UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 26, 1996

CHAIRMAN

The Honorable Sam Gejdenson
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Gejdenson:

I am responding to your letter of January 2, 1996, concerning the Nuclear Regulatory Commission's Office of the Inspector General report addressing allegations raised by Mr. George Galatis regarding the Millstone Unit 1 plant. You were particularly concerned about the IG's finding that the NRC staff was unfamiliar with certain sections of the Updated Final Safety Analysis Report (UFSAR) governing appropriate refueling practices at Millstone Unit 1.

As you know, I asked the staff on November 30, 1995, to take a comprehensive approach to address the problems specifically related to Millstone Unit 1 full core offload, including the findings of the Inspector General's report (Enclosure 1), and suggest changes that should be made across the board. In the Executive Director for Operation's response dated December 28, 1995 (Enclosure 2), he indicated that the staff will issue instructions that will modify, in the near term, our approach to inspection activities by focusing attention on licensee implementation of the UFSAR. The staff will also develop recommendations on ways to improve the quality and timeliness of NRC's regulatory response to situations in which there are discrepancies between the UFSAR and its implementation. In addition, the staff will review the description of the spent fuel pool contained in the UFSAR and will review the licensees' implementing procedures to provide assurance that the licensee for each facility is in compliance with the facility's UFSAR.

Other steps are being taken to address longer-term implementation of the lessons from the Millstone Unit 1 experience. On October 27, 1995, I asked the staff to review several policy questions concerning changes made to facilities pursuant to Section 50.59 of Title 10 of the Code of Federal Regulations (10 CFR 50.59) (Enclosure 3). On December 15, 1995, the EDO responded (Enclosure 4) that the staff is developing an action plan. Within the next few months the staff will review guidance on implementation of the 50.59 process, determine the extent to which the information is internally consistent, and define areas where the guidance needs to be amended. In addition, the action plan will address recommendations for modifying guidance in place on implementation of the 50.59 process, for defining and addressing inconsistencies in the implementation of NRC monitoring of the 10 CFR 50.59 change process, and for developing and issuing more definitive guidance.

With respect to Millstone itself, the staff has several other ongoing initiatives. By memorandum dated December 12, 1995, the EDO directed the staff to conduct an independent evaluation of the history of how Northeast Utilities (licensee for Millstone) and the staff handled employee concerns and allegations related to licensed activities at Millstone Station. A copy of this memorandum and a broad outline of the objectives and scope of the review are enclosed (Enclosure 5).

DF02

PDR per: D. Mossburg

By letter dated December 12, 1995 (Enclosure 6), the NRC requested additional information, pursuant to Section 182a of the Atomic Energy Act of 1954, as amended, and 10 CFR 50.54(f), from the licensee for Millstone Unit 1. Specifically, the licensee was asked to describe the actions taken to ensure that Millstone Unit 1 will be operated in accordance with the terms and conditions of the Millstone Unit 1 operating license; the Commission's regulations, including 10 CFR 50.59; and the Millstone Unit 1 UFSAR.

Further, the NRC monitors and assesses the operations at all three Millstone units through many ongoing activities, including inspections by the Millstone-based resident inspectors, inspections by NRC Region I personnel, and evaluations by NRC Headquarters personnel of specific technical and operational issues (Enclosure 7 describes staff being added to the Millstone site). NRC performs these functions to provide extensive oversight and assessment of the activities at the Millstone plants and focuses on verifying that these facilities are being operated safely.

The NRC staff will continue to monitor closely activities at the Millstone site and we will keep you informed on the progress of these initiatives.

Sincerely,

Shirley Ann Jackson

Shirley Ann Jackson

Enclosures:
1. November 30, 1995, Memorandum
2. December 28, 1995, Memorandum
3. October 27, 1995, Memorandum
4. December 15, 1995, Memorandum
5. December 12, 1995, Memorandum
6. December 12, 1995, Letter to Licensee
7. December 13, 1995, Memorandum w/o Attachments

CHAIRMAN

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

November 30, 1995

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

Karen D. Cyr
General Counsel

FROM: Shirley Ann Jackson Shirley Ann Jackson

SUBJECT: LESSONS LEARNED FROM MILLSTONE UNIT 1

There are several aspects related to 10 CFR 50.59 requirements, the Final Safety Analysis Report (FSAR) and recent work on the license amendment for Millstone Unit 1 core offload about which I would appreciate the staff's preparation of a lessons learned report. My purpose in this request is to explore whether existing oversight processes need improvement or new processes need to be developed which would have produced earlier NRC recognition of and action on Millstone Unit 1 noncompliance with its FSAR. This issue may have generic applicability in that these process improvements may apply to NRC's work in monitoring the safety of other operating plants.

I recognize there are many facets to NRC's oversight process to ensure public health and safety with one of the most important of these being the NRC reactor inspection program. This program should properly focus on the best and most accurate means for monitoring the safety of operating reactors and should not place undue emphasis on review of documents and paperwork -- as was criticized by the President's Commission following the Three Mile Island accident. Having said that, the NRC must strike an appropriate balance between onsite performance-based inspection and the review and full evaluation of the of safety significant changes to a facility.

I would like the staff to re-examine the adequacy of the regulatory framework that authorizes licensees to make changes to their facilities without the prior approval of the NRC. The report should address whether the existing 10 CFR 50.59 requirements sufficiently define facility changes that create unreviewed safety questions. In performing this review it is of the utmost importance to recognize that the 10 CFR 50.59 requirements must assure consistent interpretation and clearly prohibit facility changes which erode safety margins. The staff should also re-examine its oversight and monitoring of the 10 CFR 50.59 change process based upon the experiences encountered with the Millstone Unit 1 core offload practices.

I would like the staff's recommendation to include the respective roles that the NRC's Headquarters, Regional and Resident Inspection Programs should have in the review of 10 CFR 50.59 changes and monitoring of licensee's adherence to FSAR commitments. In the Millstone instance there have been apparent discrepancies between the licensees' longstanding practices and the

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Enclosure 1

description of the core offload procedures in the Millstone Unit 1 FSAR. Consideration of oversight improvements to the 10 CFR 50.59 change process should be informed by the staff answers to my request of October 27, 1995, on the general subject of facility changes pursuant to 10 CFR 50.59.

Also, generically, I would appreciate NRC staff recommendations on ways to improve NRC's regulatory response both in quality and timeliness for instances where licensee noncompliance with the FSAR and/or NRC regulatory requirements is identified similar to the Millstone Unit 1 core offload situation as revealed in the Licensee's Event Report filed with the NRC in October 1993.

As you know, there has been a significant amount of concern expressed by the public living in the vicinity of Millstone Unit 1 regarding the licensee's core offloading plans. This concern extends to the NRC staff's role in our regulatory oversight of the Millstone unit. I believed it was important that there should be a meeting to hear the public's concerns and provide information to the public on the status of the proposed license amendment prior to the NRC staff taking final action on that amendment. For the future, I would appreciate the NRC technical and legal staff's advice on determining an appropriate role for public involvement for situations where there are substantial public concerns. At the same time I would not like to see a public information process which was unduly burdensome and could interfere with completion of the substantial volume of license amendments reviewed by the NRC annually. One suggestion is to look more closely at proposed license amendments in which there are associated 2.206 petitions filed as was the case with the Millstone Unit 1 core offloading.

In considering this request please respond as expeditiously as possible while complying with the ex parte rules applicable to the ongoing litigation on this issue. In addition, the staff should consider the findings of the Inspector General's written report when issued.

In preparing this staff requirements paper, I have consulted with Commissioner Rogers.

cc: Commissioner Rogers
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 28, 1995

MEMORANDUM TO: Chairman Jackson

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: LESSONS LEARNED FROM MILLSTONE UNIT 1

With respect to the generic applicability of the issues raised in your November 30, 1995, memorandum concerning the Millstone Unit 1 full-core offload and the need to reexamine the effectiveness of the existing process for staff oversight of changes to nuclear power plant facilities, the staff will initiate two activities to determine the extent to which problems similar to those encountered at Millstone Unit 1 exist at other facilities. First the staff will review the description of the spent fuel pool contained in the Updated Final Safety Analysis Report (UFSAR) and will review the licensees' implementing procedures to provide assurance that for each facility, licensees are in compliance with their UFSAR. Project managers will be responsible for the completion of these reviews. It is envisioned that the project managers will work with the resident inspectors and, as necessary, the individual licensees to complete the reviews. Site-specific issues identified through this review will be the subject of focused facility inspections. An SES manager will oversee this review effort. We intend to complete this effort for each operating plant before the next refueling outage, but no later than May 1996.

The second activity will allow the staff to gain additional insights regarding licensee's compliance with other aspects of the facility descriptions contained in their UFSARs. Within two months from the date of this memorandum, the staff will issue instructions that will modify, in the near term, our approach to inspection activities by focusing attention on licensee implementation of the UFSAR. As a follow-on to these inspections, we anticipate developing recommendations on ways to improve the quality and timeliness of NRC's regulatory response to situations in which there are discrepancies between the UFSAR and its implementation.

As stated in my December 15, 1995, reply to your October 27, 1995, memorandum regarding 10 CFR 50.59, the staff is developing an action plan for evaluating how consistently this regulation is being applied. This regulation provides the regulatory framework under which licensees may make certain changes to their facilities without first obtaining NRC approval. This action plan will address NRC monitoring of the 50.59 change process and licensee adherence to the UFSAR, and will also consider the appropriate roles of the headquarters,

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415-1284

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Enclosure 2

resident, and regional inspectors in this monitoring process. The staff also envisions that one aspect of the action plan will include developing regulatory guidance to produce a higher level of consistency in the application of 10 CFR 50.59.

As part of the staff's evaluation of the different aspects of the Millstone Unit 1 full-core offload, the technical and legal staffs will evaluate the role for public involvement, particularly where substantial public concerns are being voiced by individual members of the public, citizens organizations, or local officials. The current license amendment process described in 10 CFR 50.91 provides for public participation in the form of an opportunity to request an adjudicatory hearing. This regulation also affords the public an opportunity to submit comments on the staff's proposed determination regarding the existence of a "significant hazards consideration," a finding made in the vast majority of situations. At present, neither the Commission's regulations nor the agency's internal management directives establish other express opportunities for public involvement in connection with license amendments. (The 2.206 process is not applicable to licensing actions, but rather is a mechanism for the public to request the initiation of enforcement action.) The staff currently processes more than 1000 license amendment actions per year. Historically, there is little evidence of substantial public interest in most license amendment actions; few comments have been submitted and yet fewer hearing requests have been filed.

Meetings between the staff and the licensee, when necessary to discuss the technical merits of a proposed license amendment, are publicly noticed and the public is invited to observe but not actively participate. Decisions to provide for meetings or for other staff interactions with the public beyond that provided for in the normal course of business or the adjudicatory process, where there are substantial public concerns or media interest, are best made on a case-by-case basis. The staff will work with OGC to develop internal guidance to assist in determining the circumstances that would indicate when a meeting with the public should be considered. Other actions to heighten the staff's sensitivity to inquiries and interest from the public and to consider the need for public meetings will also be examined.

As was discussed when the staff recently briefed you on the license amendment process, there is no explicit notice provided to the Commission in the license amendment process when a hearing is requested, after a final determination is made that a significant hazard does not exist and the license amendment is issued. The staff is developing procedures to address this issue. In the near term, NRR will revise its office procedures to require office director concurrence before issuing license amendments if a hearing that has been requested will not be conducted before the license amendment is issued.

cc: Commissioner Rogers
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CHAIRMAN

October 27, 1995

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: Shirley Ann Jackson *Shirley Ann Jackson*

SUBJECT: FACILITY CHANGES PURSUANT TO 10 CFR 50.59

Although these regulatory practices have been in place for some time, as a result of my recent briefings by the NRC staff on the subject of facility changes pursuant to 10 CFR 50.59, I believe that it is time for some systematic reconsideration and reevaluation. I would appreciate your views on the following policy questions, as well as draft proposed changes to our 50.59 process:

- How can the 50.59 process be improved? Specifically, I would like the staff to consider ways to better improve the integration and feedback of information learned from the review of 10 CFR 50.59 facility changes into the remainder of NRC's reactor regulatory program.

- What ways would the NRC staff propose for better incorporation of risk perspectives in construction of samples subject to NRC review. Here again, I realize that there are difficulties in incorporation of risk methodology in the absence of detailed plant-specific and so-called living probabilistic risk assessments for each plant. However, I would like the NRC staff to think in some depth about what is achievable in the nearer term to build in a risk-informed approach to the extent practicable.

- What is the best way to assure that the cumulative safety impact of 50.59 facility changes does not unacceptably erode reactor safety margins?

- How does one assure that the NRC staff practices in sampling and reviewing 50.59 facility changes are consistent from plant to plant within regions and consistent among the four NRC regions? I understand that there may be variations in staff practice in this connection and I think that we should review carefully what our practices in fact are and whether we need additional steps to ensure consistency.

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Enclosure 3

In addition to addressing the above issues, I would appreciate written responses to the attached questions which I discussed orally during the recent briefing.

Attachment:
As stated

cc: Commissioner Rogers
OGC
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OPA
OCA
ACRS

1. How are licensee facility changes under 50.59 documented in the Final Safety Analysis Report? How frequently are these changes documented?

2. Who are the responsible officials within the NRC for insuring proper documentation of facility changes and updating of the FSAR?

3. Please estimate the typical volume of plant facility changes annually under 50.59 for reactors.

4. How is the sample constructed for which licensee 50.59 evaluations are subject to NRC review? What role does risk assessment play in constructing the sample subject to NRC review?

5. What is the process by which unreviewed safety questions are identified in the course of NRC staff evaluations of facility changes under 50.59? To what extent does the NRC 50.59 evaluation process reveal unreviewed safety questions compared to other sources of unreviewed safety questions?

6. Given the great volume of facility changes what are the criteria for selecting which 50.59 evaluations are reviewed and which are not. Inspection guidance document.

7. How is the safety significance of licensee 50.59 evaluations determined by the NRC?

8. Is there a possibility that there could be a cumulative safety significance from a combination of facility changes made over time? How does the staff examine this type of possibility?

9. What feedback mechanisms are there from staff experience in reviewing 50.59 facility changes back into the regulatory process to insure that the safety significance of changes are properly considered by the NRC?

10. With respect to past experiences, are there ways that the NRC staff's experience in reviewing facility changes under 50.59 has influenced NRC's reactor regulatory program? If so, please highlight some of the more important.

11. For the future are there improvements in NRC's feedback procedures which you would recommend for insuring better incorporation of experience into the NRC regulatory program?

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 15, 1995

MEMORANDUM TO: Chairman Jackson

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: RESPONSE TO QUESTIONS ON FACILITY CHANGES PURSUANT TO 10 CFR 50.59

In response to your memorandum of October 27, 1995, regarding 10 CFR 50.59, "Changes, Tests and Experiments," the staff agrees with your view that a reevaluation of the staff's 50.59 review process would be beneficial, and that the staff's evaluation process can be improved.

In addition to responding to your specific requests, the staff is developing a plan for conducting a systematic evaluation of NRC inspection activities involving changes under 50.59, with the goal of identifying what short-term and long-term actions should be undertaken to improve the agency's control of the 50.59 change process.

Within 120 days from the date of this memorandum, the staff expects to review its previously issued guidance on implementation of the 50.59 process, including generic letters, inspection procedures, guidance the NRC provides to its inspectors, and information used in inspector training at the NRC. During this period, the staff will determine the extent to which this information is internally consistent, and define areas where the guidance needs to be amended. The staff will develop recommendations for modifying guidance in place on implementation of the 50.59 process as a result of this review. This information will be included in an action plan to be developed during this period. The action plan will define and address inconsistencies in the implementation and oversight of the 10 CFR 50.59 process and include plans to develop and issue more definitive guidance. The finalized action plan will be forwarded to the Commission for information. The plan is expected be completed during a period of between 18 and 36 months.

As part of the action plan, the staff plans to examine 50.59 changes licensees have made over the past year, focusing particular attention on how the licensees documented the basis for their unreviewed safety question (USQ) determinations. Specifically, the staff will look at how the possibility of a change in probability or consequences is addressed in licensees' 50.59 safety evaluations. The staff will determine what new guidance may be appropriate for improving both the licensees' implementation and the agency's control of the 50.59 change process. This will also include a review to be performed by

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Enclosure 4

OGC to determine whether there are any judicial, Commission, or adjudicatory boards' decisions addressing 10 CFR 50.59 that discuss or evaluate the past practice with regard to implementation and application.

The staff will also review recent guidance promulgated on other related matters such as commitment management, design basis reconstitution, and analog-to-digital equipment replacement, as well as work prescribed by the NRC's PRA Implementation Plan, to assure that information licensees have available to implement the requirements of 50.59 is straightforward and consistent with other requirements.

The staff recognizes that industry has been utilizing the guidance in NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," to perform 50.59 evaluations. NSAC-125 was first developed by NUMARC in 1988, after which it was generally implemented by licensees as part of their regulatory compliance procedures. The NRC conducted pilot inspections based on the guidance, with the hope that the guidance could be formally endorsed as part of the inspection process. The staff has been unable to reach closure on endorsement of NSAC-125 because it is not consistent with the rule. The staff hopes to be able to work with industry to either revise NSAC-125 or to develop a regulatory guide incorporating examples of changes that may or may not be made under the provisions of 10 CFR 50.59. Whether the staff eventually recommends endorsing NSAC-125 with changes or develops its own guidance, the new guidance will be published for public comment before becoming final.

Attachment 1 contains the staff's response to the four policy questions you raised in your request to the staff. Attachment 2 contains the staff's response to the specific questions you transmitted with your request. Attachment 3 presents a brief description of how the regulations developed after they were promulgated in 1962, some observations of how licensees currently implement the regulations, and the staff processes for evaluating licensee implementation of 50.59.

Attachments:
As stated

cc: Commissioner Rogers
SECY
OGC
OCA
OPA

Response to Policy Questions Regarding 10 CFR 50.59

- **How can the 50.59 process be improved? Specifically, I would like the staff to consider ways to better improve the integration and feedback of information learned from the review of 10 CFR 50.59 facility changes into the remainder of NRC's reactor regulatory program.**

Response:

The staff believes that both near-term and long-term improvements can be made in the way the staff reviews licensee's implementation of the 50.59 process. Over the next 120 days, the staff will develop an action plan to evaluate its review of the 50.59 oversight process. The overall approach for improvements to the 50.59 process and specific implementation tasks will be developed as part of the action plan. Long-term evaluation of the 50.59 process will consider (1) the need for improved regulatory guidance on 50.59 implementation, (2) improvements in NRC staff's inspection and oversight of the licensee's 50.59 process, and (3) the need for a formal mechanism to assess inspection results to identify potential generic or pervasive problems, and improve the integration and feedback of information learned from the review of 10 CFR 50.59 facility changes into the remainder of NRC's reactor regulatory program. In the near term, the staff intends to (1) focus attention on the use of existing risk-insights in selecting a sample of the licensee's implementations of 50.59 to review and (2) provide additional guidance to project managers on verifying that facility changes made in accordance with 10 CFR 50.59 are incorporated in the safety analysis report (SAR).

- **What ways would the NRC staff propose for better incorporation of risk perspectives in construction of samples subject to NRC review. Here again, I realize that there are difficulties in incorporation of risk methodology in the absence of detailed plant-specific and so-called living probabilistic risk assessments for each plant. However, I would like the NRC staff to think in some depth about what is achievable in the nearer term to build in a risk-informed approach to the extent practicable.**

Response:

In general, inspection procedures (IPs) require the use of available risk insights, but do not define appropriate PRA data or decision methods best suited for specific inspection applications. Under the PRA Implementation Plan Item 1.3, the staff is developing guidance to assist inspectors in making a risk-informed decision regarding the selection of a sample of items or issues for more detailed followup inspection. This guidance is expected to be generally applicable to IPs in many different areas, including inspections of 10 CFR 50.59 programs. The staff believes that careful accounting of the strengths and limitations of available PRA insights must be made before improved guidance can help better focus our inspection resources.

At this time, we would not recommend that inspection resources be applied solely on the basis of a numerical risk ranking. For example, although a modification to the high pressure decay heat removal system (a high-risk system) would be important based on risk alone, a more meaningful sample would also consider the complexity of the modification and its potential for adversely affecting system functionality.

This approach would provide a method to balance the overall impact of the modification, considering the risk significance of the system being modified, the complexity of the modification, and the potential effect of the modification, if improperly performed (whether complex or not) on system functionality.

- **What is the best way to assure that the cumulative safety impact of 50.59 facility changes does not unacceptably ercde reactor safety margins?**

Response:

10 CFR 50.59 does not permit facility changes that may increase the probability or consequences of an accident or that may create a previously unanalyzed accident or decrease the safety margins specified in the bases to the technical specifications without prior staff approval. Therefore, explicit analyses of the cumulative effect of changes to systems or procedures over the operating life of the plant is not routinely performed. If 10 CFR 50.59 were not properly implemented by licensees the possibility could exist that a small but cumulative impact on safety would occur (See Attachment 2, response to Question 8). However, based on the staff's experience reviewing licensees' 10 CFR 50.59 implementation programs and inspecting the engineering area and design change and plant modification packages, the staff has reasonable assurance there has not been an erosion of reactor safety margins as a result of cumulative impacts of 10 CFR 50.59 facility changes.

One of the most important factors that assures there is no cumulative erosion of safety/design margins through facility changes is each licensee's thorough understanding of the design and licensing bases of their facility which results from the licensee's maintaining appropriate control of the facility's configurations. This was identified as a concern through engineering team inspections in the mid to late eighties. As a result, many licensees completed design reconstitution programs to recapture and regain a more complete understanding of their facilities' design bases and to assess the cumulative effects of facility modifications by verifying system functionality.

Note that from an overall performance perspective, both the NRC and the industry have stated that the industry has improved over the last decade in the safe operation of power reactors. Improvements in the safe operation of power reactors can, in part, be attributed to a number of NRC and industry sponsored efforts such as the design basis reconstitution programs previously described and the performance of integrated plant evaluations, to improve the understanding of the license and design bases of the facilities. These efforts have revealed risk-significant deficiencies in plant design and procedures outside of those considered in licensing basis documents.

The 10 CFR 50.59 decision-making process as described in the regulations is based upon maintaining the licensing basis and safety margins as defined in the final safety analysis report (FSAR) and technical specifications. In practice, licensee implementation of the 50.59 evaluation process typically includes an assessment of changes to determine whether the changes are within the scope of 50.59. However, licensees' processes generally tend to broaden the scope of changes on which they perform evaluations to include those that may be beyond the scope of the facility described in the FSAR and the technical information captured in technical specifications. Experience with the review of licensee implementation of the 50.59 process identified only isolated instances where facility changes that involved unreviewed safety questions were made without prior NRC approval. Instances where inspections identified that a licensee had modified its facility as described in the FSAR without making an unreviewed safety question (USQ) determination, or had performed an analysis of a facility modification that did not provide a sufficent basis for a USQ determination, have resulted in escalated enforcement. A keyword search of the Enforcement Action Tracking System (EATS) from 1990 to the present has identified 15 instances where the staff has taken escalated enforcement action for inspection findings that involved 10 CFR 50.59.

In addition to the broad-based NRC- and industry-sponsored reviews of design basis documentation and analysis, one of the fundamental aspects of NRC's inspection program is to focus inspectors on evaluating the impact of changes made to licensee programs, procedures, processes, analyses, and the physical plant. While the majority of IPs do not explicitly require inspectors to review licensee 50.59 evaluations, inspectors routinely review them as they follow up issues identified during inspection. A text search of inspection reports revealed that approximately 350 inspection reports referenced to 50.59 in the last two years (1994 through 1995).

Given the broad-based licensee efforts to understand the design basis and supporting analysis and the ongoing inspections to review the licensees' 50.59 evaluation processes, a fairly effective mechanism currently exists for assuring that the cumulative impact of 50.59 facility changes does not erode reactor safety margins.

However, we believe it is necessary to promulgate more comprehensive regulatory guidance for use by both the industry and the staff on the implementation of the 50.59 process and to reevaluate the current inspection guidance for review and assessment of licensee implementation of the 50.59 process.

- **How does one assure that the NRC staff practices in sampling and reviewing 50.59 facility changes are consistent from plant to plant within regions and consistent among the four NRC regions? I understand that there may be variations in staff practice in this connection and I think that we should review carefully what our practices in fact are and whether we need additional steps to ensure consistency.**

<u>Response:</u>

Your understanding is correct regarding the variability of 50.59 oversight by the staff. NRR performed an assessment of 50.59 oversight activities in 1991 and found that there was large variability in the scope and extent of audit and inspection activities on the part of NRR licensing project managers. The assessment did not include regional inspection activities related to 50.59 processes. As a result of NRR's assessment, IP 37001, "10 CFR 50.59 Safety Evaluation Program," was issued in December 1992 to provide more guidance on the inspection of 50.59 programs conducted by the project managers and region-based inspectors. The IP 37001 inspection is not part of the core program and would be performed by the regions as a regional initiative if warranted by licensee performance in this area. A detailed assessment of the staff's implementation of IP 37001 has not been performed to date.

As part of the core inspection program performed by all of the regions, the licensees' implementation of 50.59 is reviewed for several different activities, including facility changes performed by corporate and onsite engineering during the implementation of the maintenance activities, control of occupational exposure, solid radioactive waste management, and liquid radioactive waste treatment. As stated in Attachment 3, the core IP 37550, "Engineering," includes requirements related to selecting a sample of 10 CFR 50.59 evaluations to review that are part of significant safety-related design changes and plant modifications implemented during the previous or upcoming refueling outages. However, no specific assessment has been made of the consistency among regions of sampling and reviewing licensees' implementation of the 10 CFR 50.59 process. In the FY 1993 inspection program assessment (SECY-93-241) it was reported that there were indications that there were variations in inspector practices and that the effectiveness of the inspection program was highly dependent on the skills and performance of individual inspectors. Based on this, it would be expected that there may be variations related to sampling and reviewing 10 CFR 50.59 facility changes. Current information also suggests that wide variability in the oversight of licensees' implementation of 50.59 among NRR project managers continues.

Near-term changes will be evaluated to achieve a more uniform oversight of licensees implementation of 50.59 by NRR licensing project managers. In the long term, the implementation of IP 37001 and other regional inspection activities, will be considered for inclusion in the action plan.

Response to Specific Questions Regarding 10 CFR 50.59

Question 1: How are licensee facility changes under 50.59 documented in the Final Safety Analysis Report? How frequently are these changes documented?

Response:

10 CFR 50.59 allows licensees to (1) make changes to the facility described in the safety analysis report (SAR), (2) make changes to procedures described in the SAR, and (3) conduct tests or experiments not described in the SAR, without prior Commission approval, unless the proposed change, test, or experiment involves a change in the technical specifications or an unreviewed safety question (USQ).

The only facility changes we would expect to be documented in the Final Safety Analysis (FSAR) are those described in Item (1) in the first paragraph that represent direct changes to material already contained in the FSAR. Because of the level of detail contained in the FSAR, the majority of facility changes would not be documented or may be only partially documented in the FSAR because they involve changes to the facility at a level of detail below that which was contained in the FSAR at the time the operating license was granted. The level of detail included in the FSAR generally correlates to the facility age and the number of 50.59 evaluations performed by the licensee, and is a function of the scope and depth of information documented in the FSAR.

10 CFR 50.59 requires that a report containing a brief description of changes, tests, and experiments be submitted to the NRC as specified in 10 CFR 50.4. The reports may be submitted annually or along with the FSAR updates as required by 10 CFR 50.71(e) or at shorter intervals as specified by the licensee. Updates to the FSAR are required either annually or within six months after each refueling outage provided that the interval between successive updates does not exceed 24 months. In practice, some licensees are submitting these 50.59 reports monthly while others submit them quarterly, annually or with their FSAR updates.

Question 2: Who are the responsible officials within the NRC for insuring proper documentation of facility changes and updating of the FSAR?

Response:

As a part of the regional core inspection program and regional initiative inspections, documentation of facility changes and the effectiveness of licensees configuration control practices are reviewed on a sampling basis. It is the licensees' responsibility to properly document all changes in accordance with 10 CFR 50.59 and to appropriately change the FSAR. The NRR Project Managers have been delegated the responsibility to verify that licensees provide periodic updates to the FSAR and summary descriptions of 50.59 facility changes. Project managers are responsible for periodically reviewing a selected sample of 50.59 evaluations performed by their assigned licensee. The project managers determine the scope and depth of the reviews, and their reviews are generally directed toward understanding the process licensees' have in place for conducting 10 CFR 50.59 evaluations, with the exception of limited technical reviews in the area of the project manager's technical expertise.

Project managers are expected to determine whether prior approval would have been necessary for the changes they review, based on their knowledge and experience. However, the degree to which project managers ensure that licensees have appropriately documented facility changes or verified that the associated changes have been correctly made to the FSAR does not appear to be consistent. This will be further evaluated by the staff and additional guidance will be provided, as necessary, as part of its near-term effort to improve the consistency of the staff's oversight.

Question 3: Please estimate the typical volume of plant facility changes annually under 50.59 for reactors.

Response:

The volume of plant facility changes varies widely but generally corresponds to the level of detail included in the licensee's FSAR. As a rule, the older facilities have less detail in the FSAR and, therefore, are not required to perform the same number of these evaluations as newer facilities. However, most licensees apply 50.59 more broadly to include facility changes that have the potential to affect safe operation, thereby, capturing changes outside the scope of the FSAR in their 50.59 processes. The following table provides a sampling of 50.59 statistical data:

PLANT	NUMBER OF 50.59s per INTERVAL	REPORT SUBMITTAL INTERVAL	NO. OF VOLUMES IN FSAR
WOLF CREEK	172/12 MOS	ANNUALLY	14
FT. CALHOUN	26/18 MOS	REFUELING CYCLE (18 MOS)	7
QUAD CITIES	163/12 MOS	MONTHLY	7
PALO VERDE	255/12 MOS	ANNUALLY	31
NORTH ANNA	202/12 MOS	ANNUALLY	17
TURKEY POINT	120/18 MOS	REFUELING CYCLE (18 MOS)	5
COOPER	90/12 MOS	ANNUALLY	7

Question 4: How is the sample constructed for which licensee 50.59 evaluations are subject to NRC review? What role does risk assessment play in constructing the sample subject to NRC review?

Response:

Inspectors and NRR licensing project managers are given flexibility in selecting a sample of 10 CFR 50.59 modification packages for detailed inspection. Inspection guidance discusses the selection of packages from significant safety-related systems and components, using risk insights when available. Inspectors use information from multiple sources in their decision-making process, and also consider modification package complexity, and difficulty of construction of the facility change. They attempt to sample across the licensee's organizational boundaries, they utilize knowledge of prior problems within a given safety-system, and consider how difficult it may to be gain access to inspect the finished modification or work-in-progress. The time available will also limit the number of licensee 50.59 evaluations reviewed. The guidance in IP 37001 suggests a sample of five percent of the reported licensee evaluations. Inspectors use information from every resource at their disposal with the ultimate aim of identifying significant problems if they exist. As a mechanism to determine the scope of a problem, once identified, inspectors generally increase the number of samples (modification packages) reviewed directly, or request that the licensee review a spectrum of their modification packages to determine the scope of the problem.

The role of risk assessment in the sample selection process is often subjective and highly dependent on the inspectors' personal knowledge and experience with probabilistic risk assessment (PRA). Although inspectors have varying degrees of knowledge regarding the use of formally derived risk insights, deterministic insights based on engineering judgement, and knowledge of the plant systems gained through required training, NRC's rigorous inspector qualification process and personal experience also can provide insights that are as valuable as those gained through the application of risk techniques in selecting an inspection sample. While risk insights provide valuable information, they should be used in conjunction with experience-based insights. As part of the staff's action plan, the need for improved inspection procedure (IP) guidance and associated PRA training to define and implement the most appropriate ways to use available risk insights will be evaluated.

Specific inspection guidance on the selection of licensee 50.59 evaluations is provided in a number of IPs. IP 37550, "Engineering," which is one of the core inspection program procedures, states that about five significant safety-related design changes and plant modifications should be selected for review. Several other core IPs, such as IP 83750, "Occupational Radiation Exposure," IP 84750 "Radioactive Waste Treatment, and Effluent and Environmental Monitoring," and IP 86750 "Solid Radioactive Waste Management and Transportation of Radioactive Materials," provide guidance to the inspector to review changes made to the associated licensee programs to ensure the changes are consistent with the requirements of 10 CFR 50.59. In addition to the core IPs, regional initiative IP 37001 "10 CFR 50.59 Safety Evaluation Program," and IP 37700, "Design Changes and Modifications," provide guidance for review of licensee 50.59 programs, including guidance on the selection of 50.59 evaluations for review. Additional discussion of 50.59 related topics are presented in a large number of regional initiative IPs, listed in Appendix B to Manual Chapter 2515. A simple text search of the Inspection Manual identified 36 initiative IPs and 7 core IPs for operating power reactors that cited 50.59.

When selecting samples, inspectors also consider those changes, tests, or experiments that the licensee determined did not require a 50.59 evaluation to assess whether the licensee's evaluation was appropriate. Guidance related to the type of proposed changes, tests, or experiments that require a record of a 50.59 safety evaluation is provided, in part, in inspection manual chapter Part 9900: 10 CFR Guidance, "10 CFR 50.59 Changes to Facilities, Procedures and Test (or Experiments)."

Question 5: **What is the process by which unreviewed safety questions are identified in the course of the NRC staff evaluation process of facilities changes under 50.59? To what extent does the NRC 50.59 evaluation process reveal unreviewed safety questions compared to other sources of unreviewed safety questions?**

Response:

10 CFR Part 50.59 states that an unreviewed safety question exists if the change, test, or experiment (CTE) creates a condition where any of the following are true:

1. If the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased;

2. If a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or

3. If the margin of safety as defined in the basis for any technical specification is reduced.

To determine if a facility change has resulted in a USQ, the inspector or NRR licensing project manager must review the details of the facility change to gain an understanding of the change and any potential system interactions; and the licensees' 50.59 evaluation, which is typically part of the engineering change package. The staff's review of the licensee's 50.59 analysis will determine whether appropriate technical issues were considered when addressing each of the USQ conditions and whether the as-modified facility remains within the safety envelope defined by its licensing basis.

As noted in the response to Question 4, the principal IPs related to NRC review of licensee 50.59 evaluations are IPs 37550, "Engineering," and 37001, "10 CFR 50.59 Safety Evaluation Program." IP 37550, which is part of the core inspection program, (Core inspections are performed at each facility once per SALP cycle.) requires the inspector to evaluate the technical adequacy of facility modifications and the 50.59 evaluation prepared by the licensee and to verify that appropriate FSAR changes were planned or completed. IP 37001 is more programmatic in nature than IP 37550 and would typically be performed by an NRR licensing project manager with the aid of technical assistance as necessary. In following this IP, the inspector or project manager reviews the licensee's process for performing and documenting 50.59 evaluations to determine (1) if the licensee's procedures are adequate, (2) if they are being properly implemented, and (3) if the 50.59 evaluations are adequate with respect to USQs. IP 37001 is not part of the core inspection program and therefore would be only performed by the regions as a "regional initiative," if warranted by licensee performance. NRR project managers would typically perform IP 37001 approximately once per fuel cycle.

A review of the technical adequacy of 50.59 evaluations and the appropriateness of licensees' USQ determinations is performed through the inspection program as described. There are no other processes that would identify the licensees' effectiveness in implementing the 50.59 process and identifying USQs. The inspection program has led to regulatory actions such as the issuance of generic communications on 50.59-related topics and the consideration of escalated enforcement actions related to 50.59 safety evaluations. An assessment of the effectiveness of 50.59 inspections will be considered for inclusion in the action plan.

Question 6: Given the great volume of facility changes what are the criteria for selecting which 50.59 evaluations are reviewed and which are not? Inspection guidance document.

Response:

The response to Question 4 is also responsive to this question.

Question 7: How is the safety significance of licensee 50.59 evaluations determined by the NRC?

Response:

The safety significance of facility modifications as required by 10 CFR 50.59 is primarily determined through the use of engineering judgement based on knowledge of the facility, knowledge of the safety analysis and considerations that may affect the consequences of an analyzed accident, and the licensing basis of the facility. Although the staff, as yet, does not apply formally derived risk insights in a consistent manner, the use of risk insights is implicit in the use of engineering judgement. The safety significance of a 50.59 evaluation is related to the safety significance of the systems (including procedures or programs), structures, or components associated with the 50.59 evaluation. The majority of the facility changes performed are below the level of detail captured in an IPE, for example. Risk-informed insights, to the extent they are used, supplement deterministic judgements.

Some efforts to introduce PRA insights and methods into the inspection program have begun. These efforts include inspector training in risk assessment and the introduction of limited PRA guidance into inspection procedures. In addition, the staff has added regional and headquarters positions for senior reactor analysts to address the increasingly important role of probabilistic safety assessments in regulatory activities, including risk-informed planning for inspections.

Question 8: Is there a possibility that there could be a cumulative safety significance from a combination of facility changes made over time? How does the staff examine this type of possibility?

Response:

If 10 CFR 50.59 were not properly implemented by licensees the possibility could exist that a small but cumulative impact on safety would occur.

10 CFR 50.59 inherently has a "zero tolerance" for decreases to safety. It does not permit facility changes that may increase the probability or consequences of an accident or that may create a previously unanalyzed accident or decrease the safety margins specified in the bases to the technical specifications without prior staff approval. Therefore, an explicit analyses of the cumulative effect of changes to systems or procedures over the operating life of the plant is not routinely performed. This type of review was performed in the late eighties through the Safety System Functional Inspections, IP 93801 and the Safety System Outage Modification Inspections, IP 93803. Through these inspections the staff discovered that licensees did not have a thorough understanding of the design bases of their facilities and were performing facility modifications without a knowledge of available design margins. As a result of these inspections, industry spent considerable resources in reconstituting their facilities' design bases. As part of the design reconstitution programs, licensees systematically reviewed facility changes made since initial licensing to verify that there were no cumulative impacts and that margins had not been degraded.

10 CFR 50.59 (b)(1) requires that the licensee prepare a written safety evaluation of the bases for the determination that the change, test, or experiment does not involve a USQ. The staff expects that the safety evaluation for any particular change would reflect all prior changes to systems or procedures which are relevant to the determination (1) that the probability of occurrence or the consequences of an accident or equipment malfunction has not increased, (2) that the possibility of a different accident or malfunction has not been created, and (3) that the margin of safety in any technical specification has not been reduced. 10 CFR 50.71(e) requires that changes to the facility or procedures, to the extent described in the original FSAR, be documented and reflected in updates to the SAR. The licensees' quality assurance and design control processes ensure that the changes are reflected in appropriate plant documents, including piping and instrumentation diagrams, schematic drawings, plant procedures, and so forth. On the basis of these requirements, the staff expects that the safety evaluation for individual changes are based on evaluation of the current plant design and procedures, and thus implicitly accounts for prior changes and ensures that no degradation in design margins or safety accumulates.

Similarly, the programmatic inspection of the licensee's 10 CFR 50.59 process does not explicitly include an assessment of the cumulative effect of 50.59 changes. The staff expects, however, that inspections of specific 50.59 safety evaluations, including those for design modifications and those reviewed in regional reactive/initiative inspections in evaluating the circumstances and causes of plant events or equipment failures, would assess whether the evaluations properly reflected the current plant design and procedures. The current design would necessarily include all previous changes made in accordance with 10 CFR 50.59.

As stated in the response to the third item in Attachment 1, the improved understanding of the design and licensing bases gained by licensees as a result of design reconstitution programs, and the staff's experience reviewing licensees' 10 CFR 50.59 implementation programs have provided additional assurance that the cumulative impact of 10 CFR 50.59 facility changes has not eroded reactor safety margins. Also, work performed by licensees to include improvements to the bases section of technical specifications to give the purpose for each requirement in the specifications in connection with the Technical Specification Improvement Program (TSIP) has also led to a better understanding of the facility design and licensing bases.

Since 1989, industry has been using the guidance contained in NSAC-125, which provides guidance for conducting 50.59 evaluations. The guidance in NSAC-125 conflicts with 10 CFR 50.59 in that it suggests that where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e., there is no clear trend toward increasing the probability), the change need not be considered an increase in probability and therefore, not a USQ. 10 CFR 50.59 requires that a licensee obtain prior approval for a facility modification that may result in an increase in probability. The staff has in Generic Letter 95-02, "Use of NUMARC/EPRI Report TR-102348, Guideline on Licensing Digital Upgrades, In Determining the Acceptability of Performing Analog-To-Digital Replacements Under 10 CFR 50.59," dated April 26, 1995, advised industry that we have not endorsed NSAC-125 and nothing in NSAC-125 should be construed as a modification to 10 CFR 50.59. Since the discussion centers about changes or possible changes in probability that are incalculably small, NRR views this conflict as a process issue, which should be corrected but is not cause for a safety concern. As part of the proposed action plan, NRR intends to review the use of NSAC-125 by licensees and by the staff in evaluating licensees 50.59 programs.

Question 9: What feedback mechanisms are there from staff experience in reviewing 50.59 facility changes back into the regulatory process to insure that the safety significance of changes are properly considered by the NRC?

Response:

Inspection findings from inspections and audits of each licensee's 50.59 process are documented in inspections reports. These findings would include potential enforcement actions and inspectors' concerns on the effectiveness of the licensee's program. Appropriate enforcement actions are pursued to ensure that licensees take necessary corrective actions. (A search of the Enforcement Action Tracking System identified 15 escalated enforcement actions at power plants since 1990 that involved 50.59 safety evaluations as a major or contributory factor in the enforcement action.) These inspection reports are reviewed by the inspection staff and regional managers to identify the need for followup inspections. Licensee performance in 50.59 safety evaluations is one element for consideration in plant performance reviews and systematic assessment of licensee performance (SALP) board considerations. Licensee weaknesses in this area would be highlighted for increased inspection effort, and the concern would be communicated to the licensee.

As significant issues or generic interests are identified in inspection and licensing activities related to 50.59 processes, the NRC staff has issued a number of generic communications related to 50.59 evaluations to alert licensees of inadequately performed safety evaluations, in certain cases, and to provide guidance on those plant changes that can be made under 50.59. Examples of generic communications are discussed in the response to Question 10.

Question 10. With respect to past experiences, are there ways that the NRC staff's experience in reviewing facility changes under 50.59 has influenced NRC's reactor regulatory program? If so, please highlight some of the more important.

Response:

In NRR's effort to increase consistency in NRR project manager oversight of 50.59 safety evaluations, NRR issued IP 37001 in December 1992 to provide guidance on the scope and extent of inspections in this area and shared it with the licensees. Its issuance improved guidance to the NRC staff on their oversight activities for 50.59 safety evaluations and increased communications with industry on NRC expectations in this area.

It is unclear whether specific changes to the inspection program have resulted directly from the conduct of 50.59 inspections. However, inspection program changes in 1994 increased inspection effort in the engineering area, including the development of two revised core IPs and a major revision to IP 40500, "Effectiveness of Licensee Controls in Identifying, Resolving, and Preventing Problems," on licensee self assessment processes, which include engineering assessments. These changes reflect the NRC's recognition of the need for increased emphasis in the engineering area, which includes the preparation of safety evaluations to support license amendments, design changes, and 50.59 determinations.

As significant issues of generic interest are identified, the NRC staff has issued a number of generic communications related to 50.59 evaluations, either to alert licensees of inadequately performed safety evaluations or to provide guidance on those plant changes that can be made under 50.59. Examples include Generic Letter 95-02, which provides guidance on the conduct of 50.59 safety evaluations on analog-to-digital replacements, Generic Letter 90-02, Supplement 1, which provides guidance on 50.59 evaluations for fuel assembly reconstitution, Information Notice 91-63 on an inadequate 50.59 safety evaluation related to natural gas hazards, and Information Notice 89-81 on the need for 50.59 evaluations for temporary modifications.

Question 11. For the future are there improvements in NRC's feedback procedures which you would recommend for insuring better incorporation of experience into the NRC regulatory program?

Response:

The staff expects that implementation of the action plan, including tasks to assess the current implementation of NRC staff oversight activities, may result in the identification of areas for improvement in feedback mechanisms.

Discussion of the 50.59 Process Evolution

I. INTRODUCTION

In addition to responding to your specific requests, we thought it would be beneficial to briefly discuss the evolution of 10 CFR 50.59, the implementation process required of licensees, the staff's evaluation of the licensees' implementation, and several other issues that affect the 10 CFR 50.59 implementation process.

II. BACKGROUND

Although the regulations have been changed since 10 CFR 50.59 was first published for comment in 1961, the basic provisions of the regulations that allow licensees to change the facility and the procedures without prior NRC approval when the change does not involve the Technical Specifications or an unreviewed safety question (USQ), have remained the same. On April 8, 1961, the proposed rule published for comment contained criteria for determining whether a (USQ) is involved, specifying that when the probability or consequences of an accident may be increased, the proposed change constitutes a USQ and must be authorized by the Commission. On August 16, 1966, amendments to the regulations were proposed to address (1) the probability or consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report (SAR), and (2) the margin of safety as defined in the basis for any technical specification. On December 17, 1968, the amendments redefining the term "unreviewed safety question," as proposed in 1966, became final. 10 CFR 50.59 has not undergone significant change since these 1968 amendments. Most importantly, since it was first promulgated in 1961, 10 CFR 50.59 did not allow licensees to make changes that would increase the probability or consequences of accidents without prior NRC review.

In 1986, related changes were made to other regulations, this time to 10 CFR 50.71(e), to require periodic updates of the final safety analysis report (FSAR) to include the effects of changes made in the facility or procedures described in the FSAR and all safety evaluations performed in support of either license amendments or other changes not involving a USQ.

III. THE RULE

The staff considers 10 CFR 50.59 a process rule rather than a rule containing substantive safety requirements. As a process rule, 10 CFR 50.59 describes the circumstances under which licensees may change the facility without prior NRC approval. More specifically, the rule describes when a change may not be made. It specifies that if a change involves a USQ, and the rule provides information for determining what constitutes a USQ, the change may not be made without prior NRC approval.

10 CFR 50.59 states that a USQ is involved if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased. In other words, no matter how small a change in the probability or consequences of an accident or malfunction of equipment may result from a proposed change, the change may not be made without prior NRC review. For this reason, the NRC has not established an acceptable threshold for increased risk. The staff continues to believe that this is the best approach for making USQ determinations and safety decisions. The NRC's policy has always been that deterministic criteria and engineering judgement are fundamental to its decision making process, and that probabilistic safety assessment, though becoming more widely relied on, is still best employed as a supplement to the deterministic approach. The staff expects that where there is uncertainty concerning whether the probability or consequences of an analyzed accident is increased, the licensee will request the NRC's review and approval before the change is made. The staff believes that licensees should use reasonable engineering practices, engineering judgement, and probabilistic risk assessment (PRA) techniques, as appropriate, in determining whether the probability of occurrence or consequences of an event increase as a result of implementing a proposed change. A large body of knowledge has been developed in the area of event frequency and risk-significant sequences through plant-specific and generic studies. The staff believes that licensees should draw on this knowledge in the process of determining what constitutes an increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in and SAR.

A limitation of 10 CFR 50.59 is the scope of its applicability, in that it applies only to the "facility as described in the FSAR." This appears to be a vestige of the original rule as written in 1961 that used the term "hazards summary report." For early plants (licensed in the early to mid 1960s) a substantial portion of the bases and safety limits for a facility were contained in the Technical Specifications, but for later plants that material is contained in the FSAR. Further, some early plants have substantially revised their Technical Specifications transferring much of the material to the FSAR. Thus, the net effect has been to substantially reduce the scope of information for which a license amendment is required to change, and increase the scope of information subject to 10 CFR 50.59 review. Though the rule applies only to the facility and procedures described in the FSAR, and not to the whole current licensing basis (CLB), the licensees have taken a broader approach, and perform 10 CFR 50.59 evaluations even for changes to the facility or procedures that are not described in the FSAR. Although a strict interpretation of the language of this paragraph of the rule would not lead to performing these reviews for anything other than changes to information contained in the FSAR, the NRC has encouraged this broader approach by licensees, while still ensuring that NRC retains the same level of control over information in the CLB that is safety significant.

IV. IMPLEMENTATION

Even though the language of the rule is very specific and has not changed significantly since 1968, licensees typically apply the requirements of the rule more broadly than the language dictates. Most licensees apply 10 CFR 50.59 review process to all facility design and procedure changes that could affect safety, regardless of whether that portion of the facility is described in the FSAR. Some licensees perform a 10 CFR 50.59-type review as a "screening process" when considering a proposed facility or procedure change. If the licensee determines that the change involves a USQ, the licensee may look for other ways to make the change. When licensees use the USQ criteria to decide about whether to proceed with plant modifications, they may choose to perform proposed modifications in a way that would not involve a USQ and, therefore, avoid the need for a license amendment.

Recent efforts on the part of some licensees to perform plant design basis reconstitution and convert their technical specifications to the new improved standard technical specifications have also led to better 10 CFR 50.59 evaluation programs. With a more thorough understanding of the plant design bases and more clearly defined technical specification bases, licensees have been able to perform more comprehensive 10 CFR 50.59 reviews because they have gained a better understanding of the design and procedures they are changing.

The industry has prescribed its approach for meeting the requirements of 10 CFR 50.59 in its guidance document NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," to licensees. NSAC-125 received extensive review by industry and the NRC and is now widely used by the licensees. NSAC-125 is consistent with the approach the licensees' have been using for some time to implement the requirements of 10 CFR 50.59 in that it also recommends a broad interpretation of the language in 10 CFR 50.59. Although the NRC believes that the guidance is an appropriate extension of good design control practices and that the overall quality of safety evaluations performed by licensees has improved since it was issued, the NRC has not been able to endorse the guidance because it does not comport with 10 CFR 50.59.

First, as mentioned, NSAC-125 recommends applying the requirements of the rule more broadly than the scope of applicability described in the rule. Though not consistent with the language of the rule, the NRC agrees that this approach is perhaps better than one based on a narrow interpretation of the rule's scope of applicability. Second, NSAC-125 guides licensees to make changes without prior NRC approval where a change in probability is so small, or such are the uncertainties in determining whether a change in probability has occurred that it cannot be reasonably concluded that the probability has actually changed (i.e., there is no clear trend toward increasing the probability), thereby allowing the change to not be considered an increase in probability. The NRC has not endorsed the acceptance criteria as stated in NSAC-125. The NRC has found acceptable, the review process contained in NSAC-125 as used by licensees. As the rule states, any uncertainty renders the change a USQ. For these reasons, the staff has concluded that it would be inappropriate to endorse NSAC-125 guidance. Not withstanding these reasons, the staff thinks that the guidance in NSAC-125 provides a sound foundation for performing and determining the applicability of 10 CFR 50.59 and may explore the possibility of endorsing it in a regulatory guide, with the exceptions stated. The staff will describe its plans regarding development of a regulatory guide in its action plan.

V. INSPECTION PROGRAM AND RESULTS

Licensees are required to submit information related to changes made in accordance with 10 CFR 50.59 either annually or along with FSAR updates (which may be 6 months after each refueling outage but no more than 24 months apart); however the frequency with which licensees submit their 50.59 reports varies. Some submit the information monthly, some quarterly or semi-annually, and some submit the information along with FSAR updates.

The summary descriptions of changes and associated safety evaluations submitted vary in quality and are sometimes so brief that it is difficult to understand what the change entails without further discussion. Also, since information contained in the original FSAR must be updated according to the requirements of 10 CFR 50.71(e), older facilities with smaller FSARs would typically have fewer 10 CFR 50.59 evaluations and less of the information in these evaluations incorporated in the FSAR updates. Therefore, the level of detail of the information one licensee submits may not necessarily be the same as the level of detail of information submitted by another, depending on the size of the licensees' FSARs.

The staff has developed programs for monitoring and giving feedback to licensees on their processes for implementing the requirements of 10 CFR 50.59. The staff has developed inspection procedures to be used by headquarters' project managers and region-based inspectors for specifically reviewing implementation of 10 CFR 50.59 requirements and for reviewing safety evaluations associated with various changes, tests, and experiments. Feedback on licensees' implementation of this section is also included in the staff's systematic assessments of licensee performance (SALP) prepared for the facilities. While the majority of IPs do not explicitly require inspectors to review licensee 10 CFR 50.59 evaluations, inspectors routinely review them as they follow up issues identified during inspections. This is evident by the more than 350 inspection reports that reference 50.59 in the last two years (1994 through 1995).

The regional offices perform periodic reviews of 10 CFR 50.59 evaluations through routine site inspections. Currently a number of inspection procedures reference these evaluations. Regional inspectors monitor all aspects of the 10 CFR 50.59 program, including training and qualifications for those who perform such evaluations, the review and evaluation processes, and the review of these individual evaluations. The inspection program requires a number of licensee evaluations to be reviewed through the routine performance of core program and regional initiative inspections. Core program inspections are performed at each site each SALP cycle. The core Inspection Procedure (IP) 37550, "Engineering," includes requirements related to selecting a sample of 10 CFR 50.59 evaluations to review that are part of significant safety-related design changes and plant modifications implemented during the previous or upcoming refueling outages. Other core IPs that reference review of these licensee evaluations are 83750, "Occupational Radiation Exposure," 84750, "Radioactive Waste Treatment, and Effluent and Environmental Monitoring," and 86750, "Solid Radioactive Waste Management and Transportation of Radioactive Materials." None of these other core IPs explicitly require inspectors to select 10 CFR 50.59 evaluations to review, but provide guidance to the inspector to review changes made to the associated licensee programs to ensure the changes are consistent with the requirements of 10 CFR 50.59. If the inspector had a concern regarding a licensee's implementation of a facility change, test, or experiment without prior staff review, a reasonable expectation would be that the change package would be reviewed along with the 10 CFR 50.59 evaluation.

Headquarters' project managers are designated to review 10 CFR 50.59 evaluations. While project managers are expected to perform an annual review, they have wide flexibility in determining the depth and scope of these reviews. Reviews can be focused on either the licensee's processes or on these individual evaluations. Reviews can take the form of individual site visits, from which the project manager provides information for the monthly resident inspector report, or the project manager may join a region-based inspection team and include the review as part of a team effort. As an example, a project manager may participate in a region-based team inspection, examining the licensee's engineering and technical support staff.

In 1991, the staff performed a study to examine its process for reviewing the licensees' implementation of 10 CFR 50.59 requirements, and concluded that the headquarters' staff reviews of the licensees' 10 CFR 50.59 reviews vary widely and that the reviews yielded relatively few significant findings. As a direct result of this study, the staff prepared IP 37001, "10 CFR 50.59 Safety Evaluation Program," to be used primarily by NRR project managers in reviewing licensees' 10 CFR 50.59 programs but also occasionally by the region staffs as an initiative inspection. Although the management expectation is that project managers follow the guidance in IP 37001, the scope and depth of reviews vary. Project managers are more likely to focus on plant areas that are the current areas of generic concern such as steam generator repair, fire protection barriers, or onsite spent fuel storage. In addition, project managers typically focus on areas in which they may have previous expertise such as motor-operated valves, source term reduction, or containment leak testing. The freedom to select those areas of interest is a strength of the project manager review. Considering that project managers are periodically reassigned to new plants, over time, a diverse area of 10 CFR 50.59 facility changes are expected to be reviewed. However, variability of the scope and depth of reviews conducted by project managers is a potential weakness that needs to be evaluated. Further, the assurance provided by NRR licensing project managers that licensees accurately update their FSARs is subjective. Management needs to more clearly define the responsibilities in this area.

Headquarters' staff have also been responsible for performing various "area-of-emphasis" team inspections, such as electrical distribution system functional inspections, and service water system operational inspections, which were conducted at almost every site. These resource intensive inspections looked in depth at facility modifications in their area of interest and at the licensees' 10 CFR 50.59 evaluations on various systems to provide assurance that there was no cumulative degradation of safety as a result of modifications performed since initial licensing. Also, the Integrated Performance Assessment Program, which the regional staff performs at each facility each SALP cycle, evaluates various licensee programs, including implementation of '0 CFR 50.59.

VI. CONCLUSIONS ON THE RULE AND STAFF IMPLEMENTATION REVIEWS

The staff believes that having a process like the 10 CFR 50.59 review process is necessary because it allows licensees flexibility to make changes that do not affect the plant level of safety without incurring the resource and schedule burden associated with NRC's reviews. It also allows the NRC staff to devote its resources to matters having higher safety significance. The staff concludes that there is currently no indication that implementation of 10 CFR 50.59, as it is carried out today, has led to decreased safety, based on its inspection experience. While improvements can be made to achieve a higher degree of uniformity of review, the current process as it is being implemented provides reasonable assurance that plant safety has not been decreased.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 12, 1995

MEMORANDUM FOR: William T. Russell, Director
Office of Nuclear Reactor Regulation

FROM: James M. Taylor, Executive Director
for Operations

SUBJECT: INDEPENDENT REVIEW OF MILLSTONE STATION AND NRC HANDLING OF EMPLOYEE CONCERNS AND ALLEGATIONS

Since the late 1980's Millstone Station has been the source of a high volume of employee concerns and allegations related to safety of plant operations and harassment and intimidation of employees. NRC has conducted many inspections and investigations which have substantiated many employee concerns and allegations. The licensee has been cited for violations and escalated enforcement has been taken. Notwithstanding these NRC actions, the licensee has not been effective in handling many employee concerns nor implementing effective corrective action for problems identified.

NRR is to conduct an independent evaluation of the history of the licensee's and the staff's handling of employee concerns and allegations related to licensed activities at Millstone station. NRR's review should include in-depth case studies of selected employee concerns and allegations to identify root causes, common patterns between cases and lessons learned.

A broad outline of the objectives and scope of the NRR review is attached. The review should be led by a full time SES manager with appropriate senior NRR management oversight. You should develop a plan of action and detailed schedule for this effort by December 29, 1995. I would like to be briefed on progress in 60 days with a goal to complete your review by April 30, 1996.

By copy of this memorandum, Region I, OI, IG and OE are requested to provide records and reports and make appropriate staff available for interview by the Task Force, as requested.

Attachment: As stated

cc: (w/attachment)
T. Martin
L. Norton
G. Caputo
J. Lieberman

~~9512190427~~ 2pp

Enclosure 5

INDEPENDENT REVIEW OF MILLSTONE STATION AND NRC
HANDLING OF EMPLOYEE CONCERNS AND ALLEGATIONS

Objectives:

For the period from 1985 to the present, critically evaluate both the licensee's and NRC staff's effectiveness in addressing Millstone-related employee concerns and allegations. Determine root causes and common patterns for identified deficiencies and develop recommendations for licensee actions related to the Millstone station for improvements in handling of employee concerns and for NRC staff actions related to handling of allegations.

Scope of Effort:

1. Conduct a broad based review of licensee and NRC allegation files, 2.206 petitions, related inspection reports, OI and OIG investigations, enforcement actions, DOL actions and prior NRC management reviews from 1985 to present.

2. Select 6 to 12 cases for indepth evaluation. In addition to review of relevant documentation, conduct structured interviews of involved NRC staff, licensee management and concerned licensee employees as necessary to ensure an accurate record of the handling of selected case studies. Develop a case history outlining the problems, licensee's responses, and the NRC actions. Critically evaluate both the licensee's and staff's handling and processing of the case to identify root causes, common patterns and lessons learned.

3. Based upon the broad review and case studies, develop lessons learned and recommend both plant-specific and programmatic corrective actions.