provided by the Commission in the December 1, 1998 Staff Requirements Memorandum.

Sincerely,

Marvin S. Fertel
Enclosures

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

REVIEW OF PROPOSED REVISIONS TO
10 CFR PART 70
(MARCH 1, 1999 NRC WEBPAGE POSTING)

I. Principal Concerns

(a) Integrated Safety Assessment Summary (§70.65)

Draft §70.65(b) requires detailed information on the facility which is contained elsewhere in the license application. To reduce the repetitiveness of the application and the docketed information, only a brief synopsis of such subjects as the site description, process description and operational theory, meteorology, etc. should be required. Only those processes analyzed and found to be potentially impacted by accident sequences that could exceed the performance requirements of §70.61 need to be presented. The justification for focusing on accident sequences having a single (versus multiple) item relied on for safety is unclear (Part 5). The repetitive requirements of the ISA Summary (e.g. Part 9) should be removed.

(b) Change Process (§70.72)

The change process with provisions included in Option 1, as modified, describes an effective and workable approach for establishing whether a proposed change requires a license amendment, or whether it can be implemented with only updates to the facility's ISA and ISA Summary, if required. We have modified §70.72(d)(1) to address the concern raised at the March 23, 1999 *Public Meeting on Staff Revision to 10 CFR Part 70* that the level of experience of a facility's staff in the operation of a particular process, technology or control system proposed for incorporation into the facility should be a criterion in evaluating whether or not a license amendment is required. We strongly support the removal of subjective terms such as 'minimal increase' in the likelihood or consequence of a potential accident sequence. The provision in §70.72(c) addressing the 'training' of personnel in changes is rather broad, especially when it refers, without qualification, to *any* facility change and prohibits the 'startup' of *any* process until such training occurs. As worker training is addressed under management measures, NEI recommends that this provision be incorporated as a component of the configuration management program in §70.72(a)(3).

We believe that §70.72 Change Process mechanism with Option 1 (as modified by NEI) will create a change process that would be consistent with the December 1, 1998 *Staff Requirements Memorandum* (SRM) directive that "…*Part 70 needs to capture for submittal to NRC those few significant changes that currently would require license amendments* [underlining added]…" The §70.72 Option 1 mechanism provides symmetry and internal consistency in the Part 70 Rule and appropriately focuses the scope of this provision.

Finally with respect to reporting to the NRC of changes that did not require a license amendment, NEI recommends that the ISA Summary be updated and a listing of the changes made without prior NRC approval be prepared and submitted on an annual basis. This reporting frequency would conform to the reactor requirements in §50.59 and §50.71(e). Ninety-day and six-month submittals are very onerous and unnecessary.

(c) New Facility and Process Requirements (§70.64)

(i) Baseline Design Criteria

The baseline design criteria (BDC) should be clarified to state that BDC should not be backfitted onto existing facilities or processes, even if the new process is housed in an existing building or is adjacent to an existing process. Unless a licensee proposes a change that lies outside a facility's licensing basis, the licensee should not be subject to the provisions of §70.64. For new processes at existing facilities NEI has modified §70.64 to state that the BDC would only apply if implementation of the new process would require a license amendment under §70.72

(ii) Preliminary ISA

The requirement to prepare a preliminary process hazards evaluation (§70.64(c)) for new facilities or processes appears open-ended. The Rule specifies neither how the preliminary process hazards evaluation is to be used in the licensing process nor what response the NRC is to provide to the license applicant upon receipt and review of the submitted information. Applicants for Part 70 licenses have traditionally discussed proposed projects or facility changes with the NRC. The NRC has always supported this prudent and open exchange of information and industry will continue this approach in the future. NEI does not see a need to codify in Part 70 the requirement to submit a preliminary process hazards evaluation, especially when no approval of this analysis is required or formal feedback from the NRC is mandated. NEI recommends, therefore, that paragraphs (4) and (5) of draft §70.74 be deleted.

(d) Reporting Requirements (§70.74)

The additional reporting requirements of §70.74 appear to be duplicative of those already stated in §70.50. NEI supports incorporation of the Bulletin 91-01 ('*Reporting Loss of Criticality Safety Controls'*) reporting requirements into the proposed reporting revisions. NEI does not support creation of a new class of events that are to be reported to the NRC Operations Center within 8 hours of their discovery. We believe that event reporting should be limited to two classes:

(i) serious accidents or events that should be immediately reported to the NRC (e.g. inadvertent nuclear criticality) within a 1-hour timeframe, and
(ii) safety-significant events which pose no immediate threat to workers, the public or the environment that should be reported to the NRC within a 24-hour timeframe.

NEI views the information reporting requirements of §70.74(c) and the written reporting requirements of §70.74(d) to be sufficiently duplicative of the provisions of §70.50(c)(1) and (2) that they be consolidated with the latter.

II. Specific Comments

NEI has identified additional comments on the revisions of Part 70. Many of these propose clarifications and simplifications of the Rule language and recommended editorial improvements. On the attached red-lined version of the proposed Rule revisions, annotations are made for such issues.

NRC March 1, 1999 Revision

Part 70 -- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

1. The authority citation for Part 70 continues to read as follows:

AUTHORITY: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

2. The undesignated center heading “GENERAL PROVISIONS” is redesignated as “Subpart A -- General Provisions.”

3. In 10 CFR 70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration Management, ~~Controlled site boundary~~, Critical mass of special nuclear material (SNM), ~~Deviation from safe operating conditions~~, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety assessment ~~analysis~~ (ISA), Integrated safety assessment ~~analysis~~ summary, Items relied on for safety, Management measures, ~~New processes at existing facilities, Preliminary process hazards analysis (PHA)~~, Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows: [Comments: (1) Definitions of

terms which have been struck-through are not required as they are adequately described in appropriate sections of the proposed Rule revisions. (2) NEI has noted the Commission's use of the term '*Integrated Safety* ***Assessment***' (rather than 'analysis') most recently in its March 16, 1999 'Risk-Informed and Performance-Based Regulation' white paper. NEI recommends that the ISA be correctly referred to as an assessment, a much broader and all-encompassing term than 'analysis']

70.4 Definitions.

Acute as used in section 70.61 of this Part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

Available and reliable to perform their function when needed as used in Subpart H of thise~~e~~ Part means that, based upon the analyzed, credible conditions in the integrated safety assessment ~~analysis~~, items relied on for safety will perform their intended safety function when needed and management measures will be implemented that provide reasonable assurance of ~~ensure continuous~~ compliance with the performance requirements of §70.61 of this Part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures. [Comment: In numerous definitions and sections of the proposed revisions, the verb 'ensure' (or 'assure') is used. There can often be no absolute assurance, however, that a management measure or control, for example, will ensure no possibility of error or failure. NEI concurs with the expression used by the NRC in some sections of the proposed revisions to replace the verb 'ensure' (or '(assure')) by the phrase '*provide reasonable assurance*'. See for example, the NRC's use of this phrase in §70.64(c)(4).]

Configuration management (CM) means ensuring, as part of the safety program, oversight and control of ~~all~~ design information, safety information, and modifications (both temporary and permanent) to items relied on for safety ~~the site, structures,~~

~~processes, systems, equipment, components, computer programs, and activities of personnel~~.

~~Controlled site boundary means the physical barrier surrounding the facility that is used by the licensee to control access. It may or may not coincide with the property boundary.~~ [Comment: Rather than defining a new term, NEI recommends adoption of the existing definition of '*controlled area*' in 10 CFR 20.1003 for those sections of the proposed Part 70 revisions in which the exposure level of a member of the public is to be calculated. This definition is also consistent with that of 10 CFR 72.3]

Critical mass of special nuclear material (SNM) means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present. [Comment: The NRC's March 1, 1999 update of the proposed Part 70 revisions no longer references this definition. If the definition is to be no longer used in Part 70, consideration should be given to deleting it from §70.4.]

~~Deviation from safe operating conditions means that a parameter that is controlled to ensure adequate protection is outside its established safety limits, or that an item relied on for safety has been lost or has been degraded so that it cannot perform its intended function.~~

[Comment: This term is not used in Part 70. It should, therefore, be deleted.]

Double contingency means a process design that incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

Integrated safety assessment ~~analysis~~ (ISA) means a systematic assessment ~~analysis~~ to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items ~~site, structures, systems, equipment, components, and activities of personnel that are~~ relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this Part, the focus of the integrated safety assessment ~~analysis~~ is limited to the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

Integrated safety assessment ~~analysis~~ summary means the document submitted ~~in conjunction~~ with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety assessment ~~analysis~~ and contains the information specified in §70.65(b). ~~informs the Commission of the nature of the site, facility, and processes; the qualifications of individuals that performed the integrated safety analysis; the methodologies used; the accident sequences that, unless prevented or mitigated, could exceed the performance requirements in section §70.61 of this Part; the items relied on for safety that protect against those accidents, the measures that are implemented to ensure the items are~~

~~available and reliable to perform their function when needed; and the evaluations for compliance with the performance requirements of §70.61.~~

Items relied on for safety means structures, systems, equipment, components, and activities of personnel that are relied on to prevent or mitigate potential accidents at a facility that could result in non-compliance with the performance requirements of §70.61~~or to mitigate their potential consequences~~.

[Comment: The proposed correction makes the language conform to that of §70.61.]

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, identified in the integrated safety assessment ~~analysis~~, to provide reasonable assurance that ~~ensure~~ they are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other safety ~~quality~~ assurance measures ~~systems~~. [Comment: Throughout the proposed Rule revisions the verbs 'ensure' and 'assure' are used, apparently interchangeably. If there is not a meaningful distinction between the usage of these verbs, for the sake of consistency, only one should be used in the proposed revisions.]

~~New processes at existing facilities means systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. This definition does not, generally, include component-level design changes or equipment replacement.~~ [Comment: Definition of '*new processes at existing facilities*' is not really required as the term is adequately described and principally used in §70.64(a).]

~~Preliminary process hazards analysis (PHA) means an analysis undertaken during the early design or development phases of a process to identify the principal hazards and to enable them to be eliminated, minimized or controlled with minimal cost or~~

~~disruption. The analysis also assists in identification and optimization of potential corrective, mitigative or preventive safety controls and management measures.~~ [Comment: Definition of '*preliminary process hazards evaluation (PHA)*' is not really required as the term is adequately described and principally used in §70.64(c).]

Unacceptable performance deficiencies means deficiencies in the items relied on for safety or the management measures ~~used to assure the items are available and reliable to perform their function when needed,~~ that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

Worker means an individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation (i.e., an individual who is subject to an occupational dose as in 20 CFR 20.1003).

4. The undesignated center heading "EXEMPTIONS" is redesignated as "Subpart B -- Exemptions."

§§ 70.13a and 70.14 [Redesignated]

5. Sections 70.13a and 70.14 are redesignated as §§ 70.14 and 70.17, respectively.

6. Section 70.15 is added to read as follows:

70.15 Nuclear reactors.

The regulations in Subpart H do not apply to nuclear reactors licensed under 10 CFR Part 50.

7. The undesignated center heading "GENERAL LICENSES" is redesignated as "Subpart C -- General Licenses."

8. The undesignated center heading “LICENSE APPLICATIONS” is redesignated as “Subpart D -- License Applications.”

§ 70.22 [amended]

9. In 10 CFR 70.22, paragraph (f) is removed and paragraphs (g) through (n) are redesignated as (f) through (m).

§ 70.23 [amended]

10. In 10 CFR 70.23, paragraph (a)(8) is removed, paragraph (b) is removed and reserved, and paragraphs (a)(9) through (a)(12) are redesignated as (a)(8) through (a)(11), respectively.

11. The undesignated center heading “LICENSES” is redesignated as “Subpart E -- Licenses.”

12. The undesignated center heading “ACQUISITION, USE AND TRANSFER OF SPECIAL NUCLEAR MATERIAL, CREDITORS’ RIGHTS,” is redesignated as “Subpart F -- Acquisition, Use, And Transfer Of Special Nuclear Material, Creditors’ Rights.”

13. The undesignated center heading “SPECIAL NUCLEAR MATERIAL CONTROL RECORDS, REPORTS AND INSPECTIONS” is redesignated as “Subpart G -- Special Nuclear Material Control Records, Reports, And Inspections.”

14. The undesignated center heading “MODIFICATION AND REVOCATION OF LICENSES” is redesignated as “Subpart I -- Modification and Revocation of Licenses.”

§§ 70.61 and 70.62 [redesignated]

15. Sections 70.61 and 70.62 are redesignated as §§70.81 and 70.82, respectively.

16. The undesignated center heading "ENFORCEMENT" is redesignated as "Subpart J -- Enforcement."

§§ 70.71 and 70.72 [redesignated]

17. Sections 70.71 and 70.72 are redesignated as §§70.91 and 70.92, respectively.

18. In Part 70, a new "SUBPART H" (§§ 70.60 - 70.74) is added to read as follows:

Subpart H - Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material.

Sec.

70.60 Applicability

70.61 Performance Requirements.

70.62 Safety Program and Integrated Safety Assessment ~~Analysis~~

70.64 Requirements for new facilities or new processes at existing facilities.

70.65 Additional content of applications.

70.66 Additional requirements for approval of license application.

70.72 Facility changes and change process.

70.73 Renewal of licenses.

70.74 Additional reporting requirements.

70.60 Applicability

The regulations in §70.61 through §70.74 shall apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, ~~decommissioning of~~

~~facilities used for these activities,~~ or any other activity that the Commission determines could significantly affect public health and safety. These regulations do not apply to Gaseous Diffusion Plants.

[Comments: (1) Reference to decommissioning should be deleted. Decommissioning of a fuel cycle facility is an integral part of uranium facility, fuel fabricator, etc. and need not be singled out as a separate activity. A decommissioning contractor should not, for example, be required to first be licensed by the NRC before being able to undertake decommissioning work. (2) Because Gaseous Diffusion Plants (GDP) are certificate holders rather than licensees, §70.60 should explicitly exclude GDPscertified to Part 76.]

70.61 Performance Requirements

(a) Each applicant or licensee shall evaluate ~~demonstrate~~, in the integrated safety assessment ~~analysis~~ performed in accordance with §70.62, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

[Comment: An ISA is an **evaluation**, not a demonstration. Correcting the language as shown makes the Rule more consistent with our understanding of the ISA concept – a document not requiring NRC approval.]

(b) The risk of each credible high-consequence event must be limited, unless the event is highly unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those high-consequence events determined ~~demonstrated~~ to be highly unlikely. High-consequence events are those internally or externally initiated events that result in:

(1) an acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) an acute dose ~~outside the controlled site boundary~~ of 0.25 Sv (25 rem) or greater total effective dose equivalent to a member of the public outside the controlled area as defined in 10 CFR 20.1003; [Comment: As was discussed at

the March 23, 1999 NRC Public Meeting, doses to the public should be estimated based upon the locations where the licensee has the authority to exclude members of the public.]

(3) an intake ~~outside the controlled site boundary~~ of 30 mg or greater of uranium in soluble form by a member of the public outside the controlled area as defined in 10 CFR 20.1003; or

(4) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could endanger the life of a worker, or (ii) ~~outside the controlled site boundary~~, could lead to irreversible or other serious, long-lasting health effects to a member of the public outside the controlled area as defined in 10 CFR 20.1003. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as p~~P~~art of the application information submitted pursuant to Section 70.65 of this Part.

(c) The risk of each credible intermediate-consequence event must be limited, unless the event is unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those intermediate-consequence events determined ~~demonstrated~~ to be unlikely. Intermediate-consequence events are those internally or externally initiated events, that are not high-consequence events, that result in:

(1) an acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) an acute dose ~~outside the controlled site boundary~~ of 0.05 Sv (5 rem) or greater total effective dose equivalent to a member of the public outside the controlled area as defined in 10 CFR 20.1003;

(3) a 24-hour averaged release of radioactive material ~~outside the restricted area~~ in concentrations exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part 20 to a member of the public outside the controlled area as defined in 10 CFR 20.1003; or

(4) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could lead to irreversible or other serious, long-lasting health effects to a worker, or (ii) ~~outside the controlled site boundary,~~ could cause mild transient health effects to a member of the public outside the controlled area as defined in 10 CFR 20.1003. If an applicant possesses or plans to possess quantities of licensed material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the application information submitted pursuant to Section 70.65 of this p~~P~~art.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures shall be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with subsection (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to §70.62 of this Part, shall provide reasonable assurance that ~~ensure that each~~ items relied on for safety will be available and reliable to perform their ~~its~~ intended function when needed and in the context of the performance requirements of this section.

70.62 Safety Program and Integrated Safety Assessment ~~Analysis~~

(a) *safety program.* (1) Each licensee shall establish and maintain a safety program consisting of appropriate management measures to provide reasonable assurance that items relied on for safety will be available and reliable when needed ~~that ensures that actions taken will provide adequate protection from licensed materials, for worker and public health and safety and of the environment~~. The safety program may be graded such that management measures applied are commensurate with the reduction of the risk attributable to that item. Requirements for ~~the safety program, including~~ process safety information, integrated safety assessment ~~analysis~~, and management measures~~,~~ are described in subsections (b) through (d) of this section.

[Comment: The safety program is most effectively and simply defined to be management measures that will provide the necessary assurances that items relied on for safety are available and reliable when needed. This clear definition would still have a licensee meeting the requirements for process safety information, the ISA, etc.

(2) Each licensee shall establish and maintain records that demonstrate compliance with the requirements of this section.

(b) *process safety information.* Each licensee or applicant shall ~~compile and~~ maintain ~~a set of~~ process safety information to enable the performance of an integrated safety assessment ~~nalysis~~. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

[Comment: Deletion of 'compile' and 'set of' reduces the prescriptiveness of this §70.62(b). Licensees will have such information available, but not necessarily in a 'book'. How the information is stored is a function of the licensee's management programs.]

(c) *integrated safety assessment ~~analysis~~.* (1) Each licensee or applicant shall conduct an integrated safety assessment ~~analysis~~, that is of appropriate detail for the complexity of the process, that identifies:

(i) radiological risks ~~hazards~~ related to possessing or processing licensed material at its facility;

(ii) chemical risks ~~hazards~~ of licensed material and ~~or~~ hazardous chemicals produced from licensed material;

(iii) facility risks ~~hazards (e.g., chemical, fire, electrical and mechanical)~~ which could affect the safety of licensed materials and thus present an increased radiological risk; [Comment: (1) The NRC/OSHA MOU uses the term 'risk' rather than 'hazard' (e.g. "*radiation **risk** produced by radioactive materials, chemical **risk** produced by radioactive materials, plant conditions…. Increases radiation **risk**…"*). For consistency of the Rule revisions with the MOU, the term 'risk' may be preferable to 'hazard' in items (I), (ii) and (iii). (2) The ISA will address many industrial hazards. NEI suggests deletion of the hazard examples to afford the license applicant or licensee the flexibility of examining all relevant industrial hazards.]

(iv) potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;

(v) the consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) each item relied on for safety identified pursuant to section 70.61(e) of this ~~P~~part, the characteristics of its preventive, mitigative, or other safety function and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of §70.61.

The integrated safety assessment need not be docketed with the Commission and shall not be incorporated into the license.

(2) *integrated safety assessment ~~analysis~~ team qualifications.* In order to assure the adequacy of the integrated safety assessment ~~analysis~~, the analysis shall be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety assessment ~~analysis~~ methodology being used.

(3) *Requirements for existing licensees.* Individuals holding an NRC license on <the effective date of this rule> shall, with regard to existing licensed activities:

(i) within twelve ~~6~~ months of <the effective date of this rule>, unless otherwise specified by the conditions of a license held on <the effective date of this rule>, submit~~,~~ for NRC approval, a plan that describes the integrated safety assessment ~~analysis~~ approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. ~~Pending the correction of unacceptable performance deficiencies identified by the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.~~ [Comment: We support the concept of this sentence. However, it has no relevance to the topic of this sub-part and should, therefore, be deleted. The NRC may want to consider relocating this sentence elsewhere in the Rule text.]

(ii) within five ~~4~~ years of date of approval of the licensee's plan by the Commission, ~~<the effective date of this rule>~~, unless otherwise specified by the conditions of a license held on <the effective date of this rule>, complete an integrated safety assessment ~~analysis~~, correct all unacceptable performance deficiencies, and submit an integrated safety assessment ~~analysis~~ summary in accordance with §70.65 or the approved plan submitted under paragraph (c)(3)(i) of this section.

(d) *management measures.* Each applicant or licensee shall establish ~~safety program~~ management measures to provide reasonable ~~continuing~~ assurance of compliance with the performance requirements of section 70.61. The measures applied to a particular engineered or administrative control or control system may be commensurate with the reduction of the risk attributable to that control or control system. The ~~safety program~~ management measures shall provide reasonable assurance ~~ensure~~ that engineered and administrative controls or control systems that are identified as items relied on for safety pursuant to §70.61(e) of this Part are designed, implemented and maintained, as necessary, to provide reasonable assurance that ~~ensure~~ they are available and reliable to perform their function when needed, in the context of compliance with the performance requirements of section 70.61 of this Part.

70.64 Requirements for new facilities or new processes at existing facilities

(a) *Baseline design criteria.* Each prospective applicant or licensee ~~of the types listed in §70.60 of this Part~~ shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the ~~or~~ design of new processes at existing facilities that require a license amendment under §70.72. Applicants shall address these baseline design criteria in establishing minimum requirements for the new facility or process~~their process design and description~~. The baseline design criteria shall not apply to existing facilities or processes even if the new process is housed in, or adjacent to, an existing facility or process. Licensees shall maintain the application of these criteria unless the evaluation performed pursuant to paragraph (c) of this section demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) Quality standards and records. The design must be developed ~~established~~ and implemented in accordance with ~~a~~ established management measures ~~quality assurance program~~, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, plant conditions which affect the safety of licensed material and ~~hazards that may impact the storage, handling, and processing of licensed material, and against chemica~~l exposure to ~~an individual from licensed material or~~ hazardous chemicals produced from licensed material. [Comment: the term 'risk' is used in preference to 'hazard' to achieve consistency with the NRC/OSHA MOU.]

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

(i) Licensed material;

(ii) Evacuation of onsite personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services~~, including reliable and timely emergency power to items relied on for safety.~~

(8) Monitoring, ~~i~~Inspection, testing, and maintenance. The design of items relied on for safety must consider the need for monitoring, ~~provide for~~ periodic inspection, testing, and maintenance, to provide reasonable assurance of ~~ensure~~ their availability and reliability when needed. ~~continued function and readiness.~~

(9) Criticality control. The design must provide for criticality control including adherence to the double-contingency principle.

~~(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.~~ [Comment: Contents of item (10) have been merged into item (8).]

(b) ~~Facility and system design and plant layout must be based on defense-in-depth practices.~~ The design process shall assure that, to the extent practicable, engineered controls or control systems ~~passive systems~~ are preferable to administrative controls or control systems ~~selected over active systems,~~ to increase overall system reliability; and features are incorporated that enhance safety to meet the performance requirements of §70.61. ~~by reducing challenges to items relied on for safety. For new processes at existing facilities, the design of the new process shall, to the extent practicable, correct unacceptable performance deficiencies that are identified through the performance of the integrated safety analysis for the existing processes.~~

[Comments: (1) 'Defense-in-depth' is a term that should not be included in regulations. It is more appropriately used in guidance documents and in individual facility licensing documents. (2) The last sentence in Part (b) is unnecessary as there is a separate Part 70 requirement to remedy any unacceptable performance deficiency. This sentence is, therefore, not needed, especially as it could be construed to require backfits of existing facilities.

(c) *Preliminary process hazards evaluation~~analysis~~*. Each prospective applicant for a license or license amendment to operate a new facility or a new process at an existing facility that requires a license amendment under §70.72 shall:

[Comment: NEI recommends the term '***process hazards evaluation***' be used in preference to '*process hazards analysis*'. An evaluation embraces determination of the significance of an event or process, whereas an analysis is more narrowly defined for determination of the nature of (or relations amongst) the components of an event or scenario. The more broadly defined 'evaluation' term is recommended.,

(1) Initially design the facility or process to address ~~satisfy~~, ~~with incorporated margins for uncertainty~~, the performance requirements of §70.61~~0~~, the criticality monitoring and alarm requirements of §70.24, and the baseline design criteria in paragraph (a) of this section; [Comment: The term '*with incorporated margins for uncertainty*' is too vague and its meaning unclear. In the absence of clarification, this phrase should be deleted.]

(2) Perform a preliminary process hazards evaluation ~~analysis~~ on the initial design that evaluates the initial design against the requirements in paragraph (c)(1) of this section and identifies potential design and engineered features that are projected to be relied on for safety;

(3) Identify in the preliminary process hazards evaluation~~analysis~~:

(i) the ~~defense-in-depth strategy and~~ conceptual means for compliance with the requirements referenced in paragraph (c)(1) of this section, for the anticipated higher-risk (i.e., consideration of consequence and likelihood) facility accident sequences; and

~~(ii) administrative controls that supplement the design and engineered controls, if the administrative controls are expected to be identified as relied on for safety; and~~ [Comment: at the preliminary process hazards evaluation stage of a project, specific administrative and/or engineered controls will not be known and so the requirements of this part (ii) can not be met. This part should be deleted.]

(ii) ~~(iii)~~ any proposed, facility-specific or process-specific relaxations or additions to the baseline design criteria specified in §70.64(a), and a justification for any relaxation.

~~(4) Provide the preliminary process hazards analysis to NRC, for information, before proceeding with construction of the facility or process (NRC approval of the preliminary process hazards analysis is not required). The level of detail for the preliminary process hazards analysis that is provided to NRC shall be consistent with the maturity of the evolving design and sufficient to provide reasonable~~

~~assurance of consistency of the design and design process with the requirements in this section; and~~

~~(5) Identify in the integrated safety analysis summary submitted in accordance with section §70.62(c)(3) of this Part, any inconsistencies between the preliminary process hazards analysis and the integrated safety analysis summary.~~

[Comment: Sections (1), (2) and (3) of this Part (c) adequately address the requirement for submission of information to the Commission consistent with the phase of work being undertaken by the license applicant. Sections (4) and (5) are, however, inconsistent with this requirement in that no approval or action by the Commission is called for.]

(d) ~~For a new process at an existing facility subject to this section, the licensee shall file an application for amendment to the license in accordance with sections 70.21, 70.22, 70.34, and 70.65 of this Part, as applicable.~~ Nothing in this section shall be construed as providing relief from compliance with any of the requirements in sections 70.21(f) and 70.23(a)(7) of this Part, 10 CFR Part 51, or other applicable regulations. [Comment: Provisions of §70.72 determine when a license amendment is required and when, therefore, baseline design criteria need to be addressed and a preliminary process hazards evaluation to be conducted. The first sentence has been deleted as it arbitrarily assumes that a new process at an existing facility will require a license amendment.]

70.65 Additional content of applications.

[Comment: the ISA Summary should be properly referred to as 'integrated safety assessment summary' to be consistent with the §70.4 definition of this term.]

(a) In addition to the contents required by §70.22, each application must include a description of the applicant's safety program established under §70.62, including the~~a~~ ~~summary of the~~ ~~integrated safety analysis~~ summary and a description of the management measures established to provide reasonable assurance of ~~ensure~~ the availability and reliability of items relied on for safety when needed and in the context of the performance requirements of §70.61.

(b) The ~~summary of the integrated safety analysis~~ summary shall be submitted with the license~~,~~ or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety assessment ~~analysis~~ summary shall meet the conditions of §70.72. The ~~summary of the integrated safety analysis~~ summary shall contain:

(1) a general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology); [Comment: this information could be provided simply by referencing other applicable sections of the license application.]

(2) a general description of the facility with emphasis on those areas that could affect safety; [Comment: this information could be provided simply by referencing other applicable sections of the license application.]

(3) a description of processes ~~each process~~ analyzed in the ~~integrated safety analysis including the theory of operation~~ and a general description of the types of accident sequences for each that could exceed the performance criteria of §70.61

(4) information that demonstrates the licensee's compliance with the design requirements for criticality monitoring and alarms in §70.24;

(5)~~(4)~~ a description of the ~~integrated safety analysis~~ team, qualifications, and the methods used to perform the integrated safety assessment ~~analysis~~;

~~(5) a list of the accident sequences mitigated or prevented by more than one item relied on for safety including an evaluation of how the licensee meets the performance requirements in §70.61;~~

(6) ~~a list briefly describing all items relied on for safety which are identified pursuant to §70.61(e) in sufficient detail to explain their safety function~~ for the purpose of this integrated safety assessment summary, the items relied on for safety are described at the systems level with sufficient information to enable the Commission to understand their functions in relation to the performance requirements of §70.61;

(7) a description of the management measures applicable to such items relied on for safety

~~(7) a list of all processes (defined as a single reasonably simple integrated unit operation within an overall production line) that contain an accident sequence for which the consequences unless mitigated or prevented by more than one or more items relied on for safety, would exceed the threshold performance requirements of §70.61. This must include the maximum consequences for non-criticality radiological, chemical and criticality for each process;~~

(8) a description of the proposed quantitative standards used to assess the consequences from acute chemical exposure to licensed material or chemicals produced from licensed ~~material~~ materials which are on-site, or expected to be on-site as described in §70.61(b)(4) and (c)(4);

(9) a descriptive list of any items relied on for safety that identifies~~is the~~ sole items preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and

(10) a description of the definitions of likely, unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety assessment ~~analysis~~.

70.66 Additional requirements for approval of license application.

An application for a license to possess a critical mass of special nuclear material will be approved if the Commission determines that the applicant has complied with the requirements of §70.23 and §§70.60 through 70.65.

70.72 Facility changes and change process

(a) The licensee shall establish a configuration management system to evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system shall be documented in written procedures and shall assure that the following are addressed prior to implementing any change:

(1) the technical basis for the change;

(2) impact of the change on safety and health or control of licensed material;

(3) modifications to existing operating procedures including any necessary training /retraining before operation; [Comment: §70.72(c) is incorporated into this item (3).]

~~(4) necessary time period for the change;~~

(5) authorization requirements for the change;

(6) for temporary changes, the approved duration (e.g., expiration date) of the change; and

(7) the impacts or modifications to the integrated safety assessment ~~analysis~~, integrated safety assessment ~~analysis~~ summary, or other safety program information, developed in accordance with §70.62.

(b) Except for a new process subject to the requirements of §70.64, any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel shall be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with §70.34.

~~(c) Employees involved in operating a process, maintenance employees, and contract employees whose job tasks will be affected by a change shall be informed of, and trained in, the change prior to start-up of the process or portion of the process.~~

[Comment: The concept in this paragraph (c) has been moved to §70.72(a)(3) as it is more logically associated with this activity.]

Paragraph (d) Option 1

(c)~~(d)~~ The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel, without prior Commission approval, if the change:

(1) does not: (i) create new types of accidents not previously evaluated in the integrated safety assessment, or (ii) use new processes, technology, or types of control systems for which the licensee has no prior experience~~ new unmitigated accident sequences that exceed the performance requirements of section 70.61~~; or [Comment: The intent of this change is to clarify the wording so that it better defines what is covered and to allow a licensee to implement and manage its operations consistent with its experience.]

(2) does not remove, without a comparable~~an equivalent~~ replacement, any control or control system described~~ item relied on for safety that is listed~~ in the integrated safety assessment~~integrated safety analysis~~ summary; [Comment: 'equivalent' is too restrictive a word and could preclude superior replacements or replacements that otherwise do not affect safety.]

(3) does not alter any item relied on for safety, listed in the integrated safety assessment ~~analysis~~ summary, that is the sole item preventing or mitigating an accident sequence that exceeds ~~exceess~~ the performance requirements of §70.61;

(4) is not otherwise prohibited by this section, license condition, or order.

(d)~~(e)~~ In addition to complying with the requirements of paragraph (c)~~(d)~~, any licensee for which the initial facility license was issued after <~~[~~ the effective date of this rule>~~]~~; and those licensees that are specified by the Director of the Office of Nuclear Materials Safety and Safeguards, by license condition or order, can make changes to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel without prior NRC approval, only if the change does not result in more than a minimal increase in the risk of an accident previously evaluated in the integrated safety assessment ~~analysis~~.

(e)~~(f)~~ Upon license renewal, or as may be otherwise specified by order by the NRC Director of the Office of Nuclear Materials Safety and Safeguards, a licensee may be relieved from the requirements of (d)~~(e)~~ of this section provided that future changes will comply with the requirements of (c)~~(d)~~ of this section.

Paragraph (d) Option 2

[Comment: No mark-up has been made of Option 2, since industry strongly favors selection of Option 1 for inclusion in §70.72.]

(d)(1)A licensee may make changes in the facility described in the integrated safety analysis and integrated safety analysis summary, make changes in the procedures as described in the integrated safety analysis and integrated safety analysis summary, and conduct test or experiments not described in the integrated safety analysis or integrated safety analysis summary without obtaining a license amendment pursuant to §70.34 only if:

i) a change to a license application or license condition is not required, and

ii) The change, test or experiment does not meet any of the criteria in Paragraph (d)(2) of this section.

2) A licensee shall obtain a license amendment pursuant to §70.34 prior to implementing a change, test, or experiment if the change, test or experiment would:

i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the integrated safety analysis;

ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;

iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the integrated safety analysis;

iv) Result in more than a minimal increase in the consequences of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;

v) Create the possibility for an accident of a different type than previously evaluated in the integrated safety analysis;

vi) Create the possibility for a malfunction of an item relied on for safety with a different result than any previously evaluated in the integrated safety analysis; or

vii) Result in more than a minimal change in a method of analysis described in the integrated safety analysis.

(f)~~(g)~~(1) For any changes that affect the integrated safety assessment ~~analysis~~ summary, as submitted in accordance with 70.65, but do not require NRC pre-approval, the licensee shall submit revised pages to the integrated safety assessment ~~analysis~~ summary, to NRC annually~~, within 90 days of the change.~~

(2) For changes that require pre-approval under §70.72, the licensee must submit an amendment request to the NRC in accordance with §70.34 and §70.65.

(3) A summary of all changes to the integrated safety assessment summary ~~process safety information, integrated safety analysis, or management measures~~ required by section 70.62 of this Part, that are made without prior Commission approval, shall be submitted to NRC annually~~every 6 months~~.

[Comment: The submittal of ISA Summary change pages and a listing of changes made without prior approval should be done on an **annual** basis to more closely conform with the reactor requirements of §50.59 and §50.71(e). Ninety-day and six-month submittals are very onerous and unnecessary.]

(g)~~(h)~~ If a change covered by §70.72 is made, ~~results in a change to the on-site process safety information, integrated safety analysis, or management measures required by section 70.62 of this Part,~~ the affected onsite documentation shall be updated promptly.

(h)~~(i)~~ The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c~~d~~ or d~~e~~) of this section. These records must be maintained until termination of the license.

70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65. ~~Information provided in applications, including the integrated safety analysis summary, must be current, complete, and accurate in all material respects.~~ [Comment: This struck-through language is unnecessary. Part 70 already contains a provision (§70.9) governing completeness and accuracy of information. This includes the implicit requirement that information submitted to the NRC be current as of some specified date. The phrase '*must be current*' implies a specified date that is not defined in the Rule.] Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

70.74 Additional reporting requirements

(a) Reports to NRC Operations Center

(1) Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in section (c) in Appendix A to Part 70.

(4) Follow-up information to the reports must be provided until all information

required to be reported in paragraph (a)(3) of this section is complete.

(5) Duplicate reports to the Commission are not required for events when the reports are made in compliance with other parts of this chapter, provided that the reports comply with the requirements of this section concerning addressees, information content, and timeliness of filing.

(6) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) *Written Reports*. Each licensee who makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report shall contain the information as described in paragraph (d) of Appendix A to Part 70.

Appendix A to Part 70 – Reportable Safety Events

As required by 10 CFR 70.74, licensees subject to the requirements in Subpart H of Part 70, shall report:

(a) *One hour reports.* Events to be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information in paragraph (c) of this Appendix as it becomes available, followed by a written report within 30 days:

(1) An inadvertent ~~unintended~~ nuclear criticality;

(2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in section 70.61(b)(4).

(4) Loss of controls such that no items relied on for safety, as documented in the integrated safety assessment summary, remain available and reliable to perform their function to prevent a nuclear criticality accident.

[Comment: The event listed in section (b)(1) is of such potential severity that it should be reported within a one-hour period rather than within 8 hours. It has been classified as a one-hour reportable event.]

(b) *Twenty-four ~~Eight~~ hour reports.* Events to be reported to the NRC Operations Center within 24 ~~8~~ hours of discovery, supplemented with the information in paragraph (c) of this Appendix as it becomes available, followed by a written report within 30 days:

~~(1) Loss of controls such that no items relied on for safety, as documented in the~~ Integrated safety assessment~~Integrated Safety Analysis summary, remain available and reliable to perform their function to prevent a nuclear criticality accident.~~ [Comment: Item (1) has been reclassified as a one-hour reportable event.]

~~(2) An occurrence of a process deviation that was considered in the~~ Integrated safety assessment~~Integrated Safety Analysis and: (a) dismissed due to its likelihood, or (b) was categorized as unlikely and whose associated~~

~~unmitigated consequences would have exceeded those in 70.61(b) had the item(s) relied on for safety not performed their safety function(s).~~

[Comment: The event outlined in Part 2(a) is addressed in Part 3. Part 2(b) does not need to be reported because it was analyzed to be 'unlikely' and items relied on for safety were put in place for mitigation.

(1)~~(3)~~ Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed ~~in the Integrated Safety Analysis,~~ or is different from that analyzed in the Integrated Safety Assessment ~~Analysis~~, and which results in failure to meet the performance criteria of section 70.61.

(2)~~(4)~~ Any natural phenomenon or other external event, including fires internal and external to the facility, that ~~has~~ affected ~~or may have affected~~ the ~~intended safety function or~~ availability and reliability of one or more items relied on for safety and could have resulted in a failure to meet the performance requirements of §70.61.

(3)~~(5)~~ An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards that satisfy the requirements of section 70.61(c)(4).

(4)~~(6)~~ An event or condition that at the time of discovery could have prevented the fulfillment of the safety function of a sole ~~an~~ item relied on for safety in the context of the performance requirements of section 70.61. ~~This includes one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant means, as documented in the Integrated Safety Analysis summary, were available and reliable to perform the same safety function.~~

[Comment: The second and third sentences of this part provide examples which are better presented in the SRP. Their inclusion in Rule language is not necessary.]

(5)~~(7)~~ Loss or degradation of items relied of for safety that may result in releases of radioactive material to the environment outside the controlled area ~~restricted~~ that equal or exceed the values in 70.61(c)(3).

~~(8) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality, or inadvertent release of radioactively contaminated materials.~~
[Comment: Part 8 is not safety-related and should not be reported as an 24-hour reportable event. The substance of this part 8 and the examples presented in the second sentence have been deleted as they are better suited to the SRP.

~~(c) Licensee reports to the NRC Operations Center, as required by 10 CFR 70.74(a), shall include, to the extent that the information is applicable and available at the time the report is made, the following:~~

~~(1) Caller's name and position title.~~
~~(2) Date, time, and location of the event.~~
~~(3) Description of the event, including:~~
~~(i) Sequence of occurrences leading to the event, including degradation or failure of items relied on for safety.~~
~~(ii) Radiological or chemical hazards involved including isotopes, quantities, and chemical and physical form of any material released.~~
~~(iii) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure).~~
~~(iv) Items that remain which are relied on to prevent or to mitigate the health and safety consequences, and whether the availability and reliability of those items to perform their function has been affected by the event.~~
~~(4) External conditions affecting the event.~~
~~(5) Additional actions taken by the licensee in response to the event.~~
~~(6) Status of the event (e.g., whether the event is on-going or was terminated).~~
~~(7) Current and planned site status, including any declared emergency class.~~
~~(8) Notifications related to the event that were made or are planned to any local, State, or other Federal agencies.~~
~~(9) Status of any press releases related to the event that were made or are planned.~~

[Comment: The reporting requirements outlined in this section 70.74(c) are currently detailed in §70.50(c)(1). This section would require reporting to the NRC of additional information which §70.50(c)(2) only now requires to be included in written reports. To the best of our understanding the NRC has not experienced any significant difficulty in obtaining information from licensees under §70.50(c)(1). The proposed §70.74(c) should be revised to be consistent with §70.50(c)(1).]

~~(d) Licensee written reports required by 10 CFR 70.74(b) shall consist of a completed NRC Form 366 and shall be forwarded to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001. Each written report must include the following information:~~

~~(1) Complete applicable information required by section (c) of this appendix.~~

~~(2) Whether the event was identified and evaluated in the Integrated Safety Analysis.~~

~~(3) Cause of the event, including all factors that contributed to the event.~~

(4) ~~(4) Corrective actions taken to prevent occurrence of similar or identical events in the future.~~

[Comment: The written reporting requirements outlined in this section 70.74(d) are currently detailed in §70.50(c)(2). As noted above, to the best of our understanding the guidance provided in NRC form 366 has been particularly effective in facilitating two-way dialogue between a licensee and the NRC and need not be replaced. Incorporation of highly specific reporting requirements into the Rule which will change as the NRC's needs for information change is inappropriate. The proposed §70.74(d) should be revised to be consistent with §70.50(c)(2).]