

Summary of Comment Disposition
Part 70 Proposed Rule

No.	Source	Rule Section	Comment	Disposition
1	Dept of Energy (DOE)	§70.4	The following change should be made to the definition provided: "... from licensed sources of radiation, and radiation from man-made non-regulated sources (e.g., an individual). As originally defined, persons who are subject to occupational doses from natural sources of radiation, for example airline pilots and astronauts subject to high cosmic background might be included, whereas workers involved with the manipulations of unlicensed radioactive materials might not be. The proposed change removes this source of confusion.	The staff agrees in principle with the comment. However, the comment's proposed change does not eliminate the confusion (e.g., some man-made unlicensed sources of radiation are part of background or otherwise not included in Part 20 Occupational dose.) Therefore, §70.4 definition is changed to: <i>Worker</i> , as used in Subpart H, means an individual who receives an occupational dose as defined in 10 CFR 20.1003.
3	DOE	§70.22, §70.65	Section 70.22 (f) should be coordinated with §70.65. As written, it is not clear whether the requirements are collateral, complementary, or redundant.	No changes needed. The requirements are not viewed as redundant considering the time frame for submittal of information required by the two sections could be different. See similar comment #20.

4	DOE	§70.23 (b)	Section 70.23(b) should be examined to clarify the need for this requirement in light of similar information being submitted pursuant to §70.65. Irrespective of §70.65, §70.23(b) appears to be an unnecessary step and should be considered for deletion by NRC. If NRC chooses to retain §70.23(b), NRC should clarify how the authorization process would be conducted, given that the procedural step has never been exercised to the knowledge of DOE. Furthermore, NRC should identify how the "design basis" authorization is defined, why it is necessary, and how it relates to the ISA.	<p>No change needed. With regard to the authorization process the NRC staff has clarified this previously and documented this clarification in a letter to DCS dated September 10, 1999. The design basis was also identified in this letter.</p> <p>See related comments #21, 22 and 23.</p>
5	DOE	§70.61	This section of the rule sets the dose limits only for high-consequence and intermediate-consequence events with the likelihood of highly unlikely and unlikely and does not set the limits for anticipated occurrences similar to that in 10 CFR 72, Parts 104 and 106. The dose limit for anticipated occurrences is much less than the limits for high-consequence and intermediate-consequence events and the anticipated occurrences, when analyzed unmitigated, could result in doses that potentially exceed the limits for high-consequence and intermediate-consequence events. The NRC should specify the dose limits for potential anticipated occurrences at the nuclear fuel cycle facilities. This part of the rule then will cover the range of likelihood (anticipated, likely, unlikely, and highly unlikely) of potential accidents that could occur at nuclear cycle facilities. This could result in an increase in the number of structures, systems, and components relied on for safety and will impact the design, operation, and licensing of the MOX facility.	<p>No changes needed. The dose limit for any event or condition of normal operation is set by Part 20 (viz., 5 rem TEDE/yr for a trained worker). The staff views anticipated occurrences to be conditions of normal operations.</p> <p>The proposed rule adds an accident analysis and identification and management of items relied on for safety for those accidents identified in the accident analysis. NRC staff believes that the measures currently used by Part 70 licensees to comply with Part 20, have been successful, and there is insufficient justification to further identify 'items' for purposes of compliance with 10 CFR Part 20 during normal operations.</p>

6	DOE	§70.61	<p>Section 70.61(d) is not related to 70.61(b) or 70.61(c) yet the three conditionals are all linked together. Subpart (d) should be segregated from (b) and (c) if (d) is preserved as an independent entry (as would seem preferable). Otherwise, (d) should be subsumed under (b) and/or (c), and the regulatory basis for criticality prevention should be predicated on the risks and/or consequences of the accidents, rather than the presence of initiator precursor per se. (editorial)</p>	<p>No change needed. The staff believes that a separate performance requirement for nuclear criticality prevention is appropriate. The staff recognizes that many (but not all) nuclear criticality accidents would reasonably be expected to result in worker doses that exceed the high- and intermediate-consequence standards in §70.61(b) or (c). However, regardless of the dose directly resulting from the accident, an inadvertent nuclear criticality should be avoided. The Commission position on this matter is reflected in the NRC Strategic Plan (NUREG-1614).</p>
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7	DOE	§70.61	<p>These requirements consider the individuals working in the nearby facilities as public when performing an accident analysis to determine the consequences of the accidents that may occur at the facility. This would result in a more stringent application of safety requirements for the protection of workers (e.g., additional items relied on for safety) at the Mixed Oxide (MOX) Fuel Fabrication Facility (FFF), Pit Disassembly, Conversion Facility, Immobilization Facility, and any other nearby DOE facilities. This also would have a substantial impact on the cost of the MOX facility. The workers in the nearby DOE facilities are protected under DOE Code of Federal Regulations 10 CFR 835, "Occupational Radiation Protection" and DOE Order 5400.5, "Radiation Protection of the Public and the Environment," and potentially by draft 10 CFR 834, "Radiation Protection of Public and the Environment," which are comparable to the protection afforded the workers under NRC 10 CFR 20. Therefore, the NRC should consider changing Section 70.60(f)(1) to read as follows: Demonstrates and documents, in the integrated safety analysis, that those individuals at the location of their activities do not exceed the performance requirements of paragraphs (b)(1), (b)(3), (b)(4)(ii), (c)(1) and (c)(4)(i) of this section, including the Section 70.60(f)(2) requirement in Section 70.22 (h)(2)(ii)(3). Accordingly, the paragraph could be rewritten as follows: "Each licensee must ensure that a controlled area can be established as defined in Sec 20.1003 in which the licensee has the authority to enable control over all activities.</p>	<p>Agree. The first sentence in Section 70.61(f) was changed to read as follows: "Each licensee must establish a controlled area as defined in 20.1003 and in which the licensee retains the authority to exclude or remove personnel and property from the area."</p> <p>Section 70.61(f) requires licensees to establish a controlled area and sets conditions for activities <u>within</u> the licensee's controlled area. The licensee can set the controlled area at any location around their facility as long as it maintains control of that area as specified in Part 20 and retains the authority to exclude or remove personnel and property from the area. If the controlled area included the nearby DOE facilities, then personnel working at those facilities would be considered "workers" by the NRC for the purposes of the performance requirements of §70.61, provided the conditions of §70.61(f)(2) are met, which could be met through agreements with DOE/DOE contractors to document that the requirements of 10 CFR 19.12(a)(1)-(5) were satisfied. To emphasize that the 10CFR70(f)(2) requirements, regarding 10CFR19 training, can be satisfied in combination with existing training, rather than separate training solely devoted to 10CFR19, 10CFR70(f)(2) has been changed to read:</p>
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7 Cont	DOE	§70.61		<p>“...Provides training that satisfies 10CFR19.12(a)(1)-(5)...”</p> <p>To emphasize that the training provided to satisfy 10CFR70(f)(2) requirements includes making individuals aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, the word “to” was changed to “and” so that it now reads “...to these individuals and ensures that they are aware of the risks associated with accidents...”</p> <p>See similar comments #1, 19 and 52.</p> <p>Incidentally, the provisions in both 10 CFR 20 and 10 CFR 70 must be satisfied. Part 20 establishes acceptable dose limits for the public and occupational dose limits, whereas Part 70 establishes acceptable risk (i.e., the performance requirements) from accidents. The consequences (in some cases doses) stated in §70.61 must be viewed in conjunction with the associated likelihoods since consequences and likelihoods are equally important components of risk.</p>
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8	DOE	§70.62 (d)	<p>Section 70.62(d) Management Measures. Second sentence: "The measures applied to a particular engineered or administrative control or control system may be commensurate with the reduction of risk attributable to that control and control system."</p> <p>The management measures are to be applied to items relied on for safety based on their contribution to a reduction in risk. The failure data for most fuel facility equipment are not well documented. The frequency of failure of equipment is a major factor in determining the reduction of risk. Therefore, the NRC should consider the graded approach to management measures, using risk as one of the factors in applying the management measures to items relied on for safety. Other factors should include consequences, life cycle, and magnitude of hazard involved. Balanced and integrated criteria for determining the appropriate management measures can ensure the safety and integrity of the facility.</p>	<p>Agree. The term "graded" has been inserted before "commensurate" to be consistent with §70.62(a).</p> <p>The staff agrees with the point but notes its intent that grading of measures to consequences, life cycle and magnitude of hazard involved are part of grading the measures to risk. The phrase used in the rule, "commensurate with the reduction of risk attributable to that item," does not imply requiring a quantitative determination of any particular item relied on for safety's risk significance.</p> <p>The rule is non-prescriptive with regards to the grading approach and criteria to be used, allowing flexibility for such details to be proposed by applicants.</p> <p>See similar comment #58.</p>
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9	DOE	§70.64 (a)	<p>This section requires that the design provide for adequate protection from environmental conditions and dynamic effects associated with normal operation, maintenance, testing and postulated accidents that could lead to loss of safety functions.</p> <p>This requirement is unclear. What does it mean? Is formal Equipment Environmental Qualification Program required similar to that required under 10 CFR 50.49 and Regulatory Guide 1.89? The NRC should clarify this requirement and should not impose requirements that may not be appropriate or necessary because of the nature of the processes at non-reactor nuclear facilities.</p>	<p>No change needed. The Baseline design criteria on environmental and dynamic effects does not mean that a formal Equipment Environmental Qualification Program is required similar to that required under 10 CFR 50.49 and RG 1.89.</p> <p>For new facilities and new processes only, this requirement means that potential ambient conditions are considered during the design of the facility.</p>
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10	DOE	§70.64 (b)	<p>This section requires that facility and systems design and layout must be based on defense-in-depth practices. The defense-in-depth definition as used in Section 70.64 does not reflect the defense-in-depth design philosophy as defined in WASH-1250, "The Safety of Power Reactor and Related facilities," which outlined three levels of safety concepts in the design of a nuclear Facility. The three levels concern different design considerations in the facility; however, these design considerations intermesh and overlap so that distinctions as to whether certain design features belong to one or the other of these levels are somewhat arbitrary.</p> <p>The definition in the rule oversimplifies the concept of defense in depth, to where it loses its basic purpose. For example, Sections 70.64(b)(1) and (2) do not adequately represent the implementation of defense-in-depth philosophy in the design. The selection of engineered controls over administrative controls and features that reduce challenges to items relied on for safety are partially implemented in the concept.</p> <p>For non-reactor nuclear facilities, one level of safety by itself may not be sufficient to protect against the release of radioactive materials. However, a combination of any of these levels should provide a sufficient level of protection to the public, workers, and environment. The NRC should reexamine the definition and the application of the defense-in-depth philosophy to be commensurate with the level of hazard and associated consequences and risk.</p>	<p>No changes needed. The staff believes that the footnote to §70.64(b) that describes defense-in-depth does reflect the defense-in-depth design philosophy as defined in WASH-1250. Further, it reflects the Commission's current guidance on the relationship between defense-in-depth and risk-informed regulation that is discussed in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards."</p> <p>Agree with the suggestion to change §70.64(b). Section 70.64(b) requires the use of defense-in-depth practices in designing the facility. The footnote to §70.64(b) does mention the need for successive levels of protection. The staff did not mean to imply that the provisions in §70.64(b)(1) and (2) encompassed the defense-in-depth philosophy. However, to assure that this is not misinterpreted, the rule language has been changed to remove §70.64 (b)(1) and (2) from the rule but the concepts of these sections have been added in the form of guidance in the Standard Review Plan.</p> <p>See similar comment # 61.</p>
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10 cont			NRC should clarify how defense-in-depth philosophy applies to the regulation of facility types stated in section 70.60.	See resolution above.
11	DOE	§70.65	Section 70.65(9). The NRC should define the terms likely, unlikely, highly unlikely, and credible in the rule so that there will be one set of definitions applied to all nuclear fuel facilities. This will minimize the interpretation and application of these terms in the integrated safety analysis	No change needed. Part 70 applies to different types of facilities, some of which are more complex and have more accident sequences than others, which may necessitate different definitions. The Part 70 SRP will contain guidance concerning the definitions of likely, unlikely, and highly unlikely.
12	DOE	§70.73	Section 70.73 states that a description of changes made to structures, systems, components, etc., should be sent periodically by the licensee to the NRC. The term "periodically" should be defined.	Agree. The referenced language is in the Statement of Considerations (SOC), not the rule. The specific time requirements were defined in the proposed rule, and are included, as revised, in the final rule. See similar comment #13.
13	DOE	§70.72	On the ISA update summary, the 90 day period appears to be too cumbersome. An annual update (similar to the annual FSAR updates for reactors per 10CFR50.71(e)) should suffice. If the spirit of the regulation is not being met based on experience, the licensee should face enforcement action.	Agree in part. Based on this and other similar comments the rule language was changed to require changes to the IROFS to be submitted quarterly (only if changes were made) and all other ISA summary changes to be submitted annually along with the changes described in 70.72(d)(3). See similar comments # 28,39, 69, 76, and 86.

14	DOE	Backfit	A backfit process similar to that in 10 CFR 50.109 or 10 CFR 76.76 should be incorporated into the revisions to Part 70 and should apply to the current proposed changes to the extent they apply to existing facilities.	<p>Agree in part. A backfit provision has been included in the rule similar to §70.76. The provision goes into effect after publication of guidance documents for facility requirements not covered by subpart H. For subpart H requirements, this provision shall become effective for a licensee as soon as NRC approves that licensee's ISA summary. NRC will publish guidance which will address, among other matters, the qualitative versus quantitative analysis issue. Under the §70.76 backfit provision, a backfit analysis is not required for modifications necessary to bring the facility into compliance with the rule, including subpart H, which includes meeting the performance requirements.</p> <p>See similar comments #43, 49, 71, and 73.</p>
15	DOE	§70.38	Because DOE facilities do not have the uncertainty of continued corporate sponsorship inherent in commercial facilities, the timeliness and schedule requirements in the decommissioning requirements of § 70.38 should be revised to include separate requirements for DOE facilities.	<p>No change needed. This section of the rule was not affected by the proposed rule and is therefore outside the scope of the rulemaking.</p> <p>See related comment #24.</p>

16	DOE	§70.24	The criticality requirements of §70.24 should be revised to permit alternate criticality control provisions to be accepted for DOE facilities without requiring an exemption.	<p>No change needed. This section of the rule is not affected by the proposed rule and is therefore outside the scope of the rulemaking.</p> <p>Further, the current version of 10 CFR 70.24, which deals with criticality alarms, is desirable for current and foreseeable licensees. §70.24 was reconsidered at the time of the §50.68 rulemaking related to criticality alarms at reactors and the current provisions of 70.24 were found to be acceptable.</p>
17	DOE		As additional DOE facilities are licensed by the NRC under the provisions of Part 70, NRC should ensure that the requirements address the full range of fissionable and fissile materials at these facilities.	This issue is beyond the scope of the rulemaking. It will be addressed if necessary in the future.

18	Duke Cogema Stone & Webster (DCS)	§70.4	<p>DCS notes that NEI has commented, with regard to 70.64(a)(8), that the use of “item relied on for safety” (IROFS) is problematic in the context of design, inspection, and maintenance, owing to the definition of IROFS including “activities of personnel” (§70.4). DCS shares this concern and proposes that changing the definition in 70.4 to limit IROFS to “structures, systems, equipment, and components” would ameliorate this concern. It is reasonably straightforward to classify physical items as being relied upon for safety, and to apply graded QA controls, including management measures, to design, construction, operation, maintenance, etc., of those physical items, based on their respective safety functions. It can be confusing to try and classify and grade items when they include “personnel activities,” since an activity has little importance absent the context of its influence on a physical item’s safety function. Removing “personnel activities” from the definition of IROFS would not limit their importance, but rather would put activities in context with the structures, systems, equipment, or components to which they are related, without necessitating a change in the balance of the proposed rule. Doing so will also help address the concern raised by NEI with regard to §70.65(b)(6), where they recommend that IROFS listed in the ISA Summary be limited to the systems level and that they not include personnel activities such as the use of procedures, which change constantly.</p>	<p>No change needed. Human actions that are relied on to prevent an accident (i.e., administrative controls) are as real as the “physical items” needed to prevent an accident. Just as there are measures (e.g., maintenance, configuration management) needed to assure the availability and reliability of physical controls, there are analogous measures (e.g., training, procedures) needed to assure the availability and reliability of human actions. Just as a graded approach could be applied to the maintenance of a physical control, depending on its risk significance, a similar graded approach could be applied to the training of a human, depending on the risk significance of the human’s actions.</p> <p>See related comment # 66.</p>
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19	DCS	§70.4	<p>DCS notes that NEI has addressed this issue in part in its comments associated with §70.61, noting further that they selected the MOX facility as an example of the problem associated with the current proposed language. DCS fully endorses and reiterates NEI's comments in this regard.</p> <p>As indicated in the definition of "worker" in §70.4, it is apparent that the NRC intends to consider individuals outside of the controlled area boundary as workers if they are subject to 10 CFR 20 requirements. We expect that the US Department of Energy (DOE) will also comment on this matter, and concur with their position that 10 CFR 835 provides an equivalent level of protection, such that collocated workers – inside or outside the controlled area – who are subject to the requirements of <i>either</i> 10 CFR 20 <i>or</i> 10 CFR 835 (or other equivalent control) should be considered "workers," provided the licensee can demonstrate the ability to provide management measures (e.g., notification, evacuation, etc., as appropriate) in the event of an emergency.</p>	<p>As discussed in comment #7 an NRC licensee can define the controlled area to include nearby facilities under defined circumstances.</p> <p>See similar comments #1, 7, and 52.</p>
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20	DCS	§70.22 (f)	<p>§70.22(f) states that plutonium-related applicants shall provide information on the plant site, design basis of principal structures, systems, and components (SSCs), etc., as part of the license application. This section requires information that is also required in other sections of the revised rule, and is at best redundant in this regard (and therefore unnecessary).</p> <p>More importantly, this section has not been revised to reflect the provisions of §70.65, which calls for an ISA Summary (containing the results of the safety assessment, also required in §70.22(f)) to be submitted <i>with</i> the license application, but not to be included as <i>part of</i> the license. As written, §70.22(f) seems to contradict §70.65 in this regard.</p>	<p>No changes needed. See response to comment #3.</p> <p>With regard to the relationship of the ISA summary to the license, see response to comments #29 and 53.</p> <p>See similar comments #31.</p>
21	DCS	§70.23	<p>§70.23(a)(8) states that the Commission will approve a plutonium facility's license application only after construction of principal SSCs has been completed in accordance with the application. Certainly this is not a requirement unique to plutonium facilities. The NRC already has the authority to grant licenses conditional upon successful completion of certain actions (such as successful startup testing, training, etc.). Completion of construction in accordance with the license application seems such an obvious condition that this specific provision seems redundant and therefore unnecessary.</p>	<p>See response to comment #4, 22, and 23.</p>

22	DCS	§70.23	<p>§70.23(b) states that the Commission will approve construction only after determination that the design bases of those SSCs, and the attendant quality assurance program, are adequate to protect against natural phenomena and the consequences of potential accidents. Our concerns are:</p> <p>(1) This provision as written seems contrary to other changes being proposed under the draft rule, as it addresses <u>consequences</u> of potential accidents, as opposed to the <u>risk</u> associated with <u>credible</u> accidents. Further, if this provision were amended to address risk as opposed to consequences – i.e., for consistency with the proposed §70.61 – it would be redundant to those proposed changes.</p> <p>(2) The standard set in §70.23(a)(7) for other 10CFR70 licensees is that construction can commence based on a conclusion by the Director of NMSS that environmental impacts have been appropriately addressed. Even in the absence of a mandated PHA [Preliminary Hazards Analysis] submittal (a provision of the earlier draft also struck from the latest version), the discretion afforded the NRC under §70.23(a)(7) – i.e., NRC’s authority over construction associated with “any...activity which the Commission determines will significantly affect the quality of the environment” – is adequate to ensure the sufficiency of information provided to NRC to authorize or disallow construction.</p>	<p>No change needed. The reference to “consequences” in the rule language does not preclude a risk informed approach in satisfying this requirement. The staff’s determination of reasonable assurance of protection against the consequences of potential accidents can be made on the basis of the capability to mitigate consequences and/or the capability to reduce the likelihood.</p> <p>See related comments #4, 21, and 23.</p>
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23	DCS	§70.23	<p>In consideration of these issues, and in the interest of statutory efficiency, DCS proposes that §70.23(a)(7) be clarified for applicability to plutonium facilities, and §§ 70.22(f), 70.23(a)(7), and 70.23(b) be eliminated as previously proposed. Doing so would avoid the preconception that, irrespective of design features and material composition, plutonium is “more special” than other special nuclear materials.</p>	<p>No changes needed. The Commission specifically established these requirements (see <u>Federal Register</u> Vol. 36, No. 104 dated May 28, 1971 and No. 171 dated September 2, 1971) for Pu facilities recognition of the potential exposures and ground contamination levels that may result if only a small fraction of the dispersible plutonium in process were released (see SECY-R 188, March 17, 1971). The current revisions to Part 70 do not impact this section and therefore, the suggested change is outside the scope of the rulemaking. A letter from NRC to DCS, dated September 10, 1999, addresses the licensing process.</p> <p>See related comment #4, 21 and 22.</p>
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24	DCS	§70.22	While not a part of the proposed change under consideration, DCS anticipates DOE will submit a comment requesting consideration of modifying the current rule to account for DOE-owned facilities. DCS shares this concern, which would presumably affect §§ 70.22(a)(9) and 70.38. In SECY-99-177, NRC Staff proposed that this issue could be resolved without a change to current regulations, but DCS is unaware as to a final Commission position in this regard. DCS intends to engage the NRC in this issue soon, to understand whether the decommissioning requirements for the MOX fuel fabrication facility will require a rulemaking. If it is apparent to the NRC that such a rulemaking will be required, DCS suggests, in the interest of efficiency, that it be addressed in this revision to 10 CFR 70.	No change needed. Section 70.22 is outside the scope of the rulemaking. See related comment #15.
25	DCS	§70.61	DCS proposes that the NRC maintain consistency with past precedent in this regard (i.e., the Commission's rationale in Part 60), and eliminate the specific worker dose limits in 10 CFR 70.	No change needed. The regulatory experience and industry events that initiated the effort to add a systematic accident analysis to Part 70 primarily involved health impacts to workers as opposed to the public. The staff believes that the rule's focus on both the potential impacts to workers and the public is appropriate. Based upon the discussions and correspondence with the industry and public during development of the proposed rule, and all other comments on the proposed rule, there appears to be general consensus on this approach.

26	DCS	§70.62	DCS reiterates NEI's comments regarding the redundancy of a failure log (§70.62).	<p>Agree in part. The rule was revised to eliminate the requirement for a specific log but includes the requirement for the licensees to be able to rapidly obtain such data for its own use as well as for NRC use. The language suggested in comment #34 was accepted with slight modification to emphasize the readily retrievable aspect and other conforming changes.</p> <p>See similar comments # 34, 54, and 80.</p>
27	DCS	§70.72	DCS reiterates NEI's comments regarding requirements for notification of "any change" to the facility (§ 70.72(a)).	<p>No change needed. See response to comment #47 and similar comment #67.</p> <p>See related comments #40, and 70.</p>
28	DCS	§70.72	DCS notes NEI has commented extensively on these very important issues, and reiterates NEI's comments in this regard, especially with regard to ...the unnecessarily onerous 90 -day notification requirements of § 70.72(d).	<p>See response to comment #13, and similar comments #39, 69, 76, and 86.</p>

29	DCS	§70.65	<p>DCS notes in §70.65(b) that, consistent with discussions to date, the NRC anticipates the ISA Summary will be submitted with the license application, but not incorporated in the license. The wording in §70.65(a), however, seems to contradict this position, given the general heading <i>Additional Content of Applications</i>. DCS proposes removing “including the integrated safety analysis summary and a description of the management measures” to clarify the issue. Absent this or some other clarification, DCS is concerned that §70.65(a) as written leaves the impression that the ISA Summary is part of the application (and by reference in the material license certificate, part of the license). The requirement to include the ISA Summary is adequately covered in §70.65(b). If necessary (i.e., if not sufficiently implicit in the ISA Summary requirements), additional discussion of the inclusion of management measures as part of the ISA Summary could be included in §70.65(b). DCS...suggests that the NRC clarify the relationship of the ISA Summary to the license and the safety basis to ensure consistency throughout the rule with the intent expressed in §70.65(b).</p>	<p>Agree. With regard to §70.65(a), the rule language was changed to remove reference to the ISA summary. With this change, the implication that the ISA summary is part of the application has been removed.</p> <p>With regard to the relationship of the ISA summary to the management measures, although under the proposed rule, the elements of the ISA summary did not explicitly include management measures, one of the elements (70.65(b)(4)) required information that demonstrates compliance with the performance requirements. Such a demonstration requires information about management measures. As suggested in the comment, the language in 70.65(b)(4) has been clarified to explicitly include a description of the management measures.</p> <p>See similar comments #20 and 31.</p>
30	DCS	§70.65 (b)	<p>DCS reiterates NEI’s comment with regard to §70.65(b)(3), regarding the extent of information required in the ISA Summary for processes which have been evaluated but have no safety implications.</p>	<p>No changes needed. The staff needs some information on each process analyzed in the ISA to assess completeness of the licensee’s ISA and to better understand the completeness and functions of the items relied on for safety.</p> <p>See related comments #38, 62, 64, 65, 68.</p>

31	DCS	§70.65	DCS also notes that NEI has expressed a related concern (i.e., under the heading “Safety Program Definition [§70.65]. DCS shares this concern as well and suggests that the NRC clarify the relationship of the ISA Summary to the license and the safety basis to ensure consistency throughout the rule with the intent expressed in 70.65(b).	<p>With respect to the safety program, see response to #53.</p> <p>See related comments #33, 37, 45.</p> <p>With respect to the relationship of the ISA summary to the license, see responses to comments #20, 29, and 53.</p>
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32	BWX Technologies (BWXT)	§70.4	<p>The definition of "available and reliable to perform their function when needed" appears throughout the proposed revisions to the rule. This definition requires measures be implemented that "ensure continuous compliance". BWXT believes this language indicates a level of certainty that is not realistic. A better choice of terminology would be "provides reasonable assurance."</p>	<p>Agree in part. With regard to changing "ensure" to "provide reasonable assurance," the term "ensure" is used liberally throughout NRC's regulations, in the context of a licensee's obligations, to connote "make sure" or "make certain." Specifically, elsewhere in Part 70 alone, the term is used in this context eight times: §§ 70.24(a)(3), 70.32(j), 70.38(g)(4)(iii), 70.51(a)(10), 70.52(c), and 70.57(b)(3),(4), and (6). Whereas, the term "reasonable assurance" is used just once in Part 70, in § 70.23(b), to describe the level of assurance that the Commission must find in order to approve construction. We believe the use of "ensure" in the definition of <i>'available and reliable to perform their function when needed'</i> in §70.4 is appropriate and consistent with prior regulatory usage that has been implemented without problems. With regard to the issue of "continuous compliance," the definition of "available and reliable" in 70.4 has modified to delete the word "continuous." This change recognizes the concept that a failure of an item relied on for safety does not automatically infer a failure to meet the performance requirements of 70.61. A discussion has been added to Chapter 3 in the Standard Review Plan to address the relationship of</p>
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32 Cont	BWXT	§70.62		failures of items relied on for safety to meeting the performance requirements. See similar comment #50.
33	BWXT	§70.62 (a)	This section implies the Safety Program has only three elements. This may be true when discussing an Integrated Safety Analysis, which will identify Items Relied on for Safety and their associated Management measures. This is not true, however, in relation to the requirements of 10CFR70.22 for contents of a license application. BWXT believes the Safety Program is much more comprehensive and includes occupational safety (e.g., Radiation Protection Program required by 10CFR20) as well as accident safety, which is the focus of Subpart H. BWXT suggests that attempts to define the Safety Program be deleted from 70.62(a). The requirements contained in 70.62 a-d can be retained without creating a less than comprehensive definition of the Safety Program.	See response to comment #53 and related comments #31, 37, and 45.

34	BWXT	§70.62 (a)	This section is very-prescriptive in requiring a "log" to be available which documents failures of items relied on for safety. BWXT believes the requirement should be rewritten to be performance based rather than prescriptive. A performance-based requirement could state "each licensee shall maintain records of failures...which are retrievable and available for inspection". Most licensees have an incident reporting and corrective action system, which is used for all activities at the facility. As long as these systems meet the performance objective it seems unnecessary for the rule language to be prescriptive in how it is met.	See response to comment #26 and related comments #54, and 80.
35	BWXT	§70.62 (c)	This section requires a plan to be submitted within 6 months of the effective date of the rule. This requirement should pertain only if a licensee has not already completed the actions outlined in §70.62(c)(3)(ii).	No changes needed. The implementation plan and the ISA must satisfy the requirements in the final rule. If the actions outlined in §70.62(c)(3)(ii) have been completed, then all that would be required to satisfy §70.62(c)(3)(i) is a description of any additional work that must be performed to meet the requirements of the rule (Subpart H) or a confirmation that the work already submitted does, in fact, meet the requirements of the rule (Subpart H) .

36	BWXT	§70.62 (c)	<p>There is no mention of time frame for a licensee to come into compliance with the revisions to the rule that are <u>not</u> related to completion of the ISA and submittal of a summary. When 10CFR20 was revised, licensees were given one year until the requirements become effective in which to implement programmatic changes. 10 CFR 20.1008 specifically addressed potential contradictions between license applications and regulations. It seems probable that conforming license amendments will be required to correct inconsistencies in areas not related to the ISA (e.g., reporting requirements) and to achieve compliance with §70.65(a). BWXT recommends an effective date sufficiently far into the future that programmatic changes can be implemented at the operating facilities and that any necessary conforming license amendments can be completed.</p>	<p>Agree. Section 70.60 was revised to include the following: “Unless specifically addressed in Sec. 70.61 through Sec. 70.74, implementation of the Subpart H requirements shall be completed no later than the time of the ISA summary submittal required in §70.62(c)(3)(ii).”</p> <p>The Federal Register Notice states “The final rule is effective [on the effective date stated in the final rule]. In §70.76, it states that “this provision shall become effective for subpart H requirements as soon as NRC approves the licensee’s ISA summary pursuant to § 70.66. For requirements other than Subpart H, this provision becomes effective immediately after NRC publication of backfit guidance.” This provision would apply immediately (i.e., 30 days after publication of the rule in the Federal Register) to other facility activities not covered by subpart H.</p> <p>In Appendix A reporting requirements, it states “The reporting requirements in this appendix, except for (a)(1), (a)(2), and (b)(4), are effective when the ISA summary is submitted in accordance with §70.62(3)(ii). Requirements (a)(1), (a)(2), and (b)(4) are effective on [on the effective date of the final rule].”Section 70.62(c)(3)(ii) was revised to further clarify implementation schedules for existing</p>
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37	BWXT	§70.65 (a)	The concept of establishing a safety program under §70.62 is confusing. As stated in the previous comment on §70.62(a), the requirements for including the additional information as part of a license application can be included without creating a narrowly focused definition of the safety program.	See response to comment #53 and related comments #31, 33, and 45.
38	BWXT	§70.72 (c)	This section seems clear until the reader tries to understand the footnote, which attempts to explain new types of accident sequences. Taken literally, which we must be able to do with regulations, this footnote will require nearly all process changes to require a license amendment. This outcome is in direct conflict with commission directives issued during the development of the rule. BWXT recommends the footnote be deleted. The language in §70.72(c)(1)(i) is completely adequate in the absence of the footnote.	<p>Agree. The footnote was removed. The staff will develop a guidance document, with input from stakeholders, to describe the change process in more detail. The degree of detail provided in the ISA summary, together with the other information available, must be sufficient for the staff to make the determination specified in 70.66. A discussion has been added to Chapter 3 of the Standard Review Plan to address the level of detail in the identification of the types of accident sequences</p> <p>See related comments #30, 62, 64, 65 and 68 related to the degree of detail in the ISA summary.</p>
39	BWXT	§70.72 (d)	BWXT believes the 90-day update requirement is unnecessary and is inconsistent with the requirements in 10 CFR 50.71 for reactor licensees whose potential consequences are significantly greater than those at fuel facilities. BWXT supports an annual update of the ISA Summary.	See response to comment #13 and similar comments #28, 69, 76, and 86.

40	BWXT	§70.72 (d)	This section requires annual submittal summarizing all changes to records required by §70.62(a)(2). The requirements for records in §70.62(a)(2) apply to all records described in §70.62(b) through (d). These records include Process Safety Information (70.62(b)) which enables the performance of the Integrated Safety Analysis. This would include procedures, drawings, detailed equipment lists, etc. BWXT does not believe NRC requires a summary of changes to this type information.	<p>No change needed. The regulation currently reads: A brief summary of all the changes to the records required by §70.62(a)(2)....be submitted..” This does not require the submittal of actual charts and drawings but a written summary of the changes made. It is important that NRC be knowledgeable of changes made to this information because it is part of the safety basis of the facility.</p> <p>See similar comment #70 and related comments #27, 47, and 67.</p>
41	BWXT	§70.73	NRC should consider including a maximum timeframe for license renewal that is substantially longer than the current practice of 10 years. If a "living license" is truly the outcome, as described in the Supplementary Information, it seems renewal periods as long as 20 years would be appropriate.	<p>No change needed. A specific time for renewals is not specified in Part 70 and to establish a rule provision that would specify a particular time would require consideration of many factors (e.g., EIS) not addressed in the current rulemaking. Further, since the current rule does not specify a license renewal period, the staff may consider a longer time frame for license renewals in the future as has been done in the past. For example, the time frame was extended from 5 years to 10 years for licensees who volunteered to perform an ISA. In any case, considering the living license nature under the new Subpart H, the burden of license renewal should be significantly reduced.</p> <p>See similar comments #77 and 87.</p>

42	BWXT	App A	<p>The terminology in (b)(1) clearly ties the failure to the performance requirements. The phrase, "and which results in failure to meet the performance requirements of §70.61", is very clear. This phrase should be consistently included in (b)(2)-(5) using the exact same wording.</p>	<p>No change needed. The linkage to the failure to meet the performance requirements is already included in §70.61(b)(2) and (b)(3). For the events described in §70.61(b)(4) and (5), the staff desires to be informed when such events occur, regardless of the licensee's determination with respect to the performance requirements. For these events, the staff will independently assess whether the performance requirements were met, on the basis of the information reported.</p>
43	BWXT	Backfit	<p>BWXT believes the Backfit Provision should be immediately effective. This view has been clearly articulated in past meetings and in the NEI comments on this rule.</p> <p>If the backfit provision is not immediately effective, an alternative would be to make it effective for facilities or systems for which the ISA has been completed and the ISA Summary submitted to NRC.</p> <p>In either case, backfit language should be included in the rule now with dates or circumstances under which it is effective.</p>	<p>See response to comment #14.</p> <p>See similar comments #49, 71, and 73.</p>

44	USEC	§70.61	<p>The Federal Register Notice requests comments with respect to the clarity and effectiveness of the language used per the June 1, 1998 Presidential Memorandum. We find the language in §70.61(b) and §70.61(c) could be substantially clearer and have offered a plain language version of this section in the attachment.</p>	<p>Agree in part. Although the current language in the proposed rule was written in response to public comments to focus on risk (i.e., probability and consequences), the language was changed for the sole purpose of clarity in response to this comment. The proposed revisions provided by the commenter, however, were not merely editorial but represent substantive changes. The proposed revisions provided by the commenter appear to have eliminated the concept of limiting risk, and instead, focused on the probability factor in the risk equation. The revised language in the rule attempts to retain the concept of risk in response to earlier comments while making the language clearer.</p>
45	USEC	§70.62	<p>The safety program is broader than the three elements identified in §70.62(a)(1) as: 1) process safety information, 2) integrated safety analysis, and 3) management measures. Fuel cycle facility safety programs encompass the three elements identified plus all of the other topics addressed in the license application. This includes, for example, radiation safety, criticality safety, chemical safety and fire protection in addition to the three elements directly associated with the integrated safety analysis.</p> <p>This comment can be readily addressed by deleting the reference to the three elements in §70.62(a)(1) and clarifying the application requirements in §70.65(a) as provided in the attachment.</p>	<p>See response to comment #53.</p> <p>See related comments #31, 33, 37.</p>

46	USEC	§70.72	<p>...We would note one other differences between the submittal requirements of §70.72 and §50.59. §50.59 requires a brief description and summary safety evaluation be submitted for each change. §70.72 requires a brief summary of changes that do not affect the ISA Summary and revised ISA Summary pages without explanation for changes affecting the ISA Summary. USEC believes that NRC will benefit from a description of changes made to the ISA Summary. Accordingly, §70.72 should require brief descriptions and summary safety evaluations of each change made pursuant to §70.72 and require that an updated ISA Summary be provided on a biennial basis. More current information will be maintained available for NRC inspection at the site as required by §70.72(f). The text of proposed 10 CFR 70 has been modified accordingly in the attachment.</p>	<p>No change needed. Staff notes that the brief summaries of changes submitted under the requirements of §70.72(d)(3) would be expected to include an explanation of each change, the reasons why the change was made, and why it did not require pre-approval. The staff views this as sufficient and does not anticipate the need to submit a summary safety evaluation for each change, which the staff would view as more onerous on the licensees.</p>
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47	USEC	§70.72	<p>§70.72 adds requirements for a configuration management system and for making changes. As written, the requirements apply to <u>all</u> site, structures, processes, systems, equipment, components, computer programs and activities of personnel regardless of safety significance. Compliance with these requirements would appear to require configuration management and change control applied to everything on the site of the licensed facility. This could include the wastewater treatment facility, a laser facility, the administration building, maintenance of the shrubbery, etc. Every change would require an evaluation and a summary submitted to the NRC.</p> <p>Inclusion of items on the site that make no contribution to the NRC regulated safe operation of the facility would place an undue burden on the licensee. To remedy this, we propose that the configuration and change process be limited to any "...changes to the site, processes or items relied on for safety as described in the ISA Summary, without prior...". The text of proposed 10 CFR 70 has been modified accordingly in the attachment.</p>	<p>No changes needed. Once the licensee has established a configuration management system in accordance with §70.72(a) it is important the licensee use the system to evaluate every change made at a facility to ensure that any impacts of those changes are known. In some cases, the analysis would be trivial because no known hazards would be involved in the change. (e.g., certain changes in the administration building, or changes to shrubbery), often it is clear that there are no safety implications. In addition, every change which is assessed in the CM does not need to be submitted to NRC. §70.72(d)(3) states that only those changes to records required by §70.62(a)(2) need to be submitted. These would include changes to the process safety information, ISA documents, and management measures.</p> <p>Also see similar comments #27 and 67, and related comments #40 and 70.</p>
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48	USEC	§70.23 (a)	<p>The Statements of Consideration at 64 FR 41346 indicates that applicants for licenses to operate new facilities or new processes at existing facilities would be expected to update their ISAs based on as-built conditions and submit the results to NRC before operation. The process for uranium enrichment facilities that must comply with §70.23a would differ from this description. Uranium enrichment facilities would submit a complete license application, including an ISA summary, for construction and operation. This application would be the basis for NRC review, and culminate in issuance of a license for construction and operation. Following issuance of the license, the licensee would institute a change control pursuant to §70.72. The licensee would then be required to submit summaries of changes and ISA summary updates as required by §70.72. An inspection would verify that the facility has been constructed in accordance with the license prior to operation as required by §70.32(k). No pre-operational submittal and review of an updated ISA summary is anticipated for uranium enrichment facilities as their configuration would be controlled since issuance of the construction and operation license. No changes to 10 CFR 70 are needed to resolve this comment.</p>	No changes are needed as stated in the comment.
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49	USEC	Backfit	<p>...USEC firmly believes that deferring consideration of a backfit provision would be evading an extremely important issue... It is vital that a formal, systematic, and disciplined review of new, changed or differing positions that could backfit existing facilities be applied to increase regulatory certainty. The backfit provision provides for this systematic review...No change to the backfit language in 10 CFR 50.109 is needed to allow for qualitative analysis. There has been considerable discussion of a qualitative versus a quantitative backfit provision. NEI proposed and USEC endorses the use of the tried and true backfit language used successfully in 10 CFR 50.109. This is neither a quantitative nor a qualitative backfit provision...The Statements of Consideration state: "Without a baseline determination of risk, as provided by the initial ISA process, it is not clear how a determination of incremental risk, as needed for a backfit analysis, would be accomplished." USEC does not believe that a comprehensive risk baseline is necessary before reasoned judgements can be made on the benefits and risks of a proposed backfit...</p>	See response to comment #14 and similar comments #43, 71, and 73.
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50	NEI	§70.4	<p>NEI recommends that the term “<i>reasonable assurance</i>” be used in place of “<i>ensure</i>” in the definition of ‘<i>available and reliable to perform their function when needed</i>’ in §70.4. “<i>Ensure</i>” connotes a high degree of certainty – bordering on a guarantee – that a goal or objective will be met. In the Part 70 context, it may be interpreted to require certainty that an items relied on for safety will be available and reliable when required... NEI believes this meaning is conferred by the definition by the words “when needed” and that “<i>continuous</i>” be simply deleted. The definition should read:</p> <p>§70.4 Definitions: Available and reliable to perform their function when needed: “...<i>means that...items relied on for safety will perform their intended safety function when needed and management measures will be implemented to <u>provide reasonable assurance of compliance with the performance requirements of §70.6...</u></i>”</p> <p>For consistency in the Part 70 revisions, NEI recommends that the term “adequate assurance” in §70.64(a)(1) be replaced by “reasonable assurance.”</p>	See response to comment #32.
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51	NEI	§70.50	<p>The reporting requirements of §70.50 continue to misrepresent the principles of the 1988 NRC-OSHA Memorandum of Understanding (MOU).</p> <p>§70.50(c)(1)(iii)(A) requires the reporting of chemical hazards and §70.50(c)(1)(iii)(B) requires the reporting of personnel exposures to chemicals. Although the MOU principles have been correctly incorporated into other proposed revisions to 10 CFR 70 (e.g. §§70.4, 70.61(b), 70.62(c), 70.64(a), 70.74 Appendix A), they are incorrectly referenced in §70.50. MOU principle (2) limits NRC jurisdiction to regulation of chemical hazards of licensed material and hazardous chemicals <u>produced from licensed material</u>. The two aforementioned sections of §70.50 should be corrected to properly incorporate the MOU principles.</p>	<p>Rule was revised in response to the comment to reflect the language in the NRC-OSHA MOU.</p>
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52	NEI	§70.61	<p>§70.61(f) requires a licensee to establish a ‘controlled area’ for a facility in which it can control the activities of personnel. §70.61 states that any individual located outside of the controlled area is subject to the lower (public) radiation dose limits. NEI is concerned with the manner in which §70.61 could set radiation exposure limits for co-located workers. We are particularly concerned with the treatment of radiation exposures from an NRC-licensed facility present on a DOE site (e.g. a MOX fabrication facility on a DOE property). As currently written a worker (as defined in §70.4) who leaves the controlled area to perform a work-related function would have to be treated as a member of the public when performing the ISA and would be subject to the more stringent public radiation exposure limits. Outside of the controlled area the TEDE limit of 0.1 rem for members of the public would apply (cf. 10 CFR 20.1301(a)(1)) rather than the annual TEDE occupational dose limit of 5 rems (10 CFR 20.1201). Such a problem has arisen at the Hanford Tank Waste Remediation System-Privatization where NRC subjects ‘co-located’ workers to the appreciably lower public dose limit. NEI recommends that the NRC apply constant radiation exposure limits to all plant workers, regardless of their presence inside or outside of the controlled area. The 10 CFR 70 regulations should be harmonized with comparable DOE radiation exposure limits. NEI recommends that the phrase “...<i>any individual</i>...” in sections b(2) and c(2) be clarified to exclude facility workers who may have occasion to work outside of the controlled area. This phrase should be amended to read “...<i>any individual (other than a worker)</i>...”</p>	<p>This comment appears to be related to comments #1, 7 and #19. NRC regulations do not address personnel designated as “co-located” workers. With regard to the concern related to the worker who leaves the controlled area, the risk levels of §70.61 for the public pertain to <u>any</u> individual outside the controlled area. As noted in the response to comment #7, the controlled area can be defined broadly by the licensee under certain circumstances.</p> <p>Note that a worker can receive an occupational dose (and be subject to Part 20 occupational limit of 5rem/yr TEDE) regardless of his location - including activities outside the controlled area. The “assigned duties performed in the course of employment” is the distinguishing factor for radiation workers. The changes of Part 70, including the worker definition, do not affect this. In this comment, the relationship between Part 20 annual limits for radiation exposure and the §70.61 standards for a forward-looking severe accident assessment have been misinterpreted. Part 70 revisions do not limit doses outside a controlled area to 0.1 rem/yr.</p> <p>See similar comments #1, 7, and 19.</p>
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53	NEI	§70.62	<p>There is inconsistent use of the term “safety program” throughout the proposed revisions. For example, sometimes the rule implies that the ISA Summary is part of the safety program (it is not), and thereby part of the license. The explanatory notes in the <u>Federal Register</u> also erroneously describe the safety program; for example, on page 41346, it (correctly) states that the ISA comprises one component of the safety program, but then (erroneously) states that the results of the ISA must be submitted for NRC approval. This is inconsistent with our understanding developed during the NRC workshops and clearly not consistent with the direction given by the Commission in the Staff Requirements memorandum dated December 1, 1998. §70.62(a)(1) defines the licensee’s safety program to consist of three components (process safety information, ISA, management measures). This definition is too narrow. The safety program includes these important components, but also includes the commitments and programs addressed in the eleven chapters of the Standard Review Plan (e.g. radiation protection, compliance with 10 CFR 20 occupational radiation exposure limits, etc.). In this regard, NEI recommends that the last sentence in §70.62((a)(1) be deleted. The content of §70.22 adequately defines the requirements for a licensee safety program.</p>	<p>The term “safety program” as used in §70.62 (a) is related to the elements to demonstrate compliance with the performance requirements in §70.61. There is no intent to indicate that these elements represent the total safety program at the facility. Rule language was clarified by changing “The three elements of the safety program...” to “Three elements of this safety program...” See similar comments in #31, 33, 37, and 45.</p> <p>With regard to the comment that the SOC erroneously “states that the results of the ISA must be submitted for approval”, the assertion that the SOC is erroneous is incorrect - the SOC is accurate. In response to this comment, and in response to comments #20, 29, and 31, and to clarify the role of the ISA summary in licensing determinations, changes have been made to §70.62(c)(3)(ii) and §70.66. In particular, §70.62(c)(3)(ii) has been modified to specifically state that the ISA summary is submitted for approval consistent with the SOC for the proposed rule, and §70.66 states that this submission will be approved if the Commission determines that “the applicant has complied with the requirements of Sec. 70.21, Sec. 70.22, Sec. 70.23 and Sec. 70.60 through Sec. 70.65”.</p>
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53 Cont				<p>The degree of detail provided in the ISA summary, together with the other information available to NRC staff, must be sufficient for the staff to make the determination specified in §70.66.</p> <p>See related comments #31, 33, 37, and 45.</p>
54	NEI	§70.62	<p>The regulatory reporting requirements of §70.62(a)(2) and §70.74(a)(1) direct a licensee to report to NRC Headquarters <u>within one to twenty-four hours</u> instances in which an item relied on for safety or management measure has failed or been discovered to be non-operational. The NRC will, therefore, already possess all of the information sought in the “log” of §70.62(a)(3). Tabulating data that the NRC already possesses and has presumably internally analyzed, seems to be a wasteful and inefficient use of licensee and NRC resources that should be focused exclusively on safety-significant issues. This is an unnecessarily prescriptive requirement.</p> <p>NEI, therefore, recommends that §70.62(a)(3) be deleted from the rule.</p>	<p>With respect to the redundancy of reporting, the rule currently requires the licensee to report only the loss or degradation of IROFS that results in failure to meet the performance requirements of §70.61. The requirements of §70.62(a)(3) includes a much broader set of items, that is all IROFS or management measures that have failed to perform its function.</p> <p>With regard to the concern of the prescriptiveness of the requirement, the rule language has been modified. See response to comment #26 and related comments #34, and 80.</p>

55	NEI	§70.62	<p>NEI has two comments with the timing requirements specified in §70.62(c)(3) for completion of an ISA by existing licensees:</p> <p>for consistency the phrase “...<i>[the date of publication of the final rule]</i>” in the first sentence should be replaced by “...<i>the effective date of the rule...</i>” as has been done in subsections (i), (ii) and (iii)...</p>	<p>Agree. Modification to rule language was made to clarify the relationship between §70.62(c)(3) and the subparagraphs of §70.62(c)(3).</p> <p>See similar comments #36 and 72.</p>
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56	NEI	§70.62	<p>...the 4-year period for conducting the ISA and for modifying the plant to address any identified unacceptable performance deficiencies may be too short. Also, we recommend that the period should start on the date on which the NRC approves the plan required in subsection 3(i). If the clock starts on the effective date of the rule and the NRC takes one year to approve the ISA plan, the licensee will be unduly hampered. There should be some incentive for the NRC to complete its approval process in a timely manner. NEI is also concerned over the limited time available for a licensee to not only conduct the ISA, but also to implement any modification to the facility as is required by §70.62(c)(3)(iii). Based on the fact that licensees who have already committed to perform ISAs were generally given five years to complete them, NEI recommends that an existing licensee be granted 5 years to complete the ISA. We also recommend that appropriate and sufficient time be allowed for the licensee to present to the NRC and to implement a plan to correct any identified unacceptable performance deficiencies.</p>	<p>With respect to changing the rule language from 4 years to 5 years for conducting the ISA and correcting all unacceptable performance deficiencies, no changes needed. The 4 year time period is reasonable to complete the ISA and most resulting modifications. However, the staff recognizes that there may be some instances where modifications resulting from the ISA cannot be completed within the 4 years specified and has modified 70.62(c)(3)(ii) to accommodate these instances. With respect to the licensee being unduly hampered because of the time required for the staff to approve the plan required by 70.62(c)(3)(i), the staff expects to complete the licensing review within 90 days, assuming that the information submitted is complete. However, the time it takes NRC to approve the plan will depend on the quality and completeness of the plan which is under the control of the licensee.</p> <p>See similar comment #57 regarding the plan.</p> <p>In addition, current industry development of an ISA summary guidance document should facilitate the licensing process.</p>
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57	NEI		Finally, we recommend imposition of a 90-day time frame on the NRC to issue a decision on the acceptability of a licensee's ISA approach. NEI recommends that subsection (ii) be re-written to read: "... (ii) Within 5 years of the date of NRC approval of the licensee's plan, complete an ..."	No change needed. The staff expects to complete the licensing review within 90 days, assuming that the information submitted is complete. See related comment #56.
58	NEI	§70.62 (d)	For consistency with the language in §70.62(a) (... <i>"the safety program may be graded such that management measures applied are commensurate with the reduction of risk attributable to that item..."</i>), NEI recommends that the second sentence in §70.62(d) be revised to include the term "graded." This sentence would then read: "... <i>The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system.</i> "	Agree. See response to comment #8.
59	NEI	§70.64	NEI recommends that §70.64(a)(6)(ii) be written as: "... <i>Evacuation of on-site personnel; and...</i> "	Agree. This change has been made; it is consistent with the original intent.

60	NEI	§70.64	<p>NEI recommends that baseline design criterion (8) be rewritten as follows:</p> <p><i>“...the design of items relied on for safety must provide for adequate inspection, testing, and maintenance, <u>or adequate training, testing and qualification for personnel whose activities relied on for safety</u>, to ensure their availability and reliability to perform their function when needed</i></p>	<p>No change needed. The baseline design criteria are applied from the outset of new design work, and are primarily focused at physical design and facility features. The intent is to achieve a conservatively designed facility that is tolerant to upsets and human errors. Adequate training, testing, and qualification, as noted in the comment, will be required as management measures under §70.62, but NRC does not see a need for the facility physical <i>design</i> to incorporate such training, testing, and qualification of personnel.</p>
61	NEI	§70.64	<p>Consistent with the ability granted a licensee to grade all aspects of its safety program (cf. §70.62(a)), grading of the defense-in-depth safety concepts in the design of the facility should also be permitted. Safety design criterion (b)(1) appears unnecessarily prescriptive by discouraging a licensee from using anything but an engineered safety control. So long as the licensee can satisfactorily demonstrate that an administrative safety control or a system of administrative and engineered controls will enable the performance criteria to be satisfied, the choice of items relied on for safety and the nature of ‘defense-in-depth’ practices that is applied should be flexible.</p>	<p>Agree. See response to comment #10.</p>

62	NEI	§70.65	<p>The rule should not prescribe an acceptable level of detail, but should defer this issue to be developed in the SRP. Use of terms such as “...<i>types of accident sequences</i>...” rather than detailed description of each accident sequence in §70.65(b)(3) is commended. However, in §70.65(b)(6) the required level of descriptive detail for items relied on for safety (“...<i>sufficient detail</i>...”) remains vague. NEI recommends that information at the ‘systems level’ should be required, rather than at the ‘component’ or ‘sub-component’ level.</p>	<p>No change needed. The current language permits the description of information at a systems level provided that there is enough detail to understand the function in relation to the performance requirements. The degree of detail provided in the ISA summary, together with the other information available, must be sufficient for the staff to make the determination specified in §70.66.</p> <p>See related comments #30, 38, 64, 65, and 68.</p>
63	NEI	§70.65	<p>Thus, NEI believes the §70.65(b)(7) requirement for information on the locations of on-site chemicals is unnecessary.</p>	<p>No change necessary. §70.65(b)(7) does not require information on the locations of onsite chemicals to be submitted to NRC. It requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed material.</p>
64	NEI	§70.65	<p>§70.65(b)(3) seeks information on <u>each</u> process analyzed in the ISA including the hazards identified for each...The ISA Summary should, consequently, only address those processes for which accident sequences have been identified that would produce consequences that exceed the performance criteria of §70.61.</p>	<p>No changes needed. See response to comment #30. The degree of detail provided in the ISA summary, together with the other information available, must be sufficient for the staff to make the determination specified in §70.66.</p> <p>See related comments #30, 38, 62, 65, and 68.</p>

65	NEI	§70.65	<p>§70.65(b)(6) requires the applicant to list all items relied on for safety for high- and intermediate-consequence events and any other accident sequences for which the licensee has defined items relied on for safety. This is far too broad a requirement. The items should only need to be described at the systems level, rather than at the component or sub-component level.</p>	<p>No change needed. See response to comment # 62. The degree of detail provided in the ISA summary, together with the other information available, must be sufficient for the staff to make the determination specified in §70.66.</p> <p>See related comments #30, 38, 62, 64, and 68.</p>
66	NEI	§70.65	<p>While this list will include “...<i>activities of personnel relied on for safety</i>...” it should not include procedures that the personnel must follow. As procedures are constantly being adjusted, revised and improved, their inclusion in the list of items relied on for safety would necessitate frequent revisions to the ISA Summary that may have little if any safety significance.</p>	<p>No change needed. §70.65(b)(6) requires a list briefly describing each item to be in the ISA summary. It does not require measures (procedures) to be listed in the ISA summary. Therefore, the rule language permits the approach described in the comment. The typical approach would be that the <i>item relied on for safety</i> is the actual <i>personnel action</i>; and that the procedures, behind this action are <i>management measures</i> that apply to that item.</p> <p>See related comment #18.</p>

67	NEI	§70.72	<p>§70.72(a) requires that <u>any change</u> to the facility be formally evaluated by means of the configuration management (CM) system to evaluate, among other things, its potential impact on safety and the need to modify the ISA and ISA Summary. This requirement is too broad and all-encompassing and would require CM evaluation of changes having no or absolutely minimal effect on health and safety (e.g. office remodeling, planting of shrubbery, changing paint colors). Rather than to first evaluate every change by means of CM, the licensee should first rely on internal procedures to initially screen any proposed changes for their potential adverse safety impacts.</p>	<p>No change needed. As noted in response to comment #47, in some cases the analysis would be trivial because no known hazards would be involved in the change. This is consistent with the view expressed in this comment that “the licensee should first rely on internal procedures to initially screen any proposed changes for their potential adverse safety impacts.”</p> <p>See similar comments #27, and 47 and related comments #40 and 70.</p>
68	NEI	§70.72	<p>However, the footnote appended to “<i>new types of accidents</i>” is contrary to the stated goal of limiting requests for license amendments to those that are safety significant. The footnote’s reference to accident initiators, changes in consequences and changes in the safety function of a control could be literally interpreted to require essentially <u>any change</u> to the facility to require NRC pre-approval and a license amendment. NEI strongly recommends that the footnote be deleted for consistency with the intent of 10 CFR 70.72.</p>	<p>Agree. See response to comment #38.</p> <p>See related comments #30, 38, 62, 64 and 65.</p>

69	NEI	§70.72	...For consistency with the Facility Change Mechanism reporting requirements (§70.72 (d)(3)), NEI recommends that all changes be reported annually to NRC headquarters...;	See response to comment #13, and similar comments#28, 39, 76, and 86.
70	NEI	§70.72 (d)(3)	The wording of this section will inadvertently and significantly expand the information that would have to be reported. 70.62(a)(2) requires records not only related to ISA and ISA summary, but also pertaining to process safety information and management measures. 70.72 (d) would therefore require the licensees to submit voluminous information that could include the update to process safety information including drawings, flow process diagrams, piping and instrumentations.... This section should be reworded to read: “... <i>a brief summary of all changes to the integrated safety analysis and ISA Summary, that are made without prior Commission approval, must be submitted to the NRC every 12 months...</i> ”	No changes needed. See response to comment #40, and related comments #27, 47, and 67.
71	NEI	Backfit	In summary, NEI recommends that: (i) backfit language be included as part of the proposed 10 CFR 70 revisions, and (ii) the backfit provision be immediately effective to those processes or parts of an existing facility for which the ISA has been completed..	See response to comment #14.

72	NEI		The proposed revisions to 10 CFR 70 should have an implementation provision similar to that presented in 10 CFR 20.1008. NEI believes that such an implementation provision should be included in the Part 70 revisions to address potential conflicts between existing license conditions and the new Part 70 requirements. We believe this additional provision is necessary, especially in light of license conditions modeled after proposed Part 70 revisions that have added to licenses recently renewed by the NRC.	See response to comment #36, and related comment #55.
73	GE	Backfit	GE believes that the backfit provisions should be immediately effective for the new rule. The Commission has granted this to virtually all facilities – with the exception of the fuel fabricators.	See response to comment #14
74	GE		As GE understands the proposed rule, it describes a situation wherein the current terms of the MOU between NRC and OSHA are incorporated into the regulations to avoid misunderstanding. This should result in more effective implementation for all concerned parties. GE supports the proposed rule in this respect.	No change needed.
75	GE		GE believes that the current proposed rule offers sufficient flexibility in selecting ISA methodology so that a broad spectrum of facilities can be addressed and such that licensees have flexibility to interface with their site processes, procedures and resources.	No change needed.

76	GE	§70.72	<p>GE believes that the 90 day reporting of changes is entirely too frequent. It would mean that the facility and the NRC would always have change reporting in progress. There is no need to have such real time knowledge. It is important that the licensee has real time knowledge. The NRC only needs reasonably current knowledge, as the current is available and accessible to them at the site.</p> <p>GE believes that the 12-month to 24 months as used in other places is satisfactory and is more efficient. This seems clearly justified based on the fact that all the information is available at the site and accessible to the NRC at any time.</p>	<p>See response to comment #13.</p> <p>With regard to the concern that there would always be a change reporting in progress, the specification of a quarterly report rather than a 90-day report in the revised language addresses this concern.</p> <p>See similar comments #28, 39, 69, 86.</p>
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77	GE	Living License	<p>GE is also concerned that there has not been more consideration of extended license term along with the discussions of the timing of updates. One of the largest problems the NRC has experienced is the load of license renewals. A large part of this is the fact that facilities are required to completely resubmit their license application and re-demonstrate the safety of the plant even though it is operating and approved by the NRC. This is a highly inefficient process for both the NRC and the licensee.</p> <p>An alternate that needs to be considered in association with this proposed revision to 10 CFR 70 is a more permanent license. With updates every 12 months for example there is no real need for the NRC to renew the license – it only becomes a maintenance chore to periodically see that all the information is there and acceptable. The NRC has periodically referred to this as a “living license”. GE believes that the living license concept provides advantages for the NRC and the licensee.</p>	See response to comment #41.
78	GE	§70.4	<p><i>Critical mass of special nuclear material (SNM) means</i> This definition uses 4 percent by weight of uranium-235 as one of the benchmarks. Since most of the LWR fuel manufacturing now operates at enrichments, the rule would be better served to be updated and use 5 percent by weight of uranium-235.</p>	The definition <i>critical mass of SNM</i> in Part 70 is solely used to determine when Subpart H applies. It was defined to be consistent with §70.24 regarding criticality alarms. The 4 percent is consistent with the quantities stated in §70.24.

79	GE	§70.4	<p>Regarding “items relied on for safety,” with the definition presented, a better choice would be to use the term “measures relied on for safety”. Additionally, where “items relied on for safety” is used in the rule it should be changed to “measures relied on for safety”.</p>	<p>No change. The reason for the comment is not clear, but perhaps the comment objects to the use of the term ‘item’ to refer to a personnel action.</p> <p>See related NEI comment #66.</p> <p>Part 70 does allow human actions to be items relied on for safety, and permits flexibility in selection of how the <i>items</i> and <i>measures</i> are defined.</p> <p>See similar comments #83, 85, and 88.</p>
80	GE	§70.62 (3)	<p>70.62(3) Identifies a log to be maintained. GE believes that it is inappropriate to add this extra record-keeping burden on the licensee, because the licensee already has to generate records of this nature to manage their business and some different log is unnecessary work.</p> <p>The wording should be changed from “Each licensee shall establish and maintain a log, available for NRC inspection, documenting each discovery . . .” to “Records shall be established and maintained by the licensee, and available for NRC inspection, documenting . . .”.</p> <p>The other places the “log” is mentioned needs to be changed to “records”.</p>	<p>Agree. See response to comment #26, and similar comments #33, and 54.</p>

81	GE	§70.65 (b)	70.65(b) is written to represent the ISA summary to be a single document. In practice it will be a sequence of documents that cover the facility. All should be in the same format, but it should be clear that it is not a single summary – but of course in some cases, it could be.	No change needed.
82	GE	§70.65 (b)	70.65(b)(3) defines a process description as a requirement. In actual process, the process may well be broken down differently. The AIChE guidelines give guidance about the requirements for applying the hazard analysis techniques to the process being studied. So specifying here it should be the segment or node, and several of these could be combined and called a process if and only if the boundaries established for the hazard analysis match.	Agree. No change needed. The intent of the §70.65(b)(3) requirement is to provide process information so that the staff can understand: (1) what activities are performed at the site that involve hazardous materials, including any use, storage, manufacturing, or handling of those materials; (2) what was analyzed in the ISA; and (3) the hazards identified in the ISA. The AIChE guidelines use the term “process nodes” with respect to HAZOP analyses and define it as “sections of equipment with definite boundaries...within which process parameters are investigated for deviations...” In HAZOP analyses, the term “node” designates a pipeline or vessel that has a common design intent. In meeting the §70.65(b)(3) requirement, several nodes may be combined.
83	GE	§70.65 (b)	70.65(b)(6) requires a brief list describing all items relied on for safety. See GE’s comments under 70.4 Definitions. To be clear, this should read “measures relied on for safety”.	No change needed. See response to comment #79.

84	GE	§70.72	<p>70.72(c)(1)(i), (c)(2), and (c)(3) use the term of ISA summary as the decision making document for change and change process. It is incorrect to use the ISA Summary in this manner.</p> <p>The ISA, which is the detailed licensee generated document that the licensee uses to manage their program, is the reference document. Summaries are just that – to provide a general level of information about the more important elements of the safety system for operations as determined in accord with the licensed program.</p>	<p>No change needed. Although the root document of the ISA summary is the ISA, the ISA summary is to contain key information that is directly related to facility safety such as a list of items relied on for safety, a description of hazards identified in the ISA, general description of the types of accident sequences. The staff could base the change process decision on the ISA instead of the ISA summary but would be an unnecessary burden for the licensee.</p> <p>See related comment #53.</p>
85	GE	§70.72	<p>§70.72(c)(2) and (c)(3) use the term of “item relied on for safety”. This is in error and should read “measure relied on for safety”.</p>	<p>No change needed. See response to comment #79.</p>
86	GE	§70.72	<p>§70.72(d)(1) uses 90 days for making reports of the change. This is discussed elsewhere and should be of a frequency of 12 – 24 months.</p>	<p>See response to comment #13, and similar comments #28, 39, 69, 76, and 86.</p>
87	GE	§70.73	<p>Since the NRC is considering mandatory reporting of changes to the license making a living license for the facility, it is appropriate for this section to eliminate the requirement for renewal since it is not necessary.</p>	<p>See response to comment #41, and similar comment #77.</p>

88	GE	App A	<p>(a)(4) Needs to be looked at by the NRC in view of the need to change “items relied on for safety” and change “ISA summary” to “measures relied on for safety” and “ISA”.</p> <p>The most appropriate wording here would seem to be “measures relied on for safety as described in the ISA summary”.</p>	No change needed. See response to comment #79.
89	EPA		EPA agrees with the Commission that the proposed rule is entirely consistent with EPA's RMP regulations and the general duty clause of the Clean Air Act, and contains appropriate complementary safety measures for facilities possessing a critical mass of special nuclear material.	No change needed.
90	NFPA		<p>NFPA strongly recommends the NRC adopt by reference the 1998 edition of NFPA 801, Facilities Handling Radioactive Materials. NFPA 801 would apply to Section 70.62, Safety Program and Integrated Safety Analysis, which addresses protection from all relevant hazards, including radiological, criticality, fire and chemical. The NFPA standard would also apply to Section 70.64, Requirements for New Facilities or New Processes at Existing Facilities, which addresses fire protection.</p> <p>Reference of NFPA 801 is in keeping with the requirements of Public Law 104-113 “<i>National Technology Transfer and Advancement Act</i>” which requires Federal government agencies to use private sector-developed national consensus technical standards in carrying out public policy wherever appropriate.</p>	No changes needed. The suggested change would result in an unnecessarily prescriptive rule requirement. However, the SRP refers to NFPA 801 and 600 as acceptable standards.

91	Siemens		Siemens Power Corporation (SPC) has participated with the Nuclear Energy Institute's (NEI's) Facility Operations Steering Committee in a review of the subject proposed rule. SPC agrees with the comments forwarded by NEI on behalf of the industry in its October 13, 1999 letter.	See responses to NEI comments #50 through 72.
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