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July 3, 1997

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Subject: Comments on Draft Report NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)"

CNRO-97/00016

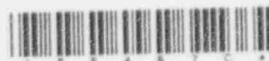
Gentlemen:

Entergy Operations, Inc. appreciates the opportunity to comment on Draft NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)." Specific comments are provided in Attachment 1. Attachment 2 contains our perspective regarding potential impact of NUREG-1606 on plant operations including specific examples involving unnecessary licensee burden. Entergy also endorses the comments submitted to the NRC by the Nuclear Energy Institute (NEI), the Nuclear Utility Backfitting and Reform Group (NUBARG), and the Licensing and Design Bases Clearinghouse.

In many respects, large portions of the NRC discussion regarding 10CFR50.59 parallels the thought process currently used throughout the nuclear industry. Also, it serves to endorse processes and practices which are consistent with established industry guidance found in NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations." Industry development of NSAC-125 and its widespread acceptance as guidelines for utility §50.59 processes demonstrates general industry commitment to high quality §50.59 programs. Entergy is pleased to see that much of the NRC thinking presented in NUREG-1606 parallels that of NSAC-125.

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Even though never officially endorsed, NSAC-125 guidance has been generally found acceptable for industry use by the NRC. Regional inspection acceptability of §50.59 processes and programs has often been based on NSAC-125.

As stated in the December 16, 1995, memo from the Executive Director of Operations to Chairman Shirley Jackson, the current process as it is being implemented provides reasonable assurance that plant safety has not been decreased. Also, there is currently no indication that implementation of §50.59, as it is carried out today, has led to decreased safety based upon NRC's inspection experience.

As the NRC acknowledges in NUREG-1606, just because a change involves an unreviewed safety question (USQ) does not necessarily mean the change is not safe. Under the proposed guidelines, a change which results in large increases in overall reactor safety may still result in a USQ if there is a negligible increase in probability or consequences for the change. In pursuing additional regulatory guidance or rulemaking in the 10CFR50.59 regime, the NRC should understand and appreciate that concluding a change involves a USQ may be a disincentive for a utility to pursue the change. This situation occurs because of the schedule impact involved in requiring review and approval by the NRC and the burden applied by 10CFR50.90 amendment application for approval of a USQ. Thus, the trend toward longer NRC review times for submittals, complicated by the increased number of submittals under the proposed guidance, could be counterproductive to reactor safety.

In addition to the discussion above, Entergy would like to identify several key points of concern:

- Judgment - We do not believe the regulatory process can be so clearly defined as to address all situations that a licensee or the NRC will encounter. The current §50.59 safety evaluation process relies on the effective use of management and engineering judgment in applying the regulations. Therefore, limiting the use of licensee judgment should be approached judiciously. However, NUREG-1606 appears to impose such limits.
- Malfunctions - The NRC position treats different causes of a failure as a malfunction of a different type. This position diverts focus of a safety evaluation from the effects of the malfunction, imposes a level of detail beyond the intent of §50.59, and represents a new regulatory position.

- Probability - By defining any increase in probability as a USQ, the NRC has established a requirement which will force changes which result in negligible increase in probability (i.e., no discernible or measurable increase) into the license amendment process with little or no added safety benefit. This approach is inconsistent with the comments provided by the NRC¹.
- Consequences - The NRC position states any increase in consequences, even if the overall consequences are well below acceptance limits, results in a USQ. This position is inconsistent with established regulatory and industry practices and precedent. As above, this approach is also inconsistent with the comments provided by the NRC².
- Margin of Safety - The acceptance limit for determining a margin of safety as currently defined by the NRC is overly restrictive and will result in unnecessary USQs that would be a burden on both the NRC and the industry. In addition, the scope of the documents to be reviewed is more conservative than established by the §50.59 regulations.
- FSAR Issues - The inability of licensees to remove extraneous or obsolete information from the FSAR without a §50.59 evaluation is burdensome with no safety benefit. Requiring §50.59 safety evaluations for these types of minor changes would divert resources that could be applied in other ways that would have a greater positive impact on plant safety. We appreciate the NRC's willingness to develop a process for removing extraneous information from the SAR as discussed in the Staff Requirements Memorandum (SRM), "Staff Requirements - SECY-97-036 - Millstone Lessons Learned Report, Part 2: Policy Issues," dated May 20, 1997.
- Prohibiting Plant Start-up with a USQ - Prohibiting a plant from restarting with a degraded condition involving a USQ should not be imposed unless the action is prohibited by technical specifications (TS) or involves an operability concern. The existence of a USQ does not mean that a safety issue exists, but only that NRC review is required prior to implementing the change. This action is overly restrictive and will likely involve increased outage time and expense with no safety benefit.

Entergy believes the above positions by the NRC staff are counterproductive to the overall safety and effective use of licensee and

¹ Letter dated May 10, 1989, from Mr. Charles E. Rossi, Division of Operational Events, NRR, to Mr. Thomas E. Tipton, Operations, Management, and Support Services Division, NUMARC

² Ibid.

NRC resources. The additional USQs generated based on the guidance presented in NUREG-1606 could result in a substantial increase in the number of license amendment requests per cycle per site. This additional burden on both the NRC and licensees to prepare, submit, and gain approval of license amendments may be so overwhelming that safety-significant issues could be impacted due to re-focusing of resources onto USQs that have no safety benefit.

As you are aware, the industry is working on improving the guidance provided in NSAC-125 via NEI 96-07, "Guidelines for 10CFR50.59 Safety Evaluations," which is currently in draft form. Entergy believes the approach historically taken by the industry as presented in NSAC-125 and subsequent improvements being proposed in NEI 96-07 are within current rule considerations. As such, rulemaking is not necessary. This position is substantiated in the Analysis of Industry Guidance being provided in the NEI NUREG-1606 comment package.

Based on reviews of available documentation, it appears the vast majority of the NRC Staff's comments on NSAC-125 made in 1989 were incorporated into the NSAC. It also appears the NRC has rethought their positions and are no longer accepting the industry guidance. It is not clear why the change in several key issues exists. If the NRC Staff and legal counsel conclude the rule cannot support the approaches taken by NSAC-125 and NEI-96-07, further rulemaking is required. Even if rulemaking is determined to be the long-term means to improve the process for identifying when NRC review is necessary, the current guidance provided by NEI 96-07 should be used until rulemaking is approved. Further, any rulemaking should fully utilize and account for risk-informed processes in proposing any revisions to §50.59. Approaches which allow for implementing non-risk significant USQs without prior NRC approval would be, in our opinion, in the best interest of licensees, NRC, and, through improved focus on nuclear safety, the public.

Typically, several hundred individuals are trained and qualified at each site to conduct §50.59 reviews. Significant changes to current programs for little to no safety benefit would not be in the best interests of either the NRC or the industry. Entergy estimates implementing the NUREG guidelines would result in an average increase of 20 USQs/unit while providing little or no safety benefit.

In addition to the comments regarding NUREG-1606, Entergy is concerned many of the actions contained in SECY-97-036, "Millstone Lessons

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Learned, Part 2," are not justified and are unwarranted. We recognize that improvements may be needed for managing commitments; however, Entergy believes wholesale changes to licensing basis documents and increases in scope are not appropriate. The issue of expanding the SAR and current licensing basis has been considered previously by the NRC and found unnecessary³. Findings from Millstone and other related inspections have not, in our opinion, provided a basis that would change this position. Any actions taken as a result of the May 20, 1997, SRM should be considered for backfit under 10CFR50.109. As a minimum, actions taken that may not involve a backfit should be discussed with the industry prior to implementation.

The industry, as well as Entergy, is willing to work with the NRC to further revise NEI 96-07 to improve and enhance the 50.59 process. We would suggest that more effective use of resources may be gained if the NRC and the industry work together to address the issues raised in NUREG-1606 with the goal to be an NRC endorsed document.

Again, thank you for the opportunity to provide our comments.

Sincerely,


for JGD/SJB/GHD/baa
attachment

cc: (see next page)

³ SECY-92-314, "Current Licensing Basis for Operating Plants," dated September 10, 1992
SECY-94-066, "Evaluation of Issues Discussed in SECY-92-314, 'Current Licensing Basis for Operating Plants,'" dated March 15, 1994
SECY-95-300, "NEI's 'Guidelines for Managing NRC Commitments,' Rev 2, December 19, 1995," dated January 24, 1996

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COMMENTS ON NUREG-1606

No.	Description	Section, Page Paragraph	Comments/Basis
III.A	Definition of Change	<p data-bbox="560 431 748 495">III.A.2 p. 5 / 1st para.</p> <p data-bbox="560 597 748 661">III.A.4 p. 5 / 2nd para.</p> <p data-bbox="560 921 748 985">III.A.4 p. 5 / 2nd para.</p>	<ol style="list-style-type: none"> <li data-bbox="797 431 1463 559">1. The word "identical" should be changed to "functionally identical". A change to a component that does not change any design characteristics should not require a 50.59 review. <li data-bbox="797 597 1463 885">2. Maintenance activities, in themselves, should not require 50.59 reviews. The NUREG concerns are properly addressed through plant on-line maintenance programs, 10CFR50 Appendix B programs, and the Maintenance Rule (§50.65). The 1984 version of the NRC's I&E Manual 9800 provides a good definition of "maintenance activities". Maintenance activities return the plant to its original design requirements. <li data-bbox="797 921 1463 1144">3. Removing a SSC from service even if it is not discussed in the TS should not require a 50.59 review since the overall system operability is still reviewed by the SRO. The NUREG guidance would likely require that Job/Work Orders be reviewed under 50.59 which would result in massive additional burden and provide no safety benefit. <p data-bbox="846 1176 1463 1698">A licensee needs to ensure that removing equipment from service does not invalidate licensing and design bases. If the actions to change a procedure that allows equipment to be out of service that has not been previously evaluated, then a 50.59 review is required. It is excessive to perform 50.59 reviews for SSCs removed from service which are not addressed by TS LCOs. Allowance for routine maintenance should be an inherent assumption in the design of any plant. The draft guidance would paradoxically make it less burdensome to take TS equipment out of service under an LCO than to take non-TS equipment, which should have a lower inherent safety significance, out of service. However, the NRC's concern on overturning design basis by maintenance activities is founded.</p> <p data-bbox="846 1730 1463 1919">The NUREG-1606 concerns for maintenance activities are properly addressed through plant on-line maintenance programs, which for Entergy include risk screenings (using PSA tools) and account for operator experience and engineering judgment through the maintenance scheduling</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		<p>III.A.4 p. 5 / 3rd para.</p>	<p>process, which functions similar to an expert panel. In general, maintenance which simply temporarily removes a piece of equipment from service without impacting the operation of any other system is not a change to the plant. Such Maintenance should be addressed under other programs (e.g., the 10CFR50.65 Maintenance Rule) instead of 10CFR50.59. Additional restrictions through the 50.59 process would add burden with no enhancement to plant safety.</p> <p>4. Implicit changes will be reviewed as long as the potentially impacted SSC is explicitly discussed and not a general review conducted.</p>
III.D	Definition of Test or Experiment	<p>III.D.3 p. 8</p> <p>III.D.4 p. 8</p>	<p>1. The NRC is in error with regards to the statement that neither NSAC 125 nor NEI 96-07 provides any guidance on defining tests and experiments. Specific discussion as to what is considered tests and experiments are found in these documents.</p> <p>2. Definitions of "test or experiment" should note that it is a special procedure where plant systems are operated different from or in conflict with the description of system operations in the SAR. The reference to a "special procedure for a particular purpose or an evolution performed to gather data" in the NUREG is vague and does not account for the fact that the need for a 50.59 safety evaluation is associated with how the equipment and/or plant is operated rather than the data which is being obtained during such operations.</p>
III.E	Definition of "as described"	<p>III.E.2 p. 9</p> <p>III.E.4 p. 9</p>	<p>1. The word "evaluated" should be "reviewed". It may not require an evaluation.</p> <p>2. There are areas within the FSAR, if changed, that will obviously not impact the safety analyses or NRC conclusions. This may include clarifications, editorial changes, tag number changes, etc. Special exceptions for such information should be provided for in the NUREG.</p>
III.F	Definition of FSAR	III.F.4 pp. 10 - 12	<p>1. NUREG-1606 is unclear on whether references in the FSAR (e.g., topical reports) are considered as FSAR information and subject to §50.59. In our opinion, the scope of the SAR includes its text, tables, figures and drawings, as well as supplemental information</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		<p>III.F.4 pp. 10 - 11</p>	<p>specifically incorporated by reference (the SAR includes documents that are referenced as part of the description, but not documents merely listed as references).</p> <p>Additional guidance should be provided on the information in the SAR which is outside the scope of §50.59, e.g., similar to the area population data given as an example in the NUREG.</p> <p>2. The NRC should define cases where updates to the SAR are expected; i.e., this should be explicitly called out in NRC Generic Letters or Bulletins requesting the licensee to perform analyses.</p>
III.H	Definition of Accident Previously Evaluated	<p>III.H.4 p. 13 / 1st para.</p> <p>III.H.4 p. 14 / 2nd para.</p>	<p>1. The NUREG considers all events evaluated in the FSAR beyond the Chapter 15 accidents to be "accidents". Only accidents of the type contained in Chapters 6 and 15 are considered accidents that would be addressed under USQ questions pertaining to probability, consequences, and accidents of a different type. Other events are considered malfunctions of equipment to be evaluated under the questions regarding malfunctions of equipment. Recognizing that the same conclusion would be reached, it would be reached under a more accurate definition and a more appropriate application.</p> <p>2. No enforcement actions should be imposed upon Licensees for not having previously included new analyses based upon Commission request. This is an action being considered in SECY-97-036, "Millstone Lessons Learned, Part 2."</p>
III.I	Malfunction of equipment is of a different type	<p>III.I.4 p. 15 / 1st para.</p> <p>III.I.4 p. 15 / 4th, 5th, 6th para.</p>	<p>1. The expanded definition of "malfunction" is unnecessary. The concern addressed by the definition is prevented by good engineering practice.</p> <p>2. The NRC requests that licensees also evaluate the potential "cause of a malfunction as a condition that would be a USQ, this could substantially expand the actions that would require NRC review. If the new component functions differently but results in the same probability or consequences then this would be a USQ. The determination as to whether a USQ exists is whether a different "type" of malfunction exists or not. The concern is whether a</p>

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			<p>component's potential failure can propagate to other systems or components. In addition, postulated, non-mechanistic failures of non-safety as well as safety-related equipment are typically assumed in SAR analyses. Exact failure modes are typically unknown and detailed failure information is not important to safety. These modes should not be addressed unless specifically addressed in the SAR. This is consistent with the definition of design basis under §50.2 which <u>defines</u> a safety function as opposed to <u>how</u> the function is performed.</p> <p>Entergy disagrees with the NRC approach to categorically treat different causes of failure as a failure of a different type than that evaluated in the SAR. This does not provide a reasonable regulatory basis for the definition. Equipment malfunctions should be treated based upon the effects of the malfunction, given that probability or consequences of the malfunction do not increase. NSAC-125 takes a proper and reasonable approach to this subject.</p> <p>The proposed regulatory guidance is also counter to the increased NRC interest in Performance Based Regulation. The overall results and performance of the equipment must be assessed; if a different failure mode results in no different failure impacts to the rest of the plant, then there is no change in the performance of the equipment in question, or upon any other SSC influenced by the subject equipment.</p> <p>The non-NSAC-125 example provided by the NRC is a particularly weak example. If a pressure transmitter fails, what is of interest is if that pressure transmitter can fail in a manner that propagates to other systems in a new or different way, rather than merely the mode of failure. However, if there are no different effects on other equipment and the failure does not influence plant response and does not influence the response of any SSC important to safety, it is improper to categorize this as a failure of a different type than that described in the SAR.</p>
III.J	Modifications associated with TS	III.J p. 16	Entergy agrees that any "proposed" modification associated with a TS should receive a license amendment. However, it should be clear compensatory actions (e.g., increased administrative controls) associated with finding a TS not conservative is allowed.

No.	Description	Section, Page/Paragraph	Comments/Basis
			(See item III.L.)
III.L	TS Not Adequate for Design Bases	III.L.4 p. 18	<p>The NRC has issued related guidance in GL 91-18 on evaluation for operability. The first action is to write a condition report (nonconformance report) this will ensure that the condition is identified and will provide for a §50.72/73 review. Entergy agrees the TS should be changed; however, there is no safety basis that such a condition would require an immediate action. The actions resulting from the condition report may involve additional design changes which may require a different TS action, and Bases. There is also the potential that other actions which may be a refueling cycle away will return the condition to its required status. These do not require a TS change.</p> <p>If a condition is identified where a TS is non-conservative and the timing is such that a unit is approaching an outage or other period where the condition will be corrected, there should be no need to temporarily place more restrictive actions in the TS. If it is determined that the TS will require modification to resolve the nonconservatism, the licensing should pursue a "timely" TS change with the NRC. See also Item III.O on degraded and nonconforming conditions.</p>
III.M	PRAs in 50.59 Evaluations	III.M.4 p. 19 / 2nd para. III.M.4 p. 19 / 2nd para.	<ol style="list-style-type: none"> 1. The discussion in the NUREG fails to recognize the widespread industry commitment to update and maintain living PSAs for their plants. 2. PRA may not be the appropriate tool for determining whether a USQ exists, but it does provide a potential benefit for characterizing the potential change in probability if a USQ has been determined to exist. This should not be inferred that PRAs cannot be used, but only that they may not represent the best tool. PRA results and risk insights can play a significant role in evaluating a potential USQ. Risk insights on the proposed change could also provide an additional dimension to the safety test of the 50.59 process relative to the purely deterministic perspective. <p>Note: The potential role of PSA in determining when overall impact on nuclear safety should be acceptable without NRC review (e.g., where there is a very small increase in probability combined with a great decrease in consequences, or vice versa) in a</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
			risk-informed arena should be pursued as part of any rulemaking concerning §50.59.
III.N	Deleting Information from FSAR	III.N.4 pp. 20 - 21	<p>The NRC staff position of disallowing removal of information from the SAR is overly conservative, not well justified, and not technically based. It is reasonable to believe that NRC did not rely on all information contained in the SAR to establish the basis for the Operating License. In addition, later vintage plants generally contain more general information that does not effect safety. Allowing the licensee to remove non-relevant or nonsafety-significant information from the SAR results in more effective 50.59 safety evaluations.</p> <p>Excessive detail placed in a SAR can increase the burden upon both NRC and industry. NRC should allow SAR streamlining, particularly for more recent vintage plants that have a large cross-section of detail in the SAR. NRC has Standard Review Plans and Regulatory Guides that describe what information should be contained in a SAR. NRC should ensure that the guidance provided in such regulatory documents is proper. Licensees should be expected to meet such expectations, as well as allowing plants to remove excess detail which is well beyond the requirements of the NRC approved regulatory guidance.</p> <p>Recognizing the reference to GL 80-110 for not deleting information from the SAR, it is inconsistent with a desire for SAR value and increases burden. If the SAR is to be a vital, living document, there is no need to maintain information no longer applicable (e.g., initial training programs and preoperational test programs). The additional information can dilute the safety focus of the SAR and impose additional burden to update extraneous information.</p>
III.O	50.59s on Degraded/ Nonconforming Conditions	III.O.4 p. 24 / 3rd para.	<p>1. Compensatory actions taken to address nonconforming conditions may not, in and of themselves, require evaluation under 10CFR50.59 on a stand-alone basis. If compensatory actions are not already fully addressed under existing 50.59 reviews, additional 50.59 reviews should be performed for the compensatory actions only to the extent that they would require a facility or procedure change. When a 50.59 evaluation is conducted it need only consider that portion of the activity that involves the compensatory action and not the full</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		<p>III.O.4 p. 24 / 5th para.</p> <p>III.O.4 p. 25 / 3rd para.</p>	<p>scope of the concern. Clearly conservative compensatory actions that place the plant in a safer condition can be implemented while the 50.59 for such compensatory actions is being prepared. We believe no other 50.59 reviews are needed.</p> <p>2. Even though the policy of conducting 50.59 reviews on long-standing conditions (i.e. beyond the next available outage) is a conservative action that has merit, there is no legal basis for requiring 50.59 reviews for these cases.</p> <p>3. Prohibiting a plant from restarting with a degraded condition involving a USQ has no basis in regulation unless the action is prohibited by TS or involves an operability concern. The existence of a USQ does not mean that a safety issue exists, but only that NRC review is required prior to implementing the change. The licensee would have to first show that the condition is not a safety or operability issue that warrants continued plant shutdown. A licensee should therefore be allowed to startup under an operability evaluation while the USQ is being reviewed by the NRC. Just because a USQ exists with no operability issue, it is inappropriate to require a licensee to remain shutdown.</p> <p>Note: Use of the term "available opportunity" is somewhat ambiguous and may lead to future disagreements of interpretation.</p>
III.P	Increase in Probability of Occurrence	III.P.4 p. 26 / 1st para.	<p>1. The NRC position to invoke that "any" increase in probability as a USQ is not within the original intent or capability of licensees or NRC during the original 1962 rulemaking. Note that measurement uncertainties are involved in any process. Hence, when the NRC originally promulgated §50.59, inherent in the rule was the fact that any increase in probability or consequences had to be a measurable one. Any increase which could not be measured was practically not an increase, as recognized by the NSAC 125 guidance. It remained a licensee responsibility to ensure that combinations of negligible increases also remained negligible, i.e., there is no discernible or measurable change.</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		III.P.4 p. 26 / 3rd para. - p. 27 / 1st para.	2. The discussion provided in the NUREG for determining whether a probability increase has occurred is confusing. Probability changes should only be a consideration if there is a definitive change in occurrence that would actually indicate a probability change. During this time frame, probabilities were considered in the four categories of ANSI N18.2 (currently ANSI N 51.1). To consider any increase would represent a new NRC position and should require backfit consideration. The NRC Staff discussion on page 29, line 15-36 is the proper interpretation.
III.Q	Probability Still within Design Basis	III.Q p. 27	Entergy agrees with this section. Note, however, that example (a) provides a good example of the treatment of design margin for plant equipment. This same philosophy should be applied to the definitions of "Consequences" and of "Margin of Safety" in the draft regulatory guidance.
III.R	Increase in Consequences	III.R.4 p. 30 / 1st & 2nd para.	<p>1. NRC is improperly treating use of design margin as an "increase in consequences" in Section III.R. Any increase in consequences must be with respect to NRC-imposed acceptance limits, specifically those in the Standard Review Plan or in a plant SER. As written, there is ambiguity in this phrase as to the exact nature of the qualifier "previously evaluated in the SAR." Past industry and regulatory practice and precedent has clearly established that the term does not refer to an increase in the values documented in the SAR. Specifically for an accident or malfunction of equipment important to safety previously evaluated in the SAR, the rule asks if there is an increase in consequences. The rule does not establish the SAR as the baseline for such an increase. The NRC promulgation of acceptance criteria in accident analyses different from the values submitted by licensees in the SAR is <i>de facto</i> acceptance that the SAR is not the baseline upon which to judge if changes to dose consequences are acceptable.</p> <p>NRC agreement with the fact that the SAR is not the baseline for determining if there is an increase in consequences is documented in the May 10, 1989, NRC letter from C. E. Rossi to Mr. T. E. Tipton of NUMARC. In this letter, the NRC states:</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
			<p>"If a proposed change, test, or experiment, would result in an increase in dose from an accident or equipment malfunction above that previously reviewed and approved by the staff as part of the licensing basis for the plant (i.e., the acceptance limit), then the proposed change, test or experiment involves an unreviewed safety question and would require prior NRC approval."</p> <p>The NRC also states in this letter:</p> <p>"...if in licensing the plant the staff explicitly found that the plant's response to a particular event was acceptable because the dose was less than the SRP guidelines (without further qualification) then the staff implicitly accepted the SRP guideline as the licensing basis for the plant and the particular event, and the licensee may make changes that increase the consequences for the particular event, up to this value without NRC approval. However, if the staff cited some value other than the SRP guideline as its criteria for licensing the plant then that value is considered the licensing basis for the plant."</p> <p>Thus, the NRC has clearly established that the acceptance basis in the SER, which is often that of the SRP, is the proper licensing basis for the plant. Therefore, any value for the dose consequences which remains less than that acceptance basis has been reviewed by the NRC as within the plant licensing basis, and is not a USQ.</p> <p>Note: An example exists where NRC has explicitly used the SRP alone as the basis for limits on a plant's licensing basis. In 1992, a PWR submitted to the NRC, as a potential USQ, a case where the calculated percent of fuel rods experiencing DNB as the result of a transient analysis exceeded the value previously documented in its SAR and SER. The SER had repeated the results of the utility analysis and had concluded, without an explicit basis, that the results were acceptable. Since there was no clear acceptance basis discussed in the SER, the utility had submitted this case to the NRC as a potential USQ. The NRC responded to the utility and stated:</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		<p>III.R.4 p. 30 / 3rd para.</p>	<p>"However, even if all of the pins experiencing DNB were to fail, a coolable geometry would be maintained and the consequences remain a small part (less than 10 percent) of 10CFR Part 100 limits."</p> <p>Note that the SRP acceptance limits for this event are that the dose consequences remain a small part (less than 10 percent) of 10CFR100 limits. The Staff also concluded that the §50.59 criteria had been met for this change and that the change satisfied §50.59 criteria.</p> <p>2 The dose consequences considered in this question should only be considered as offsite dose consequences, not onsite doses. The analyses performed in Chapter 15 were for the public health and safety and not for onsite worker doses.</p>
III.S	Reduction in Margin of Safety	III.S.4 pp. 31 - 34	<p>Acceptance limits should not necessarily, or in general, be the values for calculated performance which are documented in the SAR. The acceptance limits should be the values which are the NRC acceptance limits per the SRP/SER. Any regulatory guidance needs to differentiate between "Margin of Safety" and "operating margin," which the current proposal does not. Under the proposed guidance, any value that has been established in the SAR that reflects an established limit will be considered a margin that would represent a USQ. This would create a significant increase in USQs that would require NRC review.</p> <p>In addition, to tie the margin to safety to values in the SAR would be counterproductive to NRC's interest in SAR integrity. Licensees who have provided detailed information in their SAR would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the SRP/SER acceptance limits would result in a USQ.</p> <p>The containment pressure example used in Figure 3-2 of NEI 96-07 is a good example. The difference between the containment failure point and the analyzed maximum operating "acceptance limit" is the margin of safety (if it is discussed in the bases of the TS). Any value discussed below the acceptance limit value (such as a peak pressurization value) would establish only an operating margin, and would not be subject to a USQ.</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
			The application for determining "Margin of Safety" in NEI 96-07, Section 3.8 should be endorsed by the NRC.
III.T	Scope of Basis for Any TS	<p>III.T.2 p. 34</p> <p>III.T.4 p. 34 / 2nd para.</p> <p>III.T.4 p. 35 / 3rd para.</p>	<ol style="list-style-type: none"> 1. The clear original legal intent of the rule applies only to the TS Bases. NSAC 125 and NEI 96-07 guidelines apply a broader interpretation than the strict legal requirement to the term "basis." Thus, NSAC 125 and NEI 96-07 represent a more conservative application over the §50.59 rule. 2. The last sentence of the second paragraph in III.T.4 states: "The staff acknowledges that the TS BASES sections do not consistently define margins of safety, even in qualitative terms." It should be recognized that TS themselves do not have a high level of consistency; LCO times may or may not be based on the amount of risk involved. This lack of consistency has driven licensee efforts, such as that within the CEOG, to reexamine Allowed Outage Times within TS and to apply risk insights to improve TS. 3. The previous position taken in NRC Inspection Manual Chapter 9900 is the proper legal position for the margin review scope. Even though the level of information contained in the TS Bases has varied from licensee to licensee and over time, the intent of the original regulations are specifically intended to be the TS Bases. However, with the application of the new revised standard TS, the content and focus of the Bases are more focused on supporting what is considered important and what information would establish a margin of safety that the NRC would consider within the scope of needing NRC review to change and would be within the scope of a USQ.
III.U	Application of New Methods for USQ	III.U.3 p. 36	<ol style="list-style-type: none"> 1. In the period since most plants were licensed, there have been advances in technologies and methodologies which allow licensees to better analyze the design of systems, structures, and components and plant operation. If the new methodologies are standard to other industries and are generally accepted practices, their use should not be defined as an unreviewed safety question. <p>Few methodologies require explicit Commission approval, for example, those used for compliance</p>

No.	Description	Section, Page/Paragraph	Comments/Basis
		<p>III.U.4 p. 36 / 3rd para.</p>	<p>with §50.46. In cases where the SER specifically calls out use of approved methodology as one of the bases for Commission approval, use of alternate methodology would have to be evaluated against the SER. If the new methodology is consistent with these criteria (e.g., includes features required by the appropriate regulatory guidance), then the change should be permissible under 50.59.</p> <p>Note also there should be a significant difference in the treatment of a methodology under §50.59 depending on the nature, complexity, and safety significance of the application of that methodology. While methodologies for Chapter 15 NSSS and core analyses require explicit NRC approval, and codes used for certain structural analyses are required to be documented within Chapter 3 of the SAR, the requirements for methodologies for other subjects (e.g., room heatup, radiological releases) are less stringent. In such cases whatever methodology is used must be properly and thoroughly qualified and undergo verification and validation, but a change in methodology is not inherently in and of itself a potential USQ. Changes in input assumptions or analysis assumptions must be addressed within the format of §50.59, but would not be USQs if they continue to meet the appropriate acceptance criteria of SRPs, SERs, Regulatory Guides, etc.</p> <p>2. In the last paragraph of III.U.4, the staff does not review and approve methodologies for all analyses which are included within the SAR. Such a discussion should be deleted. Appropriate software control programs ensure that software used to support licensee analyses is adequate for its purpose where explicit NRC approval is not required.</p>
III.V	Use of Compensating Actions for USQ	III.V.4 p. 38	NRC should endorse the guidance offered in NEI-96-07, including its treatment of "change". It is reasonable and proper to account for the impact of compensatory actions as a means to counterbalance any potential negligible increase in probabilities or consequences, provided that the compensatory actions can stand on their own. The compensatory action may need to be subject to a separate §50.59 review to demonstrate this.
IV.A		IV.A	The scope of what should be included in the SAR is

No.	Description	Section, Page/Paragraph	Comments/Basis
		pp. 39 - 41	within the scope of §50.71(e) and should be addressed under the actions for SECY-97-036 and not this NUREG.
IV.B		IV.B pp. 41 - 45	<p>In considering potential redefinition of the term "USQ," the NRC should be open to the use of risk insights in the treatment of this term. For example, if certified PSA techniques can demonstrate that a proposed change, while it may increase consequences negligibly or slightly, would dramatically decrease the probability of the associated accident or equipment malfunction, then the change would obviously enhance plant safety. It may be unnecessarily burdensome to treat such changes as USQs which require NRC review, and the associated potential schedule delay, prior to implementation. Thus, application of this type of risk-informed regulation would streamline processes within both utilities and the NRC and allow both to focus more energy on topics important to safety.</p> <p>This is consistent with the thinking discussed in the second paragraph of B.3, <u>Other Options</u>. An approach which would allow for implementation of non-risk significant USQs without prior NRC approval (but possibly with prompt NRC notification) could be in the best interest of licensees, the NRC, and, through more focus on nuclear safety, the public.</p> <ol style="list-style-type: none"> 1. Item B.2: Entergy takes exception to the NRC statements that the industry attempts to interpret §50.59 in a manner not consistent with how the rule is written. 2. Item B.3, <u>Increase in Consequences</u>: Entergy disagrees with the NRC interpretation that any increase in radiological consequences above the value calculated in the SAR is a USQ. (see III.R discussion). Entergy does not think that rulemaking would be required to clarify that the purpose of §50.59 is to ensure that consequences remain within acceptance criteria, i.e., those spelled out in the SRP or SERs. 3. Item B.3, <u>Margin of Safety</u>:

No.	Description	Section, Page/Paragraph	Comments/Basis
			The thought process in the first paragraph should also be applied to the definition of radiological consequences; i.e., the SRP or SER provides the acceptance criteria, not the value documented in the SAR.
Other	Changes Required by 10CFR50.90	—	Rulemaking to delete the §50.90 requirements for a USQ approval should be pursued. §50.59(c) requires that a licensee who desires to make a change to the TS or to request NRC approval of a proposed change that involves a USQ, to submit an application for license amendment under §50.90. Such action is applicable for a change to a TS, but is not applicable for addressing a USQ. A change to the SAR which would require NRC approval is not directly applicable to the license, but only the supporting documents (i.e. SAR). To require an amendment under §50.90 requires some portion of the license be changed. No part of the license deals with the a change which is being made to the SAR. Similar to that which was proposed during initial licensing of the plants, a request for a SAR change should be nothing more than a request to review and approve a change to the SAR given a justifiable basis. The accuracy of the information provided to the NRC would be within the requirements of §50.9 enforcement without imposing a §50.90 amendment process. The more stringent actions of §50.90 would slow the approval process with no commensurate level of safety. Rulemaking should be performed to simplify the review/approval process for changes involving a USQ.

DRAFT NUREG-1606

EXAMPLES OF POTENTIAL IMPACT TO PLANT OPERATION

Section III.I: Malfunction of Equipment Important to Safety - of a Different Type

NRC Position:

"The staff believes that a more complete definition of 'malfunction' than what is contained in NSAC-125 is *an undesired response of equipment, for example, failure to operate, inadvertent operation, operation in an unexpected manner, operation with less than rated capacity, and failure to perform function as designed.*"

Impact of the Position:

1. Per NUREG-1606, if an electro-mechanical protective relay in a Class 1E circuit is upgraded to a digital relay, a USQ is created since the digital relay has a different failure mechanism. Only the effects of the relay failure would be considered under NEI 96-07.
2. Replacement of a safety-related valve having a hard seat with one having a soft seat could be considered a USQ since the soft-seated valve has a potentially different failure mechanism.
3. In the case of the oil-filled transmitter mentioned in NUREG-1606 guidance, there could be other differences between the types of transmitters which, by their design differences, could be a USQ. The oil-filled (Rosemount) transmitter works on a change in capacitance vs. differential pressure and uses capacitance to control frequency of an oscillator, followed by a frequency-to-voltage converter. The other transmitter may use a diaphragm or Bourdon tube connected to a strain gage, which is connected to a resistance-measuring bridge. The two transmitters represent different failure mechanisms: a failure in the frequency-to-voltage converter in one and a failure in the resistance-measuring bridge in the other. Normally, a failure of either transmitter would be considered a "failure of the electronics", and not a USQ as defined in NUREG-1606.

Section III.P: Definition of Increase in the Probability of Occurrence

NRC Position:

"Section 50.59 uses the term 'may be increased,' and therefore, any increase, however slight, will trigger an unreviewed safety question and thus require staff review. Accordingly, the staff's position is that the language of 10 CFR 50.59 (probability may be increased) indicates that any uncertainty or doubt about whether an increase, even a negligible one, has occurred should lead to the conclusion that a USQ is involved."

Impact of the Position:

1. Plugging steam generator tubes leads to lower steam generator pressures. Lower steam generator pressures brings that plant parameter slightly closer to the main steam isolation valve (MSIV) setpoint (and slightly closer to MSIV closure on plant trips). This indiscernible change in the probability of MSIV closure events would preclude any steam generator plugging without NRC approval. Based on NEI 96-07 this would be considered indistinguishable and not a USQ.
2. Periodic failure of normally energized solenoid actuation valves may prompt the need to modify the reactor trip circuitry to avoid spurious main steam isolation valve (MSIV) closure. A change from normally energized to normally de-energized MSIV solenoid actuation valves would be a USQ under NUREG-1606 since the change could be considered to involve a minor change in probability of a failure to actuate the solenoid valves.
3. (General Comment) A change that introduces an additional component within a system can introduce failure probabilities not previously considered. Therefore, if a new component is equipment important to safety, the change, by definition, has increased the probability since there is a net probability increase of total components which can fail.

Section III.R: Definition of Increase in Consequences

NRC Position:

1. "The language in 10 CFR 50.59, is 'consequences of an accident...previously evaluated in the safety analysis report may be increased.' Therefore, the staff concludes that ***the dose calculated in the SAR should be considered as the threshold for when an increase in consequences (and thus a USQ) results*** (emphasis added). Further, failure to comply with this position could result in enforcement action.

"The staff also notes that for radiological consequences associated with accidents evaluated in the SAR, the staff SER is generally based upon independent calculations performed by the staff, using the data provided by the license applicant. The staff's assumptions on such parameters as decontamination factor may be different from licensee assumptions. Thus, the staff does not generally approve the methods or results of the SAR analysis, but finds the consequences of the accident acceptable if the staff-calculated results meet the applicable acceptance guidelines (Part 100 or SRP values which may be less for particular types of accidents). This fact would make it more difficult to allow licensee consideration of the NRC acceptance value (see discussion on Margin of Safety) as the benchmark for determining whether the increase is within the bounds of what the staff has previously reviewed and accepted, even if the rule language would allow such an interpretation.

2. "The staff agrees that 'consequences' refers to radiological consequences, with other results of accidents/malfunctions being addressed under margin of safety. In a letter to NUMARC dated May 10, 1989, the staff provided its view that **'consequences' should be in terms of dose to either onsite or offsite persons** (emphasis added) that would likely result from any accident or equipment malfunction associated with the proposed change. The staff concludes onsite doses must be considered to the extent they were considered before in the accident analysis (such as to show compliance with GDC 19)."

Impact of the Position:

1. While reviewing a dose calculation for a non-bounding event, the engineer finds an incorrect assumption were made. The incorrect assumption causes the calculation results to be about 10% nonconservative. The limiting offsite doses in the SAR are on the order of 0.1 Rem thyroid for an event where the SRP acceptance limit is 30 Rem. This condition becomes a USQ under the NRC's new thought process because it is an increase in the dose reported in the SAR.
2. The upgrade of an ECCS pump seal could be a USQ. The upgraded seal is more resistant to accident condition, but is not qualified with slightly higher operating leakage. Because of this situation, the upgrade would slightly increase post-LOCA ECCS leakage specified in the SAR but would remain well below regulatory limits. As with the example above, this upgrade would be a prudent enhancement which would also involve a USQ under NUREG-1606.

3. Adopting more conservative assumptions regarding operator actions to cooldown the reactor coolant system (RCS) following a steam generator tube rupture could be a USQ. No changes in operator guidance were made, only a less optimistic characterization of their effects. The more conservative modeling resulted in a noticeable increase in offsite dose, but was still well below regulatory limits.

Section III.S: Definition of Reduction in Margin of Safety

NRC Position:

"In determining what changes represent a reduction of the margin of safety, it should be recognized that the technical specifications and the accident analyses on which they are based, provide assurance that the response of the plant to various design basis accidents and transients is acceptable.

"Accordingly, for purposes of this criterion, a reduction of margin of safety as defined in the basis for any technical specification will be deemed to have occurred when an acceptance limit is no longer met as a result of a proposed change, test, or experiment. If the staff's acceptance limit in the safety evaluation is explicit, the licensees can consider the values in the staff safety evaluation as a reference for determining the 'acceptance limit', rather than being limited only to values contained in the plant safety analysis report. If the staff's acceptance limit is not explicit, the 'acceptance limit' is the value as reported in the SAR."

Impact of the Position:

1. In the electro-mechanical protective relay case above, if the setpoint is discussed in the SAR then this could be considered a USQ since the NRC may interpret this as a margin. NEI 96-07 would not consider this a margin since it is not a potential "regulatory margin" having higher level failure point significance.
2. Upon reviewing current meteorological data, a plant engineer determines the plant's ultimate heat sink (UHS) expected maximum temperature may be increased from 90° F to 92° F. The TS establish 95° F as the limit for ensuring adequate post accident cooling. The TS Bases indicate that the TS value is to ensure that the UHS water temperature does not exceed the analysis for the worst-case post accident design conditions of the reactor building. The SAR reports a value of 90° F as the estimated expected maximum temperature of the UHS conditions based on worst-case meteorology. The NRC's SER reiterates 90° F as the expected worst-case temperature for the UHS and that the design maximum temperature is 95° F

per the TS. Under the NUREG guidance, a change to reflect a UHS maximum temperature of 92° F would be considered a USQ since the 90° F value would be considered an operating margin which could not be changes without NRC approval.

3. (General Comment) Because of the "give and take" in the numerous inputs to accident analyses that are possible without appreciably effecting the results, the NRC's approach would greatly limit reanalysis efforts to respond to slight changes in plant operating condition.